

Case Number	EU Gateway Record Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Region	Literature Reference	Patient Age Group	Patient Sex	Patient Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Incidenting Drug List (Drug Class - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Associated Drug List (Drug Class - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form	
			Professional	Non-Eurozone Economic Area		Years	Not Specified	Male	No	Bradycardia (n/a - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diabetic ketoacidosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Drowning), Dizziness (n/a - Fatal - Results in Death, Drowning), Hepatic failure (n/a - Fatal - Results in Death, Drowning), Laboratory test (n/a - Fatal - Results in Death, Drowning), Renal failure (n/a - Fatal - Results in Death, Drowning), Vertigo (n/a - Fatal - Results in Death, Drowning)	Immunisation - Not applicable - (n/a - [DPT - Unknown])		
EUEC-1001076868	25/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Male	No	Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Drowning), Dizziness (n/a - Fatal - Results in Death, Drowning), Hepatic failure (n/a - Fatal - Results in Death, Drowning), Laboratory test (n/a - Fatal - Results in Death, Drowning), Renal failure (n/a - Fatal - Results in Death, Drowning), Vertigo (n/a - Fatal - Results in Death, Drowning)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - Product used for unknown indication - Not applicable - (n/a - [DPT - Intramuscular])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Male	No	Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aspiration pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haematuria (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Massive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mechanical ventilation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Male	No	Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - Results in Death), Positive airway pressure therapy (n/a - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition), Acute renal impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac pacemaker insertion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (20 - Fatal - Results in Death, Other Medically Important Condition), Vaccine breakthrough infection (20 - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccine breakthrough infection (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (16 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (16 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (16 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiorespiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Central line dislodgement (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (16 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (246 - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Minor valve incompetence (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (16 - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (206 - Fatal - Results in Death, Other Medically Important Condition), Venous thrombosis (206 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	SPRIVIA [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (16 - [DPT - Intramuscular])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiorespiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Central line dislodgement (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (16 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxic-ischaemic encephalopathy (246 - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Minor valve incompetence (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (16 - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (206 - Fatal - Results in Death, Other Medically Important Condition), Venous thrombosis (206 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	SPRIVIA [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (16 - [DPT - Intramuscular])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypoxia (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - Product used for unknown indication - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Cerebral ischaemia (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Death (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Drainage (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Dyspnoea extensor (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haematuria decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Haemoglobin decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Loss of consciousness (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Monocyte count increased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Protein total decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Pulmonary oedema (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning, Other Medically Important Condition), Rectal blood clot content decreased (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), Tooth extraction (6m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Drowning), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Covid-19-Jah disease (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Prostatectomy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - [DPT - Unknown])	Not reported	CSR
EUEC-1001076868	24/11/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-66 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death), Blood albumin decreased (6m - Fatal - Results in Death			

Number	EV Entry Point	Report Type	Primary Source Country	Primary Source Country Regulatory Authority	Literature Reference	Patient Age Group	Patient Age Group (as per report)	Patient Sex	Parent/Child Report	Reaction List PT (Duration / Outcome - Seriousness Criteria)	Supplies/Marketing Drug List (Drug Chn - Indication PT - Action taken - (Duration - Dose - Route))	Concomitant/Other Administered Drug List (Drug Chn - Indication PT - Action taken - (Duration - Dose - Route))	CSR Form
										Fatigue (75 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (75 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Orchitis/epididymitis (75 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (75 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory tract congestion (75 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Rhinorrhoea (75 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (15 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (75 - Unknown - Caused/Prolonged Hospitalisation), Death (15 - Fatal - Results in Death, Other Medically Important Condition), Fall (15 - Unknown -), Injury (15 - Unknown -), Loss of consciousness (15 - Unknown - Other Medically Important Condition)	COVID-19 mRNA VACCINE MODERNA (CX-024414) [COVID-19 mRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (75a - 100T) - Intramuscular)		
EUC-10015038169		Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (15 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (75 - Unknown - Caused/Prolonged Hospitalisation), Death (15 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (245 - Unknown - Caused/Prolonged Hospitalisation), Fatigue (245 - Unknown - Caused/Prolonged Hospitalisation), Pain (245 - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (245 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (245 - Unknown - Caused/Prolonged Hospitalisation), Urinary tract infection (245 - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (75a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 mRNA VACCINE MODERNA (CX-024414) [COVID-19 mRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (75a - 100T) - Intramuscular)	Not reported	CSR
EUC-10015038315		Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (15 - Fatal - Results in Death, Other Medically Important Condition), Fall (15 - Unknown -), Injury (15 - Unknown -), Loss of consciousness (15 - Unknown - Other Medically Important Condition)	COVID-19 mRNA VACCINE MODERNA (CX-024414) [COVID-19 mRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (75a - 100T) - Intramuscular)	Not reported	CSR
EUC-10015046707		Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cough (245 - Unknown - Caused/Prolonged Hospitalisation), Death (75a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (245 - Unknown - Caused/Prolonged Hospitalisation), Fatigue (245 - Unknown - Caused/Prolonged Hospitalisation), Pain (245 - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (245 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (245 - Unknown - Caused/Prolonged Hospitalisation), Urinary tract infection (245 - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (75a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 mRNA VACCINE MODERNA (CX-024414) [COVID-19 mRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (75a - 100T) - Intramuscular)	Not reported	CSR
EUC-10015054179		Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (15 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 mRNA VACCINE MODERNA (CX-024414) [COVID-19 mRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (75a - 100T) - Intramuscular)	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [CAFFEINE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [TERBUCLASIN SULFATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [FLUTICASON PROPIONATE, SALMETEROL MALEATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [FLUTICASON] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [SABAPENTIN] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [HYDROCORTISONE VALERATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [LOPELIDINE, HYDROXYLORONE, LOPELIDINE OXIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [LORATADINE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [MAGNESIUM OXIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [NORTRIPTYLINE, NORTRIPTYLINE HYDROCHLORIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [DIMEPRAZOLE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [PRODOLIPERAZINE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [BISPHENOL A, SODIUM PHOSPHATE, POTASSIUM CHLORIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [TZEDIONE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown)	CSR
EUC-100150546564		Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (75a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic stenosis (75a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (75a - Unknown - Caused/Prolonged Hospitalisation), Death (15 - Fatal - Results in Death, Other Medically Important Condition), Hypokalaemia (75a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (75a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (75a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (75a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 mRNA VACCINE MODERNA (CX-024414) [COVID-19 mRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (75a - 100T) - Intramuscular)	Not reported	CSR
EUC-10015047952		Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	45-65 Years	Not Specified	Female	No	Vaccine breakthrough infection (75a - Unknown -), COVID-19 (75a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (15 - Fatal - Results in Death, Other Medically Important Condition), Mental status changes (75a - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (75a - Recovered/Resolved - Other Medically Important Condition)	COVID-19 mRNA VACCINE MODERNA (CX-024414) [COVID-19 mRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (75a - 100T) - Intramuscular)	Not reported	CSR
EUC-10015046862		Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Vaccine breakthrough infection (75a - Recovered/Resolved - Other Medically Important Condition) Death (15 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 mRNA VACCINE MODERNA (CX-024414) [COVID-19 mRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (75a - 100T) - Intramuscular)	[ABILETY (AMIPRAZOLE)] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [KEPPRA (LEVETIRACETAM)] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [LYRICA (PREGABALIN)] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [JANHYDROS, NALOXONE HYDROCHLORIDE, NALOXONE, NALOXONE HYDROCHLORIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [CALCIUM CARBONATE, CALCIUM CARBONATE PH. EUR.] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [CALCIUM CARBONATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [CASSIA, CASSIA SENNA WHOLE, HYDROXYNATHRACENE GLYCOSIDES, SENNA PODS, SENNOSIDES B, SENNOSIDES] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [COLICALFEROL] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [DOLIPHENAC, DOLIPHENAC BETHYLAMINE, DOLIPHENAC EPOLAMINE, DOLIPHENAC POTASSIUM, DOLIPHENAC RESINATE, DOLIPHENAC SODIUM, DOLIPHENAC SODIUM PH. EUR.] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [DOLIPHENAC] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [DOLIPHENAC] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [METOPROLOL, TARTRATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [NORTRIPTYLINE, NORTRIPTYLINE HYDROCHLORIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [DIMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [DOLIPHENAC] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [PARACETAMOL] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [TERIPARATIDE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [ENALAPRIL, ENALAPRIL] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [PREGABALIN, PREGABALIN] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [FACALCALFEROL] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - 75a - (75a - 75a) - Unknown), [ACOSORIC ACID, CALCIUM CARBONATE	

EU Local Number	EV Emergency Review Date	Report Type	Primary Healthcare Profession	Primary Country Regulatory Authority	Literature Reference	Patent Case Group	Patent Age Group (see text)	Patent Sex	Patent Age Group	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Involved Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
										Vaccination site pain (n/a - Unknown -).			
EU-EC-1001046100	26/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Varicella (n/a - Unknown - Caused/Protonged Hospitalisation). Accident (01 - Fatal - Results in Death). Death (14 - Fatal - Results in Death, Other Medically Important Condition).	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (COVID-19 immunisation - Not applicable - [n/a - 100mg - Intramuscular])	Not reported	C28
EU-EC-10010422136	25/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-1001026814	22/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Caused/Protonged Hospitalisation). COVID-19 pneumonia (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Drug ineffective (n/a - Unknown -). Dyspnoea (n/a - Unknown - Caused/Protonged Hospitalisation). Hypoxia (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	AFIXABAN [AFIXABAN] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]). [DLTAZEN] OLTAZEM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 80mg - Unknown]). [ELZYFARIS] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]). [LEVOSALBUTAMOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [LUTEN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]). [OMEGA-3 FATTY ACIDS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]).	C28
EU-EC-1001040326	22/10/2021	Spontaneous	Non- Healthcare Profession	Non- European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). [Bless] (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010401313	22/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death).	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C28
EU-EC-10010402379	22/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Elderly	Male	No	Blood pressure decreased (10mm - Recovered/Resolved -). Death (n/a - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010404306	22/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Brain ischaemia (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Burns first degree (n/a - Unknown - Caused/Protonged Hospitalisation). Burns second degree (n/a - Unknown - Caused/Protonged Hospitalisation). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Enterobacter infection (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Fatigue (n/a - Unknown - Caused/Protonged Hospitalisation). Hypertension (n/a - Unknown - Caused/Protonged Hospitalisation). Pyrexia (n/a - Unknown - Caused/Protonged Hospitalisation). Somnolence (n/a - Unknown - Caused/Protonged Hospitalisation). Syncope (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Vaginal infection (n/a - Unknown - Caused/Protonged Hospitalisation). Varicella (n/a - Unknown - Caused/Protonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010303726	21/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010398375	21/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010208410	21/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). [BZOVEN] (n/a - Not Recovered/Resolved -). [Gastric haemorrhage] (n/a - Unknown - Other Medically Important Condition). Loss of consciousness (n/a - Unknown - Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010394170	21/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition). General physical health deterioration (n/a - Unknown - Other Medically Important Condition). Hypertension (n/a - Unknown - Other Medically Important Condition). Hypoxia (n/a - Unknown - Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	[CARMELOSE SODIUM, GLYCEROL POLYSPERATE 80] (C - Product used for unknown indication - n/a - 1. [CYCLOPENTHIC DITHYANINE, DICYCLOPENTHIC SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 90mg - Oral]).	C28
EU-EC-10010384206	21/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Tachycardia (n/a - Unknown - Other Medically Important Condition). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Loss of consciousness (14 - Unknown - Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010384475	21/10/2021	Spontaneous	Non- Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Muscle twitching (14 - Unknown - Other Medically Important Condition). Apnoea (n/a - Unknown - Other Medically Important Condition). Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010398942	21/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Decreased appetite (n/a - Unknown -). Dizziness (n/a - Unknown -). Dyspnoea (n/a - Unknown -). Fatigue (n/a - Recovered/Resolved -). Inappropriate schedule of product administration (14 - Recovered/Resolved -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010391110	21/10/2021	Spontaneous	Non- Healthcare Profession	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death).	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010302602	21/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Anal fistula (131 - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). COVID-19 (131 - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). COVID-19 pneumonia (131 - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Cardiac arrest (131 - Fatal - Results in Death, Caused/Protonged Hospitalisation, Other Medically Important Condition). Chen pain (131 - Unknown - Caused/Protonged Hospitalisation). Chills (131 - Unknown - Caused/Protonged Hospitalisation). Cough (131 - Unknown - Caused/Protonged Hospitalisation). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Diarrhoea (131 - Unknown - Caused/Protonged Hospitalisation). Dyspnoea (131 - Unknown - Caused/Protonged Hospitalisation). Fatigue (131 - Unknown - Caused/Protonged Hospitalisation). Neuralgia (131 - Unknown - Caused/Protonged Hospitalisation). Pain (131 - Unknown - Caused/Protonged Hospitalisation). Pleurotic pain (131 - Unknown - Caused/Protonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010395201	21/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Varicella (131 - Unknown - Caused/Protonged Hospitalisation). COVID-19 (n/a - Fatal - Results in Death, Caused/Protonged Hospitalisation, Other Medically Important Condition). COVID-19 (n/a - Fatal - Results in Death, Caused/Protonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	ELIQUIS [APRIFABAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). HYDROXYCORTISONE HYDROXYCORTISONE SODIUM SUCCINATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [FINASTERIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [FLUTICASON, SALMETEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [MEANTRINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [METHYLPREDNISOLONE, METHYLPREDNISOLONE AND CORTISONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [SIMVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]).	C28
EU-EC-10010370242	20/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Aphasia (n/a - Unknown - Caused/Protonged Hospitalisation). COVID-19 (n/a - Unknown - Caused/Protonged Hospitalisation). Cerebrovascular accident (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Confusional state (n/a - Unknown - Caused/Protonged Hospitalisation). Convulsion (n/a - Unknown - Caused/Protonged Hospitalisation). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Dysarthria (n/a - Unknown - Caused/Protonged Hospitalisation). Dysphagia (n/a - Unknown - Caused/Protonged Hospitalisation). Face injury (n/a - Unknown - Caused/Protonged Hospitalisation). Fall (n/a - Unknown - Caused/Protonged Hospitalisation). Feeling cold (n/a - Unknown - Caused/Protonged Hospitalisation). Gait disturbance (n/a - Unknown - Caused/Protonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010370095	20/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Local infection (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Death (14 - Fatal - Results in Death, Caused/Protonged Hospitalisation, Other Medically Important Condition). Myocardial infarction (14 - Fatal - Results in Death, Caused/Protonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010371169	20/10/2021	Spontaneous	Non- Healthcare Profession	Non- European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010371936	20/10/2021	Spontaneous	Non- Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Drug abuse (n/a - Unknown - Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010372626	20/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Caused/Protonged Hospitalisation). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Decreased level of consciousness (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Dysphagia (n/a - Unknown - Caused/Protonged Hospitalisation). General physical health deterioration (n/a - Unknown - Caused/Protonged Hospitalisation). Monoplegia (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Pyrexia (n/a - Unknown - Caused/Protonged Hospitalisation). Respiratory distress (n/a - Unknown - Caused/Protonged Hospitalisation, Other Medically Important Condition). Speech disorder (n/a - Unknown - Caused/Protonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [BACLOFEN, BACLOFEN RESINATE, BACLOFEN RESINATE, BACLOFEN RESINATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [CYANOCOBALAMIN, VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [VITAMIN D] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]).	C28
EU-EC-10010373255	20/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010374346	20/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Acute kidney injury (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation, Other Medically Important Condition). Atrial fibrillation (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Asthma (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Dysarthria (n/a - Unknown - Caused/Protonged Hospitalisation). Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Feeling abnormal (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Flank pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Gait instability (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Internal haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation, Other Medically Important Condition). Neuralgia (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation, Other Medically Important Condition). Pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Pulmonary oedema (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation, Other Medically Important Condition). Respiratory distress (n/a - Fatal - Results in Death, Life Threatening, Caused/Protonged Hospitalisation). Death (14 - Fatal - Results in Death, Caused/Protonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010374088	20/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010373960	20/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010373734	20/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Agnesia (n/a - Recovered/Resolved -). Agnesia (n/a - Unknown - Caused/Protonged Hospitalisation). Anosmia (n/a - Recovered/Resolved -). Anosmia (n/a - Unknown - Caused/Protonged Hospitalisation). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Decreased appetite (n/a - Unknown - Caused/Protonged Hospitalisation). Dizziness (n/a - Recovered/Resolved -). Dyspnoea (n/a - Unknown - Caused/Protonged Hospitalisation). Fatigue (n/a - Recovered/Resolved -). Fatigue (n/a - Unknown - Caused/Protonged Hospitalisation). Headache (n/a - Unknown - Caused/Protonged Hospitalisation). Nausea (n/a - Recovered/Resolved -). Nausea (n/a - Unknown - Caused/Protonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	ETAGLIFITIN [ETAGLIFITIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [AMODIACONE, AMODIACONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]). [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]). [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]). [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]). [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 300mg - Unknown]). [LUPROZED] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]). [MAGNESIUM OXIDE] (C - Product used for unknown indication - n/a - [n/a - 400mg - Unknown]). [METOLAZONE] (C - Product used for unknown indication - n/a - [n/a - 2.5mg - Unknown]). [METOPROLOL, SUCCINATE] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]).	C28
EU-EC-10010378262	20/10/2021	Spontaneous	Healthcare Profession	European Economic Area	Not available	16-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	C28
EU-EC-10010378856	20/10/2021	Spontaneous	Non- Healthcare Profession	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010393194	15/10/2021	Spontaneous	Non- Healthcare Profession	Non- European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Apnoea (14 - Fatal - Results in Death, Other Medically Important Condition). Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition). Cyanosis (14 - Fatal - Results in Death). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Fatigue (14 - Unknown -). Loss of consciousness (14 - Fatal - Results in Death, Other Medically Important Condition). Sneezing (14 - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010391462	15/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010324338	15/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Life Threatening, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010330670	15/10/2021	Spontaneous	Non- Healthcare Profession	Non- European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Myocardial infarction (n/a - Unknown - Other Medically Important Condition).	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010320321	15/10/2021	Spontaneous	Non- Healthcare Profession	European Economic Area	Not available	16-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death).	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C28
EU-EC-10010315340	14/10/2021	Spontaneous	Non- Healthcare Profession	Non- European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	Not reported	C28
EU-EC-10010314276	14/10/2021	Spontaneous	Healthcare Profession	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	COVID-19			

Number	EY Category Receipt Date	Report Type	Primary Cause Qualification	Primary Cause Country Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex (as per reporter)	Patient Ser.	Patient DM Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Supplementing Drug List (Drug Chai - Indication PT - Action taken - [Duration - Dose - Route])	Cosmeceutical Administered Drug List (Drug Chai - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form
EUEC-1001022408	06/10/2021	Spontaneous	Non Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Female	No	No	Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	[PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown) Not reported	CGR
EUEC-1001022507	06/10/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Anxiety (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (3/2 - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Unknown - Life Threatening, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Life Threatening, Other Medically Important Condition), Resuscitation (n/a - Unknown - Life Threatening, Other Medically Important Condition), Seizure (n/a - Unknown - Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Life Threatening, Other Medically Important Condition) Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	[HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [BETRALINE, BETRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CGR
EUEC-1001022560	04/10/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Vascular occlusion (n/a - Unknown - Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-1001022616	04/10/2021	Spontaneous	Non Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Female	No	No	Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	[PROCALIFONE] (S - Product under review - Not applicable - [300d - 100mg - Oral] COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-1001020648	04/10/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-80 Years	Not Specified	Female	No	Acute respiratory failure (n/a - Unknown - Other Medically Important Condition), Atherosclerosis coronary artery (n/a - Unknown -), Asthma (n/a - Unknown -), Aspirated pneumonia (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown -), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiac failure congestive (n/a - Unknown - Other Medically Important Condition), Cardiomyopathy (n/a - Unknown -), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Gout (n/a - Unknown -), Hypertension (n/a - Unknown -), Hyperkalemia (n/a - Unknown -), Interstitial lung disease (n/a - Unknown - Other Medically Important Condition), Lung consolidation (n/a - Unknown -), Lung infiltration (n/a - Unknown -), Long apnoea (n/a - Unknown -), Pneumothorax effusion (n/a - Unknown - Other Medically Important Condition), Pneural effusion (n/a - Unknown -), Pneumomediastinum (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pseudotumor (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary edema (n/a - Unknown - Other Medically Important Condition), Subcutaneous emphysema (n/a - Unknown -), Superficial vein thrombosis (n/a - Unknown -), Thrombosis (n/a - Unknown - Other Medically Important Condition), Thyroid calcification (n/a - Unknown -), Vascular occlusion (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	[ACEITYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - 60mg - Unknown), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [DOXOSPERMATE, DOXOSPERMATE DIHYDRATE, DOXOSPERMATE MONOHYDRATE], (C - Product used for unknown indication - n/a - [n/a] - 50mg - Unknown), [ETHYL ESTER] (C - Product used for unknown indication - n/a - [n/a] - 50mg - Unknown), [ISABAPENTIN] (C - Product used for unknown indication - n/a - [n/a] - 60mg - Unknown), [HYDROCHLOROAZEPATE, LOSARTAN, LOSARTAN POTASSIUM, HYDROCHLOROAZEPATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [ISSODASINE, ISSODASINE MONOHYDRATE, ISSODASINE MONOHYDRATE], (C - Product used for unknown indication - n/a - [n/a] - 50mg - Unknown), [DIASATINIL] (C - Product used for unknown indication - n/a - [n/a] - 60mg - Unknown), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - 20mg - Unknown), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - 100mg - n/a), [LYNAXAPINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CGR
EUEC-1001021436	04/10/2021	Spontaneous	Non Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Yes	Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-1001021308	01/10/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-80 Years	Not Specified	Male	No	Atrial fibrillation (n/a - Recovered/Resolved - Other Medically Important Condition), Death (3/2 - Fatal - Results in Death, Other Medically Important Condition)	[SPIKEVIA] [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	[CARVEDILOL] (C - Product used for unknown indication - Drug withdrawn - [n/a] - n/a - Unknown), [NITROGLYCERIN] (C - Product used for unknown indication - Drug withdrawn - [n/a] - n/a - Unknown)	CGR
EUEC-1001021028	01/10/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-80 Years	Not Specified	Male	No	COVID-19 (n/a) - Fatal - Results in Death), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Hypertension (n/a) - Fatal - Results in Death), Respiratory failure (n/a) - Fatal - Results in Death, Other Medically Important Condition)	[SPIKEVIA] [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-1001021825	01/10/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-80 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Presynaptic distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) Cough (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Endotracheal intubation (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Major organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	[HYDROCORTISONE, HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [ACEITYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - 60mg - Unknown), [BACLOFEN] (C - Product used for unknown indication - n/a - [n/a] - 50mg - Unknown), [LATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a] - 80mg - Unknown), [FLUTICASON] (C - Review - n/a - [n/a] - Nasal), [PELUDOCERININE, FEXOFENADINE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [TAMISULON, TAMSULINUM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - 4mg - Unknown)	CGR
EUEC-10010218970	01/10/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cough (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Endotracheal intubation (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Major organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	[SPIKEVIA] [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-10010217327	30/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-80 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Endotracheal intubation (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Major organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-100102186873	30/09/2021	Spontaneous	Non Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Female	No	No	Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-10010217632	30/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Melanoma (n/a - Fatal - Results in Death), Tumor (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	[AEROSOL, SPINERON, CAMPHOR, ESSENTIAL OILS, NOSE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [IRON, IRON] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [BIOTIN] (C - Product used for unknown indication - n/a - [n/a] - 5mg - n/a), [ESTROGEN, NOSE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [HYDROXYZINE, EMONATE] (C - Product used for unknown indication - n/a - [n/a] - 50mg - n/a), [METHYLTETRASTERONE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [MINERAL, ACID, VITAMIN, NOSE] (C - n/a - n/a - [n/a] - 5mg - n/a), [DOXYCODONE, OXYCODONE, HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - 5mg - n/a), [SALBUTAMOL, SALBUTAMOL, SULFATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CGR
EUEC-10010217657	30/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-80 Years	Not Specified	Male	No	Carbon monoxide poisoning (n/a - Fatal - Results in Death), General medical history (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Rib fracture (n/a - Fatal - Results in Death), Spinal cord hemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Endotracheal intubation (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Major organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-10010216282	26/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Spinal cord hemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Other Medically Important Condition), Endotracheal intubation (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Major organ dysfunction syndrome (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Death (n/a) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	Not reported	CGR
EUEC-10010216130	26/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-80 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [DPT] - Unknown)	[CAMPHOR, LEVOMETHOL, PH, EUR, EUCALYPTUS OIL, PH, EUR, TURPENTINE OIL, PH, EUR, CAMPHOR, TURPENTINE OIL, LEVOMETHOL, PH, EUR, EUCALYPTUS OIL, PH, EUR, LEVOMETHOL, CAMPHOR, EUCALYPTUS OIL, THYMOL, TURPENTINE ESSENTIAL OIL, LEVOMETHOL, CAMPHOR, EUCALYPTUS OIL, THYMOL, TURPENTINE OIL, LEVOMETHOL, CAMPHOR, EUCALYPTUS OIL, THYMOL, TURPENTINE ESSENTIAL OIL, LEVOMETHOL, CAMPHOR, EUCALYPTUS OIL, THYMOL, TURPENTINE ESSENTIAL OIL, LEVOMETHOL, CAMPHOR, EUCALYPTUS OIL, THYMOL, TURPENTINE ESSENTIAL OIL, LEVOMETHOL, CAMPHOR, EUCALYPTUS OIL, THYMOL, TURPENTINE ESSENTIAL OIL, LEVOMETHOL, CAMPHOR, EUCALYPTUS OIL, THYMOL, TURPENTINE 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EU Local Number	EV Gateway Review Date	Report Type	Primary Source Questionnaire	Primary Source Country Regulatory Procedure	Literature Reference	Patient Age Group	Patient Age Group (last report)	Patient Sex	Patient OHM Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-10010104569	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition). Pneumonia (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	[LORAZEPAM] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [MORPHINE, MORPHINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown)	C28
EU-EC-10010104615	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	13-64 Years	Not Specified	Female	No	Asymptomatic (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Pneumonia (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Pyrexia (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010104740	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition). Muscle atrophy (n/a - Unknown -). Muscular weakness (n/a - Unknown -). Somnolence (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010104762	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Vaccination site pain (4d - Unknown -). Altered state of consciousness (n/a - Unknown - Other Medically Important Condition). Bone pain (n/a - Unknown -). Brain stem haemorrhage (n/a - Unknown - Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Decreased appetite (n/a - Unknown -). Fatigue (n/a - Unknown -). Headache (n/a - Unknown -). Muscular weakness (n/a - Unknown - Other Medically Important Condition). Myalgia (n/a - Unknown -). Pain (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010104836	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Syndrome (n/a - Unknown - Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010104986	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010105185	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010105214	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010105592	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cyanosis (n/a - Unknown - Life Threatening). Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010105691	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest discomfort (n/a - Fatal - Results in Death). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Headache (n/a - Fatal - Results in Death). Inappropriate schedule of product administration (1d - Recovered/Resolved -). Insomnia (n/a - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular - More in CSR)	Not reported	C28
EU-EC-10010106062	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Nausea (n/a - Fatal - Results in Death). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Dizziness (n/a - Unknown -). Fatigue (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010107153	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chills (5d - Unknown - Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Decreased appetite (5d - Unknown - Other Medically Important Condition). Pyrexia (5d - Unknown - Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010107367	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Transverse (n/a - Unknown - Other Medically Important Condition). Abdominal distension (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disability). Abdominal pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disability). Bacterial abdominal infection (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disability). Cerebellar ataxia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition). Death (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition). Fluid retention (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disability). Interruption of therapy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition). Miseria (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disability). Pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disability).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	[ALTY VITAMIN & MINERAL, ASCORBIC ACID, BETA-CAROTENE, Biotin, Calcium Lactate, Choline Bitartrate, Chromium Nicotinate, Colloidal Oxyphenyl Cyanocobalamin, DCPANTHENOL, DL-SERINOMETHIONINE, FOLIC ACID, INOSITOL, MAGNESIUM LACTATE, MANGANESE GLUCONATE, NICOTINAMIDE, POTASSIUM CITRATE, POTASSIUM GOSY, PYRIDOXINE HYDROCHLORIDE, RETINOL PALMITATE, SIBCOLAN PHOSPHATE, SIBNANE HYDROCHLORIDE, TOCOPHERYL ACETATE, ZINC GLUCONATE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown).	C28
EU-EC-10010107369	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Loss of consciousness (n/a - Unknown - Other Medically Important Condition). Pneumonia (n/a - Unknown - Other Medically Important Condition). Vaccination site pain (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010107976	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anal incontinence (1d - Fatal - Results in Death). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Decreased appetite (27d - Fatal - Results in Death). Dyspepsia (n/a - Fatal - Results in Death). Fatigue (27d - Fatal - Results in Death). Loss of consciousness (1d - Fatal - Results in Death, Other Medically Important Condition). Muscular weakness (n/a - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010108873	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Pelvic (1d - Fatal - Results in Death). Pigmentation (27d - Fatal - Results in Death). Whitening (27d - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010109076	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010109077	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Dysentery (n/a - Unknown - Other Medically Important Condition). Dysentery (n/a - Unknown - Other Medically Important Condition). Hemiparesis (n/a - Unknown - Other Medically Important Condition). Loss of consciousness (n/a - Unknown - Other Medically Important Condition). Muscular weakness (n/a - Unknown - Other Medically Important Condition). Myocarditis (n/a - Unknown - Other Medically Important Condition). Upper respiratory (n/a - Unknown - Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010109226	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Erasmes (14d - Unknown - Other Medically Important Condition). Induration (14d - Unknown - Other Medically Important Condition). Mucous discharge (n/a - Unknown - Other Medically Important Condition). Nausea (14d - Unknown - Other Medically Important Condition). Pain (14d - Unknown - Other Medically Important Condition). Puffiness (14d - Unknown - Other Medically Important Condition). Peripheral edema (14d - Unknown - Other Medically Important Condition). Skin desquamation (14d - Unknown - Other Medically Important Condition). Chills (n/a - Recovered/Resolved -). Circulatory collapse (n/a - Unknown - Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Myalgia (n/a - Recovered/Resolved -). Pyrexia (n/a - Recovered/Resolved -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010113115	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Vaccination site pain (n/a - Unknown -). Chills (n/a - Unknown - Caused/Prolonged Hospitalisation). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Diarrhoea (7d - Unknown - Caused/Prolonged Hospitalisation). Dyspepsia (7d - Unknown - Caused/Prolonged Hospitalisation). Fatigue (7d - Unknown - Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010099969	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Product contamination (n/a - Recovered/Resolved -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010099921	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010091074	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010091078	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010091301	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Cardiac pacemaker insertion (n/a - Unknown - Caused/Prolonged Hospitalisation). Catheterisation cardiac (n/a - Unknown - Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Endotracheal intubation (n/a - Unknown - Caused/Prolonged Hospitalisation). Gastrostomy (n/a - Unknown - Caused/Prolonged Hospitalisation). Physical deconditioning (n/a - Unknown - Caused/Prolonged Hospitalisation). Tracheostomy (n/a - Unknown - Caused/Prolonged Hospitalisation). Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Ventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010091385	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation). Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Dementia Alzheimer's type (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Dyspepsia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010091386	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010091742	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010091900	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition). Unresponsive to stimuli (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular - More in CSR)	TRELEGY ELLIPTA [MUCILONUM BROMIDE, FLUTICASONE FUROATE, VILANTEROL] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [ATORVASTATIN] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [SABAPENTIN] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [METOPROLOL, METOPROLOLOL TARTARATE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [PARACETAMOL] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [PARACETAMOL] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [PRENOSONE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [TIMBLOSIN, TIMBLOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [THIAMINE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [VILBERTIN] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown).	C28
EU-EC-10010091964	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Pulmonary edema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010092162	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Weight increased (n/a - Unknown - Caused/Prolonged Hospitalisation). Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010092842	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 pneumonia (148d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [CARVEDILOL] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [COLCHICINE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [PROGLICERIN] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [EETINABE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [TIMBLOSIN, TIMBLOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown).	C28
EU-EC-10010093803	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Inappropriate schedule of product administration (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	Not reported	C28
EU-EC-10010093914	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (8d - Unknown - Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010093921	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Dyspepsia (n/a - Unknown - Caused/Prolonged Hospitalisation). Constipated lactate (n/a - Fatal - Results in Death, Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	[QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown). [SALBUTAMOL, SALBUTAMOL, MICRONIZED, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown)	C28
EU-EC-10010093817	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition). Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular - More in CSR)	Not reported	C28
EU-EC-10010094986	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation). Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10010095619	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Ab			

EU Local Number	EV Emergency Review Date	Report Type	Primary Source Questionnaire	Primary Country Regulatory Procedure	Literature Reference	Patient Age Group	Patient Sex	Patient Sex Report	Patient OHM Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form	
EU-EC-1001009910	23/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Victim of abuse (5G) - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Drowning. Cognitive disorder (n/a - Unknown - Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Gait instability (n/a - Unknown - Other Medically Important Condition). Peripheral swelling (n/a - Unknown - Other Medically Important Condition). Renal failure (n/a - Unknown - Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010097725	23/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010098979	23/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation). COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Fall (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010099926	23/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010099628	23/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Cerebral hypoperfusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Drug ineffective (n/a - Unknown -). Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation). Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation). Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation). Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (n/a - Fatal - Results in Death).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	RUISSONNE [RUISSONNE] (C - Product used for unknown indication - n/a - [n/a - 8mg - Unknown]). COLEBEVELAM [COLEBEVELAM] (C - Product used for unknown indication - n/a - [n/a - 1250mg - Unknown]). KAMRA [KAMRA] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]). GAPREXALIC (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown]). [LONDINE] (C - Product used for unknown indication - n/a - [n/a - 2mg - Unknown]). [ERGOALOPROLOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [FLUCLOXATINE, FLUCLOXATINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown - More in CSR]). [FLUTICASON] (C - Product used for unknown indication - n/a - [n/a - Unknown - More in CSR]).	C28	
EU-EC-10010101721	23/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death).	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a])	Not reported	C28	
EU-EC-10010077541	21/09/2021	Spontaneous	Non Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-1001009856	21/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Drug ineffective (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010060739	20/09/2021	Spontaneous	Non Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Not Specified	No	Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Cerebral arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Vascular occlusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010060573	20/09/2021	Spontaneous	Non Healthcare Professionals	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010068969	20/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Dyspnoea (2d - Unknown -). Fatigue (2d - Unknown -). Pyrexia (2d - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSR)	XARELTO [RIVAROXABAN] (C - Product used for unknown indication - n/a - [n/a - 15DF] - Unknown)	C28	
EU-EC-1001003840	17/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death).	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ARJIS [PREGABALIN] (C - n/a - n/a - [n/a - 5mg - Oral]). JARANANCE [EMPAGLAGLIZIN] (C - n/a - n/a - [n/a - 10mg - Oral]). NOVORAPID [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - Subcutaneous]). [BETAMETHASONE VALERATE, BETAMETHASONE VALERATE, CLOQUINOL, BETAMETHASONE, CLOQUINOL] (C - n/a - n/a - [n/a - n/a - Cutaneous]). [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - Oral]). [CLOBETASOL PROPIONATE] (C - n/a - n/a - [n/a - n/a - Cutaneous]). [COLCALSIFEROL] (C - n/a - n/a - [n/a - 8000U - Oral]). [COCODIMIN, COCOTAMIN, HYDROXYCORTISONE] (C - n/a - n/a - [n/a - n/a - Cutaneous]). [FLUPENTIXOL, FLUPENTIXOL DECANOATE, FLUPENTIXOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 5mg - Oral]). [FOLIC ACID, FOLIC ACID ANHYDRIDE] (C - n/a - n/a - [n/a - 1mg/kg - Oral]). [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Dyspnoea - n/a - [n/a - n/a - Respiratory (inhalation)). [LACTULOSE, LACTULOSE LIQUID] (C - Constipation - n/a - [n/a - n/a - Oral]). [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 150µg - Oral]). [METOPROLOL, METOPROLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Oral]). [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - Oral]). [DICYCLOSPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Oral]). [PANTOPRAZOLE, PANTOPRAZOLE SODIUM BESILQUINATE] (C - n/a - n/a - [n/a - 20mg - Oral]). [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - 1g - Oral]). [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 750mg - Oral]). [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Dyspnoea - n/a - [n/a - n/a - Respiratory (inhalation)). [ZOPICOLINE] (C - n/a - n/a - [n/a - 7.5mg - Oral]).	Not reported	C28
EU-EC-10010041728	17/09/2021	Spontaneous	Non Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death). Product contamination physical (n/a - Fatal - Results in Death).	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010020382	16/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (5d - Fatal - Results in Death, Other Medically Important Condition). Headache (n/a - Unknown -). Pyrexia (1d - Recovered/Resolved -). Pyrexia (n/a - Unknown -).	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010022287	16/09/2021		Non Healthcare Professionals	Non European Economic Area	Not available	Not Specified	Adult	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition).	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010023052	16/09/2021	Spontaneous	Non Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010030618	15/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Acute left ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Generalised tonic-clonic seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Migraine (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSR)	Not reported	C28	
EU-EC-10010098147	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (23d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010050146	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition). Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010007139	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition). Extra-dose administration (1d - Recovered/Resolved -). Milekier (1d - Fatal - Results in Death). Syncope (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010007180	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (1d - Fatal - Results in Death). Acute respiratory failure (1d - Fatal - Results in Death, Other Medically Important Condition). Bronchodilators (1d - Fatal - Results in Death, Other Medically Important Condition). COVID-19 (1d - Fatal - Results in Death). COVID-19 pneumonia (1d - Fatal - Results in Death, Other Medically Important Condition). Condition aggravated (1d - Fatal - Results in Death). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Dysphagia/stridor (n/a - Fatal - Results in Death). Drug ineffective (1d - Fatal - Results in Death). Dyspnoea (1d - Fatal - Results in Death). General physical health deterioration (1d - Fatal - Results in Death). Hemorrhoids (1d - Fatal - Results in Death). Leukopenia (1d - Fatal - Results in Death). Lung consolidation (1d - Fatal - Results in Death). Milekier (1d - Fatal - Results in Death). Pneumonia (1d - Fatal - Results in Death, Other Medically Important Condition). Pulmonary artery stenosis (1d - Fatal - Results in Death, Other Medically Important Condition). Pulmonary mass (1d - Fatal - Results in Death). Pulmonary valve stenosis (1d - Fatal - Results in Death, Other Medically Important Condition). Respiratory distress (1d - Fatal - Results in Death, Other Medically Important Condition). Respiratory failure (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010007340	15/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death).	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a])	Not reported	C28	
EU-EC-10010007477	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chills (n/a - Unknown - Caused/Prolonged Hospitalisation). Cough (n/a - Unknown - Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation). General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation). Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation). Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation). Pain (n/a - Unknown - Caused/Prolonged Hospitalisation). Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[DOXAZOSIN, DOXAZOSIN MESILATE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]). [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]). [MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 720mg - Unknown]). [NIFEDIPINE] (C - Product used for unknown indication - n/a - [n/a - 120mg - Unknown]). [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 500mg - Unknown]). [PIRACETAMINE, PIRACETAMINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]). [PREDNISOLONE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]). [SODIUM HYDROGEN CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 1500mg - Unknown]). [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [SULFAMETOPRIM, DMSOXYLATE] (C - Product used for unknown indication - n/a - [n/a - 70mg - Unknown]).	Not reported	C28
EU-EC-10010007797	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (4d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010009026	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal pain upper (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Organ failure (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Septic shock (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	JARANANCE [EMPAGLAGLIZIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [ALCOPIRINE, ALCOPIRINE BESILATE, ALCOPIRINE MALEATE, ALCOPIRINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [GLIPIZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [NICOTINAMIDE, NICOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, NICOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [DIMEPRIZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [VITAMIN B2] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]).	Not reported	C28
EU-EC-10010030376	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Dyspnoea (12d - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-100100107374	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010012382	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death).	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]).	ACTRAPID PENFILL 100 U/ml [INSULIN HUMAN, INSULIN HUMAN (RMAN)] (C - n/a - Unknown - [n/a - 3mc - n/a]). HUMALOG [INSULIN LISPRO] (C - n/a - Unknown - [n/a - n/a - n/a]). INSULIATARD PENFILL 100 U/ml [INSULIN HUMAN, INSULIN HUMAN (ISOPHANE) (RMAN)] (C - n/a - Unknown - [n/a - 3mc - n/a]). LANTUS [INSULIN GLARGINE] (C - n/a - Unknown - [n/a - n/a - n/a]). [ALCOPIRINE, ALCOPIRINE BESILATE] (C - n/a - Unknown - [n/a - 1DF] - n/a). [BISOPROLOL, BISOPROLOL, FLUMARATE, BISOPROLOL, HEMIFUMARATE] (C - n/a - Unknown - [n/a - 1DF] - n/a). [CEFTRIAXONE, CEFTRIAXONE SODIUM] (C - n/a - Unknown - [n/a - 1DF] - n/a). [CLOFENAC SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]). [FOLIC ACID] (C - n/a - Unknown -). [GLUCOSAMINE] (C - n/a - Unknown -). [LOSARTAN, LOSARTAN POTASSIUM, HYDROCHLOROTHIAZIDE] (C - n/a - Unknown - [n/a - n/a - n/a]). [METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 3DF] - n/a). [METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]). [METHOTREXATE] (C - n/a - Unknown - [n/a - 1DF] - n/a). [DIMEPRIZOLE] (C - n/a - Unknown - [n/a - n/a - n/a]). [BIMASTATIN] (C - n/a - Unknown - [n/a - n/a - n/a]). [CLOFENAC SODIUM] (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown). [ALPHA-TOCOPHEROL ACETATE, LUTETIN] (C - Product used for unknown indication - n/a - [n/a - 3DF] - Unknown). [CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]). [FLUTICASON, FLUTICASON, VALANTROL, TRIFENATATE, FLUTICASON, VALANTROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). [LISINAPRIL, LISINAPRIL, DRYDRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]). [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]). [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 3000mg - Unknown]). [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 400mg - Unknown]). [VITAMIN B2] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]).	Not reported	C28
EU-EC-10010013027	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010013153	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010013515	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Drug ineffective (n/a - Recovered/Resolved -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10010015383	15/09/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Life Threatening, Other Medically Important Condition). Atrial fibrillation (n/a - Unknown - Life Threatening, Other Medically Important Condition). Cardiac failure congestive (n/a - Unknown - Life Threatening, Other Medically Important Condition). Death (1d - Fatal - Results in Death, Other Medically Important Condition). Gait disturbance (n/a - Unknown - Life Threatening, Other Medically Important Condition). General physical health deterioration (n/a - Unknown - Life Threatening, Other Medically Important Condition). Hypertension (n/a - Unknown - Life Threatening, Other Medically Important Condition). Loss of personal independence in daily activities (n/a - Unknown - Life Threatening, Other Medically Important Condition). Mobility decreased (n/a - Unknown - Life Threatening, Other Medically Important Condition). Walking aid user (n/a - Unknown - Life Threatening, Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[RIBESARTAN [RIBESARTAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM BESILQUINATE] (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown). [ACETYL-SALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown). [COLCALSIFEROL] (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown). [HYDROXYCHLORQUINE] (C - Product used for unknown		

EU Local Number	EV Emergency Review Date	Report Type	Primary Source Question Problems	Primary Country Regulatory Problems	Literature Reference	Patient Age Group	Patient Age Group (see report)	Patient Sex	Patient Race	Reaction List PT / Duration ? Outcome - Seriousness Criteria	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-1000999304	14/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	[VITAMIN D] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000997065	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (22d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Paresthesia decreased (22d - Fatal - Results in Death, CausedProlonged Hospitalisation), Thrombotic thrombocytopenic purpura (22d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	AFIBAN (AFIBAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PANTOPRAZOLE PANTOPRAZOLE PANTOPRAZOLE SODIUM BESILATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), TASLART (TASLART) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), TREPICOSTINE (TREPICOSTINE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FURUSEMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [EUPIRELBIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIPANSETRON] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PREDNISONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALBUTAMOL SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BPIRONOLACTONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000999059	13/09/2021	Spontaneous	Non-Healthcare Professionals	Non-European Economic Area	Not available	18-64 Years	Adult	Male	No	Confusional state (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Exercise tolerance decreased (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Influenza like illness (2d - Not Recovered/Not Resolved -)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	C28
EU-EC-10009981304	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009991537	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009991809	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation), Death (1d - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation, Other Medically Important Condition), Dehydration (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation), Malnutrition (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation), Oral disorder (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation), Oral skin pruritus (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation), Stomatitis (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	ACETYLCHOLINE ACID (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [ALCOPLINE, ALCOPLINE RESILATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [FENOFENONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FISH OIL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FLUTICASON PHOSPHATE] (C - Product used for unknown indication - n/a - [n/a - 50ug - n/a]), [METOPROLOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [DISODIUM PHOSPHATE DODECAHYDRATE, SODIUM HYDROGEN PHOSPHATE DIBASIC, DISODIUM PHOSPHATE DODECAHYDRATE, SODIUM DIHYDROGEN PHOSPHATE DIHYDRATE, DISODIUM HYDROXYNE, LEVOHYDROXYNE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [MODERNE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [TERIPARATIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-10009982108	13/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (1d - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009982119	13/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (1d - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [1d - 5m - Intramuscular])	Not reported	C28
EU-EC-10009983636	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009983980	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (3d - Fatal - Results in Death), Death (3d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (3d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular - More in CSR)	ELIQUIS (APRABAN) (C - Product used for unknown indication - n/a - [n/a - n/a]), PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FURUSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GLIPIZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [INSULIN ASPART] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOHYDROXYNE, LEVOHYDROXYNE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOLAZONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DAPRAGLIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BPIRONOLACTONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [KALAZOL (NIGLIZIPIN)] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [PANTOPRAZOLE PANTOPRAZOLE PANTOPRAZOLE SODIUM BESILATE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [ACETYLCHOLINE ACID] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [ALCOPLINE, ALCOPLINE RESILATE, ALCOPLINE MALEATE, ALCOPLINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [ASCORBIC ACID] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL, FUMARATE, BUDESONIDE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [COLLAGENASE CLOSTRIDIUM HISTOLYTICUM] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [DICYCLIPENIC POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [DONAZOLONE, DONAZOLONE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [METOCLOPRAMIDE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [DIPYRIDONE, DIPHENOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [POVIDONE, [ODINATE]] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [THIAMINE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [ZINC] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown)	C28
EU-EC-10009983320	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Resuscitation (n/a - Unknown -), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009983824	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009983833	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (1d - Unknown - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (1d - Unknown - CausedProlonged Hospitalisation), Drug ineffective (n/a - Recovered/Resolved -), Dyspnoea (1d - Unknown - CausedProlonged Hospitalisation), Nausea (1d - Unknown - CausedProlonged Hospitalisation), Vomiting (1d - Unknown - CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009983745	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Adverse respiratory infection (3d - Fatal - Results in Death, Other Medically Important Condition), Central haemorrhage (3d - Fatal - Results in Death, Other Medically Important Condition), Cyanosis (3d - Fatal - Results in Death), Death (3d - Fatal - Results in Death, Other Medically Important Condition), Headache (3d - Fatal - Results in Death), Vomiting (3d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009983814	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute respiratory failure (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009984756	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Acute chest syndrome (1d - Fatal - Results in Death, Other Medically Important Condition), Biphasic (1d - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (1d - Fatal - Results in Death), Cardio-respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (1d - Fatal - Results in Death), Hypertension (1d - Fatal - Results in Death), Mental status changes (1d - Fatal - Results in Death), Pneumonia (1d - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (1d - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (1d - Fatal - Results in Death, Other Medically Important Condition), Respiratory failure (1d - Fatal - Results in Death, Other Medically Important Condition), Sickle cell anaemia with crisis (1d - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009985374	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Vaginal haemorrhage (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009986412	13/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009986481	13/09/2021	Spontaneous	Non-Healthcare Professionals	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Unknown -), Hematuria (n/a - Unknown -)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009987375	11/09/2021	Spontaneous	Non-Healthcare Professionals	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Product contamination (n/a - Unknown -)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009989329	10/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (n/a - Unknown -), Mental status changes (1d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009984549	09/09/2021	Spontaneous	Non-Healthcare Professionals	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Not Specified	No	Mental status changes (1d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009984825	08/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009987679	08/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009985333	08/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Marta RS, Sherva PT COVID-19 after live donor renal donation in kidney transplant recipients. Am J Transplant. 2021 Apr; 10:1113-1121	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Swelling (118d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	CYCLOSPORIN (CYCLOSPORIN) (C - Immunosuppression - n/a - [n/a - n/a - Unknown]), MYCOPHENOLATE MOFETIL (MYCOPHENOLATE MOFETIL) (C - Immunosuppression - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000931384	08/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac failure congestive (118d - Fatal - Results in Death, Other Medically Important Condition), Death (118d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (118d - Fatal - Results in Death), Incomplete course of vaccination (118d - Fatal - Results in Death), Lymphadenopathy (118d - Fatal - Results in Death), Pneumonia (118d - Fatal - Results in Death), Pneumonia (118d - Fatal - Results in Death), Pneumonia (118d - Fatal - Results in Death, Other Medically Important Condition), Swelling (118d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009982416	08/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009982370	08/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chest pain (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Dyspnoea (2d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009983345	08/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute respiratory distress syndrome (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Asthma (n/a - Unknown - CausedProlonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown - CausedProlonged Hospitalisation), Drug ineffective (n/a - Unknown -), Fatigue (n/a - Unknown - CausedProlonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Life Threatening), Cardiac failure (n/a - Fatal - Results in Death, Life Threatening), Death (3d - Fatal - Results in Death, Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009983376	08/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Angina pectoris (n/a - Fatal - Results in Death), Chest discomfort (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 5m - Intramuscular])	JENTAQUETO 2.5 MG/80 MG (METFORMIN HYDROCHLORIDE, UNALUPITIN) (C - n/a - Unknown - [n/a - n/a - n/a]), LIVETACETAM ACCORD 900 MG FILM-COATED TABLETS (LIVETACETAM) (C - n/a - Unknown - [n/a - 500mg - n/a]), [ATORVASTATIN, EZETIMIBE] (C - n/a - Unknown - [n/a - n/a - n/a]), [FURUSEMIDE] (C - n/a - Unknown - [n/a - 40mg - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1000mg - n/a]), [PANTOPRAZOLE] (C - n/a - Unknown - [n/a - 20mg - n/a]), [PERINDOPRIL, ARGININE] (C - n/a - Unknown - [n/a - 5mg - n/a]), [BPIRONOLACTONE] (C - n/a - Unknown - [n/a - 50mg - n/a]), [WAFARIN, WARFARIN SODIUM] (C - Anticoagulant therapy - Does not changed - [n/a - 5mg - n/a])	C28
EU-EC-10009984166	08/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), SARS-CoV-2 test positive (4d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009991666	07/09/2021	Spontaneous	Non-Healthcare Professionals	European Economic Area	Not available	18-64 Years	Adult	Male	No	Anthrax (n/a - Unknown - Other Medically Important Condition), Back pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	[LIVETACETAM] (C - n/a - Unknown - [n/a - 500mg - n/a]), [THEOPHYLLINE MALEATE] (C - n/a - Unknown - [n/a - 60mg - n/a])	C28
EU-EC-10009982510	07/09/2021	Spontaneous	Healthcare Professionals	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation, Disabling), Death (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation, Disabling, Other Medically Important Condition), Pain - extremely (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation, Disabling), Vasculitis (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation, Disabling)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU-EC-10009982655	07/09/2021	Spontaneous	Healthcare Professionals	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	C28
EU-EC-10009982654	07/09/2021	Spontaneous	Non-Healthcare Professionals	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Asthma (n/a - Not Recovered/Not Resolved -), Death (n/a -			

EU Local Number	EV Emergency Review Date	Report Type	Primary Report Question	Primary Country Regulatory Authority	Literature Reference	Patient Age Group	Patient Group (see report)	Patient Sex	Patient Age Group (see report)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Her Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-100062923	30/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Vomiting (2d - Unknown -) Almost state of consciousness (1d - Fatal - Results in Death, Life-Threatening, Other Medically Important Condition), Atrial fibrilla (n/a - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) Arrhythmia (n/a - Not Recovered/Not Resolved -),	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 5mL - Intramuscular))	Not reported	C28
EU-EC-100062905	30/09/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	SPKREVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - (n/a - n/a))	Not reported	C28
EU-EC-1000629615	30/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 5mL - Intramuscular))	Not reported	C28
EU-EC-1000691429	30/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiovascular disorder (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000693106	30/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-84 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hospitalisation (7d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000696094	27/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Aortic aneurysm (1d - Fatal - Results in Death), Aortic aneurysm rupture (1d - Fatal - Results in Death, Other Medically Important Condition), Atherosclerosis (1d - Fatal - Results in Death), Asthma (1d - Fatal - Results in Death), Autopsy (1d - Fatal - Results in Death, Other Medically Important Condition), Back pain (1d - Fatal - Results in Death), Cardio-respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hypertensive heart disease (1d - Fatal - Results in Death), Hypertension (1d - Fatal - Results in Death), Nausea (1d - Fatal - Results in Death), Retrolental fibroplasia (1d - Fatal - Results in Death, Other Medically Important Condition), Syncope (1d - Fatal - Results in Death, Other Medically Important Condition), Tachycardia (1d - Fatal - Results in Death), Vomiting (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000697137	27/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Vomiting (1d - Fatal - Results in Death) Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anorexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cervical fracture (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Generalised oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertakemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000814302	26/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Adverse event (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000815589	27/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000817546	27/09/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Adverse event (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Unknown))	Not reported	C28
EU-EC-1000796394	26/09/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Asthma (10d - Fatal - Results in Death, Other Medically Important Condition), Chest discomfort (10d - Fatal - Results in Death, Other Medically Important Condition), Cough (10d - Fatal - Results in Death, Other Medically Important Condition), Death (8d - Fatal - Results in Death, Other Medically Important Condition), Dizziness (10d - Fatal - Results in Death, Other Medically Important Condition), Hypertension (10d - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (8d - Fatal - Results in Death, Other Medically Important Condition), Myocardial ischaemia (8d - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (10d - Fatal - Results in Death, Other Medically Important Condition), Rhinorrhoea (10d - Fatal - Results in Death, Other Medically Important Condition)	SPKREVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - (n/a - 10PF - Intramuscular))	OLANZAPINE (OLANZAPINE) (C - n/a - n/a - (n/a - Oral)), VICTOZA (SGLT2-INHIBITOR) (C - n/a - n/a - (n/a - n/a))	C28
EU-EC-1000797379	26/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (8d - Unknown - Caused/Prolonged Hospitalisation), Death (8d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic encephalopathy (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tenderness to vertical palpation (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vocal intonation (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Subcutaneous))	DEXAMETHASONE (DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), FAMOTIDINE) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), METHANOL) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), DIAZEPAM) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), SALBUTAMOL SULFATE) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	C28
EU-EC-1000823254	26/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	SPKREVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (1d - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000894034	26/09/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000896746	26/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), White blood cell count increased (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	ACEPILSALICYLIC ACID, CAFFEINE) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), MACROGOL 3350) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), MONTELUKAST, MONTELUKAST SODIUM) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), DIMEPRIZOLE) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), BETAPROLOL, BETAPROLOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	C28
EU-EC-1000907712	26/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Atherosclerosis (n/a - Fatal - Results in Death), Cardiac failure congestive (n/a - Fatal - Results in Death, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Immediate post-injection reaction (n/a - Fatal - Results in Death), Mileuse (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000787199	25/09/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Central thrombosis (2070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1300m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (2070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (2070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000782854	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Endotracheal intubation (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Product administered at inappropriate site (n/a - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000783208	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chest pain (3d - Fatal - Results in Death), Death (3d - Fatal - Results in Death, Other Medically Important Condition), Fall (3d - Fatal - Results in Death), Life support (3d - Fatal - Results in Death), Organ donor (3d - Fatal - Results in Death), Syncope (3d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	ATORVASTATIN) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), ESABAPENTIN) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), HYDROXYZINE EMBONATE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), METOPROLOLOL, METOPROLOLOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), METOPROLOLOL, METOPROLOLOL SULFONATE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), PRENOSONE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), SALBUTAMOL, SALBUTAMOL SULFATE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), TRAZODONE, TRAZODONE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown))	C28
EU-EC-1000783422	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular - More in CSR))	Not reported	C28
EU-EC-1000783446	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (n/a - Not Recovered/Not Resolved -), Back pain (n/a - Not Recovered/Not Resolved -), Burning sensation (n/a - Not Recovered/Not Resolved -), Cardiac failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved -), Gait instability (n/a - Not Recovered/Not Resolved -), General physical health deterioration (n/a - Not Recovered/Not Resolved -), Mileuse (n/a - Not Recovered/Not Resolved -), Memory impairment (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -), Thinking abnormal (n/a - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular - More in CSR))	Not reported	C28
EU-EC-1000784162	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COVID-19 (146d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (146d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (146d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (146d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Unknown))	ELISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - (n/a - 10mg - Unknown))	C28
EU-EC-1000784710	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Arrhythmia (n/a - Fatal - Results in Death, Other Medically Important Condition), Aspiration (n/a - Fatal - Results in Death, Other Medically Important Condition), Stroke (n/a - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death), Central small vessel ischaemic disease (n/a - Fatal - Results in Death, Other Medically Important Condition), Chronic sinusitis (n/a - Fatal - Results in Death), Coma scale (n/a - Fatal - Results in Death), Concentrated long-term head abnormal (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Endotracheal intubation (n/a - Fatal - Results in Death), Pulse absent (n/a - Fatal - Results in Death), Pulseless electrical activity (n/a - Fatal - Results in Death, Other Medically Important Condition), Respiratory distress (n/a - Fatal - Results in Death, Other Medically Important Condition), Resuscitation (n/a - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	DEXAMETHASONE (DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE) (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	C28
EU-EC-1000784881	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (168d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (168d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (168d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Generalised haemorrhage (168d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000784912	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Inappropriate schedule of product administration (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000785223	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (17d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000786072	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Aplastic syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death), Resuscitation (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	KEPPRA (LEVETIRACETAM) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), LEVITEL (LEVITEL, LEVITEL) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), ACEPILSALICYLIC ACID) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), AMOCIPINE, AMOCIPINE BESILATE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), ASCORBIC ACID) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), CASSIA, CASSIA SENNA WHOLE, HYDROXYANTHRACENE GLYCOSIDES, SENNA PODS, SENNOSIDE B, SENNOSIDES) (C - Product used for unknown indication - n/a - (n/a - 10PF - Unknown)), MACROGOL 3350) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), DULCIFIC ACID) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), ZINC) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown))	C28
EU-EC-1000788152	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Lymphadenopathy (175d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lymphadenitis (175d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000789026	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-1000789203	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anticoagulant therapy (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Central haemorrhage (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Central nervous system disorder (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal infarct (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	ATORVASTATIN) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), METOPROLOLOL, METOPROLOLOL TARTRATE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown))	C28
EU-EC-10007897363	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Central haemorrhage (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Demencia (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - (n/a - 10PF - Unknown))	Not reported	C28
EU-EC-10007897172	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved -), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular - More in CSR))	Not reported	C28
EU-EC-10007897761	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Life-Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pharyngitis (1m - Fatal - Results in Death, Life-Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (1m - Fatal - Results in Death, Life-Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (1m - Fatal - Results in Death, Life-Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Unknown))	AFIBAXAN (AFIBAXAN) (C - Product used for unknown indication - n/a - (n/a - 10mg - Unknown)), DULCIFIC ACID) (C - Product used for unknown indication - n/a - (n/a - 10mg - Unknown)), INSULIN GLARGINE (INSULIN GLARGINE) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), INSULIN LISPRO (INSULIN LISPRO) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), ACEPILSALICYLIC ACID) (C - Product used for unknown indication - n/a - (n/a - 8mg - Unknown)), AMOCICILIN, AMOCICILIN TRIHYDRATE) (C - Product used for unknown indication - n/a - (n/a - 1000mg - Unknown)), BISOPROLOLOL, BISOPROLOLOL FUMARATE, BISOPROLOLOL HEMIFUMARATE) (C - Product used for unknown indication - n/a - (n/a - 10mg - Unknown)), COLICALCIPER) (C - Product used for unknown indication - n/a - (n/a - 2000PF - Unknown)), PARGOLINE) (C - Product used for unknown indication - n/a - (n/a - 20mg - Unknown)), CHAMPHRE, PIPERIDINE HYDROCHLORIDE, VITAMIN B12) (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown))	C28
EU-EC-10007897952	25/09/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute respiratory failure (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PF - Intramuscular))	Not reported	C28
EU-EC-10007898275	25/09/2021	Sp											

EU Case Number	EU Case Title	Report Type	Primary Health Professional	Primary Country Regulatory Response	Literature Reference	Patient Age Group	Patient Sex	Patient Age	Patient Sex	Patient Report	Reaction List PT (Duration PT - Outcome - Seriousness Criteria)	Superseding Drug List (Drug Class - Indication PT - Action taken - Duration - Dose - Route)	Concomitant Administered Drug List (Drug Class - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU/EC/100287/0599	17/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-66 Years	Male	No	No	No	Death (n/a - Fatal - Results in Death)	SPINEXIA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	[LORAZEPAMIDE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [LISINATAPOTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [MARTAZAPINE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [PAROXETINE MESLATE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [TAFAMIDS MESGLUMINE] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [VITAMINS N03] (C - Product used for unknown indication - n/a - [n/a - 10d] - Unknown), [COLLESTYRACOPOLYMERATE MESITOL] (C - n/a - n/a - n/a), [TOLMO [N03L] NUSLIN RESINATE] (C - n/a - n/a - n/a), [MALOPIRINE, MALOPIRINE BESILATE, MALOPIRINE MALEATE, MALOPIRINE MESLATE] (C - n/a - n/a - n/a), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - n/a), [CETIRIZINE, HYPERMELLOSE] (C - n/a - n/a - n/a), [CLOZAPINE] (C - n/a - n/a - n/a), [COLICACALCEROL] (C - n/a - n/a - n/a), [FERROUS SULFATE] (C - n/a - n/a - n/a), [FENEDONE] (C - n/a - n/a - n/a)	C28
EU/EC/100287/1114	17/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Acute respiratory failure (1d - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (1d - Fatal - Results in Death), Cardiorespiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (1d - Fatal - Results in Death), Chest pain (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Plan (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	[VORICONAZOLE (VORICONAZOLE)] (C - Product used for unknown indication - n/a - [n/a - 10d] - n/a), [ATOHAGUONE] (C - Product used for unknown indication - n/a - [n/a - 10d] - n/a)	C28
EU/EC/100287/0310	16/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Male	No	No	No	Death (n/a - Fatal - Results in Death), Plan (1d - Fatal - Results in Death)	SPINEXIA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	C28
EU/EC/100287/0330	16/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-66 Years	Not Specified	Female	No	No	Adverse (Sd - Unknown - Life Threatening), Chest pain (1d - Fatal - Results in Death), Death (Sd - Fatal - Results in Death, Other Medically Important Condition), Headache (Sd - Unknown - Life Threatening), Plan (Sd - Unknown - Life Threatening), Pyrexia (Sd - Unknown - Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [IBOTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [COLICACALCEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ESCIPTALOPRAM, ESCIPTALOPRAM OXALATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FENOFIBRATE, FENOFIBRATE MONOHYDROGEN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [VITAMINS N03] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU/EC/100287/0948	16/08/2021	Spontaneous	Not Healthcare Professional	Non-European Economic Area	Not available	65-66 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	SPINEXIA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	Not reported	C28
EU/EC/100287/0586	16/08/2021	Spontaneous	Not Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Adult	Male	No	No	Abdominal pain (n/a - Unknown - Life Threatening), Death (n/a - Fatal - Results in Death)	SPINEXIA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	Not reported	C28
EU/EC/100287/0249	16/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Male	No	No	No	Plan (n/a - Not Reported/Resolved - Life Threatening), COVID-19 (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Metabolic encephalopathy (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	C28
EU/EC/100287/0135	16/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Respiratory failure (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU/EC/100287/0149	16/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Acute kidney injury (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Adverse (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COPD (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Metabolic encephalopathy (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	[ELIQUIS (APRAXAN)] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ESCIPTALOPRAM, CITAFOPRAM HYDROBROMIDE, CITAFOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ELUCORIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BISOPROLOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BISOPROLOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BISOPROLOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BISOPROLOL] (C - Product used for unknown indication - n/a	
EU/EC/100287/0420	16/08/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-66 Years	Male	No	No	No	Pneumonia (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	[ELIQUIS (APRAXAN)] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROALAZINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NUSLIN, NUSLIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU/EC/100287/1487	16/08/2021	Spontaneous	Not Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Male	No	No	No	Arrhythmia (n/a - Fatal - Results in Death, Life Threatening, Disabling), Atrial fibrillation (n/a - Fatal - Results in Death, Life Threatening, Disabling), Bradycardia (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Disabling), Cardiac arrest (n/a - Fatal - Results in Death, Life Threat			

EU Local Number	EV Entry Review Date	Report Type	Primary Source Question	Primary Country Regulatory Province	Literature Reference	Patent Age Group	Patent Age Group (see report)	Patent Sex	Patent OM Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
			Professional	Non-Eurozone Economic Area	Not available	Not Specified	Not Specified		No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Unknown)		C38
EU-EC-100069589	11/09/2021	Spontaneous	Non-Eurozone Professional	Non-Eurozone Economic Area	Not available	Not Specified	Not Specified		No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Unknown)	Not reported	C38
EU-EC-1000693474	10/09/2021	Spontaneous	Non-Eurozone Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Patient(s))	Not reported	C38
EU-EC-1000692678	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	PROLIA [DENOSUMAB] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [ALCOPIRONE, ALCOPIRONE BESILATE, ALCOPIRONE MALEATE, ALCOPIRONE MESILATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [CALCIUM CARBONATE, COLICOLIPEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [ESOCALOPRAM, ESOCALOPRAM OXALATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [LORATADINE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [RETINOL, THIAMINE HYDROCHLORIDE, ASCORBIC ACID, ERGOCALCIFEROL, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE, RETINOYL] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [TOPRAMATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)	C38
EU-EC-1000692679	09/09/2021	Spontaneous	Non-Eurozone Professional	European Economic Area	Not available	16-64 Years	Adult	Female	No	Arrhythmia (n/a - Fatal - Results in Death), Chills (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Injection site haematoma (n/a - Fatal - Results in Death), Injection site inflammation (n/a - Fatal - Results in Death), Injection site pain (n/a - Fatal - Results in Death), Injection site warmth (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - n/a)	Not reported	C38
EU-EC-1000692684	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	16-64 Years	Not Specified	Female	No	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Unknown)	Not reported	C38
EU-EC-1000692630	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000691825	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Pulmonary haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition) Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692640	07/09/2021	Spontaneous	Non-Eurozone Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-10006917440	09/09/2021	Spontaneous	Non-Eurozone Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692628	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692640	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Vaccination complication (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692657	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest discomfort (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Disorientation (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	[LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - (n/a - 1DP) - Unknown), [METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - (n/a - 1DP) - Unknown)	C38
EU-EC-1000692678	09/09/2021	Spontaneous	Non-Eurozone Professional	Non-Eurozone Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692630	09/09/2021	Spontaneous	Non-Eurozone Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692604	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692636	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition), Cold sweat (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692609	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692687	09/09/2021	Spontaneous	Non-Eurozone Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Unknown)	Not reported	C38
EU-EC-10006926717	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692670	09/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Pain (n/a - Unknown -), Pyrexia (n/a - Unknown -), Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000695962	05/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cerebral arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692630	05/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Arteriovenous block complex (n/a - Fatal - Results in Death), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - (n/a - 5mL - Intramuscular)	Not reported	C38
EU-EC-1000695985	05/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000692630	05/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cardiovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000691602	05/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-1000907807	05/09/2021	Spontaneous	Non-Eurozone Professional	Non-Eurozone Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Unknown)	Not reported	C38
EU-EC-1000692642	05/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Seizure (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	[BUPROPION HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - 150mg - Unknown), [HYDROXYCHLOROQUINE SULFATE] (C - Product used for unknown indication - n/a - (n/a - 200mg - Unknown), [VENLAFAXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - 150mg - Unknown)	C38
EU-EC-1000695148	05/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death), COVID-19 pneumonia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Electrolyte imbalance (n/a - Fatal - Results in Death), Gastrointestinal disorder (n/a - Fatal - Results in Death), Haemodynamic instability (n/a - Fatal - Results in Death), Liver injury (n/a - Fatal - Results in Death), Shock (n/a - Fatal - Results in Death), Supraventricular tachycardia (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)		C38
EU-EC-10006957036	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - (n/a - n/a - n/a)	Not reported	C38
EU-EC-10006926773	04/09/2021	Spontaneous	Non-Eurozone Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	[DIPYRIDAMOLE, ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)	C38
EU-EC-10006926325	04/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [CYNANODOLAMINE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [ALCOPIRONE, ALCOPIRONE BESILATE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [AZELASTINE, AZELASTINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [CLONIDINE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [COLCHICINE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [DOLOPHENAC POTASSIUM] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [FLURIDOLONE PROPIONATE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [LUDOCINE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [LISINAPRIL, LISINAPRIL DEHYDRATE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [MELNOCAM] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [METOPROLOL, METOPROLOLOL TARTRATE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [NIFEDIPINE, NIFEDIPINE, NIFEDIPINE SODIUM] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [PRONALONE, PRONALONE PH. EUR.] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [SALBUTAMOL SULFATE, [PRATROLOLUM BROMIDE] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown), [SINISTATIN] (C - Product used for unknown indication - n/a - (n/a - 1DP) - Unknown)	C38
EU-EC-10006926737	03/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Chest pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - (n/a - n/a - Unknown)	[ETALOPRAM, ETALOPRAM HYDROBROMIDE, ETALOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [METOPROLOL, METOPROLOLOL TARTRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [PREDNISOLONE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)	C38
EU-EC-10006974237	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - (n/a - n/a - n/a)		C38
EU-EC-10006973376	03/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Central haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic interstitial (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition) Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ful (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1DP) - Intramuscular)	Not reported	C38
EU-EC-10006959429	03/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ful (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - (n/a - 1DP) - Intramuscular)	[ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [ATENOLOL, ATENOLOL BP] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [ATENOLOL, ATENOLOL BP] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [FANTOTINE, FANTOTINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [PARACETAMOL] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown), [VITAMINE K2] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)	C38
EU-EC-10006959727	03/09/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dehydration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)</			

EU Local Number	EV Entry Request Date	Report Type	Primary Source Question	Primary Source Country Regulatory Process	Literature Reference	Patent Age Group	Patent Age Group Low risk	Patent Sex	Patent OMI Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intending Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Her Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
										Dyspnoea (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hekatomia (85d - Fatal - Results in Death, Other Medically Important Condition), Hepatic pain (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hyperventilation (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Illness (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown -), Pleural effusion (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (85d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sleep disorder (85d - Recovered/Resolved - Caused/Prolonged Hospitalisation) Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Reactivation (1d - Fatal - Results in Death), Unresponsive to stimuli (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	XARELTO (RIVAROXABAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (FLUTICASON PROPRIONATE, SALMETEROL, XANAXOATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	628
EU-EC-100093868	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (5d - Fatal - Results in Death), COVID-19 (5d - Fatal - Results in Death, Other Medically Important Condition) Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000938415	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000937962	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000937964	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000938924	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (3d - Not Recovered/Not Resolved -), Nausea (3d - Not Recovered/Not Resolved -), Pyrexia (3d - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	MONOCLONAL ANTIBODIES, GRANULOCYTE (C - COVID-19 - n/a - [n/a - n/a - Unknown])	628
EU-EC-1000939478	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	MELATONIN (MELATONIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LIDOCAINE HYDROCHLORIDE MONOHYDRATE, EPINEPHRINE, LIDOCAINE HYDROCHLORIDE, LIDOCAINE HYDROCHLORIDE MONOHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (CALCIOTININ (SALMON)) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (COLICACALFEROL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (CYANOCOBALAMIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DOLIPHENAC POTASSIUM, DOLIPHENAC SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (FLUTICASON PROPRIONATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (LORATADINE) (C - Product used for unknown indication - n/a - [n/a - n/a - 1DP] - Unknown), (LORAZEPAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (MACRODOL 350S) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (MAGNESIUM HYDROXIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (MENTHANE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (OXYCODONE, OXYCODONE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TRAZODONE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (VALPROATE SEMISODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ARSENIC SULFONIDES) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (LANTUS (INSULIN GLARGINE)) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ALOPURINOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (AMINOGLUCOSIDE, POTASSIUM CLAVULANATE, AMINOGLUCOSIDE, CLAVULANIC ACID) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (CALCIUM CARBONATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DOPAZOL, HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (FERROUS GLUCONATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (GABAPENTIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (MIRTAZAPINE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DIMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (PANTOPRAZOLE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (PREDNISONE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TRAMADOL, TRAMADOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (VITAMINE MOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ACETYL SALICYLIC ACID, ASPIRIN BP) (C - n/a - n/a -), (COLECALCIFEROL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DOXAZOSIN, DOXAZOSIN MESILATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (FUROSEMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (LACTULOSE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (METOPROLOL, METOPROLOLOL TARTRATE PH. EUR) (C - n/a - n/a -), (DIMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (SPRONOLACTONE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TRIAMCINOLONE ACETONIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (URSODEOXYCHOLIC ACID) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	628
EU-EC-1000939523	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000939599	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Anaemia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular pump pump function (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	PLAVIN (ELPIDOREL, CLOPIDOREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (HYDROALAZINE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (PRAVASTATIN, PRAVASTATIN SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (TRAMETEREN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	628
EU-EC-1000939070	16/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown -), Confusional state (n/a - Unknown -), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Hekatomia (n/a - Unknown - Other Medically Important Condition), Myasthenia gravis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition) COVID-19 (24d - Fatal - Results in Death), Cervical cancer (24d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Failure to thrive (24d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000939069	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (24d - Fatal - Results in Death), Cervical cancer (24d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Failure to thrive (24d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000939036	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Gastrointestinal disorder (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000939129	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000939042	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (4d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000939132	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2DP] - Unknown)	Not reported	628
EU-EC-10009391578	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Alektosis (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infection (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocarditis (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	(CARVEDILOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (BICYCLOHEXANE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (GABAPENTIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (HYDROCHLORIDE, LORAZEPAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (LORAZEPAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (NORTRIPTYLINE, NORTRIPTYLINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DIMEPRAZOLE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TAMBOLOLIN, TAMBOLOLIN HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	628
EU-EC-1000939183	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-10009391947	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiac failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Overweight/obesity health deterioration (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Renal impairment (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thoracic cavity drainage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-10009391262	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (15d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hypertensive heart disease (15d - Fatal - Results in Death), Left ventricular failure (15d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-10009393470	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	XARELTO (RIVAROXABAN) (C - Adverse event - n/a - [n/a - n/a - n/a]), (ATORVASTATIN, CALCIUM) (C - Adverse event - n/a - [n/a - n/a - n/a]), (BENZONATATE) (C - Adverse event - n/a - [n/a - n/a - n/a]), (CYANOCOBALAMIN, VITAMIN B12) (C - Adverse event - n/a - [n/a - n/a - n/a]), (DILTIAZEM HYDROCHLORIDE) (C - Adverse event - n/a - [n/a - n/a - n/a]), (EUCERIN, UREA, WOOL ALCOHOLS) (C - Adverse event - n/a - [n/a - n/a - n/a]), (FLUTICASON PROPRIONATE) (C - Adverse event - n/a - [n/a - n/a - n/a]), (FURAZEPAM, FURAZEPAM SODIUM) (C - Adverse event - n/a - [n/a - n/a - n/a]), (LORAZEPAM) (C - Adverse event - n/a - [n/a - n/a - n/a]), (LOSARTAN POTASSIUM) (C - Adverse event - n/a - [n/a - n/a - n/a]), (MACRODOL 350S) (C - Adverse event - n/a - [n/a - n/a - n/a]), (METFORMIN HYDROCHLORIDE) (C - Adverse event - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - Adverse event - n/a - [n/a - n/a - n/a]), (POTASSIUM CHLORIDE) (C - Adverse event - n/a - [n/a - n/a - n/a]), (PROMICOL, PROMICOL HYDROCHLORIDE) (C - Adverse event - n/a - [n/a - n/a - n/a]), (SALBUTAMOL, SULFATE) (C - Adverse event - n/a - [n/a - n/a - n/a]), (SALICYLIC ACID) (C - Adverse event - n/a - [n/a - n/a - n/a]), (TOTOPRILAM, TOTOPRILAM BROMIDE, TOTOPRILAM BROMIDE MONOHYDRATE) (C - Adverse event - n/a - [n/a - n/a - n/a]), (ALLIUM SATIVUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ASCORBIC ACID, ALUMINOCYCLOPHOSPHATE, ACETATE) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (ASCORBIC ACID) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (FISH OIL) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (LIDOCAINE) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown)	628
EU-EC-1000939353	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	BENAZEPRIL (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), (CARBOPOL, LEVODOPA, LEVODOPA, CARBOPOL MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DOPAZOL, FURAZEPAM SODIUM) (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), (ESOPRILAM, ESOPRILAM DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), (LEVOTHYRONINE, LEVOTHYRONINE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown])	628
EU-EC-1000939341	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiac failure congestive (2d - Fatal - Results in Death, Other Medically Important Condition), Chronic kidney disease (2d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (2d - Fatal - Results in Death), Hypertension (2d - Fatal - Results in Death), Overweight/obesity (2d - Fatal - Results in Death, Other Medically Important Condition), Pneumonia septation (2d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000939348	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death), Arrhythmia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death), Haemorrhage urinary tract (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bare placement (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ventricular tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	(BENAZEPRIL) (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), (CARBOPOL, LEVODOPA, LEVODOPA, CARBOPOL MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DOPAZOL, FURAZEPAM SODIUM) (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), (ESOPRILAM, ESOPRILAM DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), (LEVOTHYRONINE, LEVOTHYRONINE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown])	628
EU-EC-1000939387	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-1000939386	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	(ACETYL SALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (ALLOPRIDINE, ALLOPRIDINE MESILATE, ALLOPRIDINE MESILATE) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (COLECALCIFEROL) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (FISH OIL) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (HYDROCODONE) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (LOSARTAN, LOSARTAN POTASSIUM) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), (PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown)	628
EU-EC-10009397177	16/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Back pain (n/a - Unknown -), Chills (n/a - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Joint swelling (n/a - Unknown -), Mobility decreased (n/a - Unknown -), Peripheral swelling (n/a - Unknown -), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-10009397218	16/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2mL - Unknown])	Not reported	628
EU-EC-10009397332	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	(WAFAPRIN SODIUM) (C - Diabetes mellitus - n/a - [n/a - 1DP] - Unknown)	628
EU-EC-10009397466	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Brain oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Organ failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	628
EU-EC-10009398070	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years							

EU Label Number	EV Emergency Review Date	Report Type	Primary Source Questionnaire	Primary CMT Country Regulatory Province	Literature Reference	Patient Age Group	Patient Age Group (see report)	Patient Sex	Patient CMT Report	Reaction List PT Duration ? Outcome - Seriousness Criteria	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	C2SR Form
										Myocardial Infarct (101 - Fatal - Results in Death).		[VITAMINS MDZ] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	
EU-EC-100003030	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Myocardial Infarct (101 - Fatal - Results in Death, Other Medically Important Condition), Oedema (131 - Fatal - Results in Death), Unresponsive to stimuli (101 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-100003032	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (14 - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Syncope (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-100003002	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Brain oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Central haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Thrombocytosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [ASCORBIC ACID] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - Unknown]), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [VITAMINS MDZ] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [ZINC] (C - Product used for unknown indication - n/a - [n/a - Unknown])	C2SR
EU-EC-100003168	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-1000026177	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Abdominal pain upper (101 - Fatal - Results in Death), Death (101 - Fatal - Results in Death, Other Medically Important Condition), Discomfort (101 - Fatal - Results in Death), Feeling abnormal (101 - Fatal - Results in Death), Vomiting (101 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[ATORVASTATIN, CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [BICALUTAMIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [FINASTERIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [PYRIDOXINE HYDROCHLORIDE, VITAMIN B6] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown)	C2SR
EU-EC-100003108	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-100003032	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chest pain (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Colic/schaemic (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constrictive state (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (131 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ejection fraction decreased (131 - Fatal - Results in Death), Ischaemic cardiomyopathy (131 - Fatal - Results in Death, Other Medically Important Condition), Thorax (131 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-1000030156	08/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-1000031103	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal pain (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anaemia (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Colic/schaemic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constrictive state (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Constipation (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coronary artery disease (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Epigastric discomfort (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Feeling cold (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypokalaemia (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver/spleen (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Neuralgia (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (131 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in C2SR)	[ELVOCYPRINOL, BROMIDE] (C - Product used for unknown indication - n/a - [n/a - 4mg - Oral]), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 15mg - Oral]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]), [METOPROLOL, METOPROLOL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown)	C2SR
EU-EC-10000293176	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[CHINBALTA, EULOXETINE, EULOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [MALICOPRIL, MALICOPRIL MESILATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown)	C2SR
EU-EC-1000028520	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cerebrovascular accident (951 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Phobia (951 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-1000028076	07/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anxiety (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Fluid intake reduced (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Liver disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[AMTOSPTIN, AMTOSPTIN HYDROCHLORIDE] (C - Sleep disorder - n/a - [n/a - n/a - Oral]), [MALICOPRIL, MALICOPRIL MESILATE, AMALOPRIL MESILATE, AMALOPRIL MESILATE] (C - Blood pressure management - n/a - [n/a - n/a - Oral]), [HYDROXYZINE] (C - Product used for unknown indication - n/a - [n/a - Oral]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C2SR
EU-EC-1000028024	07/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Coronary artery disorders (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Ischaemic cardiomyopathy (n/a - Fatal - Results in Death, Other Medically Important Condition)	SPRIVAX [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - n/a - [n/a - 10DF] - n/a)	[ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - n/a)	C2SR
EU-EC-1000029469	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (14 - Fatal - Results in Death, Other Medically Important Condition), Malaise (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in C2SR)	Not reported	C2SR
EU-EC-10000297915	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (n/a - Unknown -), Aspiration (n/a - Not Recovered/Not Reported - Other Medically Important Condition), Asthma (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Feeding disorder (n/a - Unknown -), Hemoptysis (n/a - Unknown -), Hypertension (n/a - Unknown -), Leukorrhea (n/a - Unknown -), Pyrexia (n/a - Unknown -), Thrombocytopenia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), [COLICOLICOPRIL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CUCURBITACIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [TERAZOSIN, TERAZOSIN HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [SODIUM] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown])	C2SR
EU-EC-1000028697	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Episodes (n/a - Fatal - Results in Death, Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-1000028681	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-10000273470	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Recovered/Revised - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovered/Revised -), Paracetamol (n/a - Unknown - Caused/Prolonged Hospitalisation), Phobia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-10000273206	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dry mouth (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Malaise (n/a - Unknown -), Thirst (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-10000270752	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Product dose omission issue (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-1000028042	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Abdominal discomfort (251 - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death, Life Threatening), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dehydration (n/a - Fatal - Results in Death), Diarrhoea (101 - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Leukorrhea (101 - Fatal - Results in Death), Malaise (251 - Fatal - Results in Death), Tremor (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-10000280132	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Hot flush (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-10000283843	06/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIVAX (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	C2SR
EU-EC-10000284007	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C2SR
EU-EC-10000285042	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	B cell lymphoma (1061 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1061 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (1061 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lymphoma (1061 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (1061 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in C2SR)	[TROVAVIN, DIFETILIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C2SR
EU-EC-10000285151	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[COLICOLICOPRIL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 3000mg - Oral])	C2SR
EU-EC-10000285518	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in C2SR)	Not reported	C2SR
EU-EC-10000257759	05/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition), Resuscitation (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in C2SR)	[COLICOLICOPRIL, CALCIUM CITRATE] (C - Product used for unknown indication - n/a - [n/a - 40DF] - Unknown), [DOXILATE, SODIUM CASIN] (C - Product used for unknown indication - n/a - [n/a - 42mg - Unknown]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [LAMOTRIGINE] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [LISINAPRIL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 3000mg - Unknown]), [POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 300mg - Unknown]), [VITAMINS] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown)	C2SR
EU-EC-10000281484	05/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	No	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Depressed mood of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (10 - Fatal - Results in Death, Other Medically Important Condition), Stupor (n/a - Fatal - Results in Death, Other Medically Important Condition)	SPRIVAX [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - n/a - n/a - [n/a - n/a - Intramuscular])	[KARELTO 20 MG (BIVANDANAT)] (C - n/a - n/a - [n/a - n/a - n/a]), [DONPEZIL HYDROCHLORIDE] (C - n/a - n/a -)	C2SR
EU-EC-1000028816	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (24 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - Oral]), [DOXILATE, SODIUM] (C - Product used for unknown indication - n/a - [n/a - 200mg - Oral]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 3000mg - Oral])	C2SR
EU-EC-10000241425	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic									

EU Local Number	EV Emergency Prepared Date	Report Type	Primary Questionnaire	Primary Country Regulatory Province Area	Literature Reference	Patient Group	Patient Age Group (see par)	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
												[FINASTERIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [BROMOERIN] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [MONTILAKAST, MONTILAKAST SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [BIMASTATIN] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [TOLTERODINE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown)	
EU-EC-10009180118	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chills (2d - Fatal - Results in Death), Cough (2d - Fatal - Results in Death), Death (2d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (2d - Fatal - Results in Death), Pyrexia (2d - Fatal - Results in Death), Vaccination site pain (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009180024	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardio-respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (1d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Embolism (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (1d - Fatal - Results in Death), Hypertension (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009180040	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009181104	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Arabic encephalomyelitis (n/a - Unknown - CausedProlonged Hospitalisation), Condition aggravated (n/a - Unknown - CausedProlonged Hospitalisation), Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - CausedProlonged Hospitalisation), Pneumonia (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in CSRs)	BUMETANIDE (BUMETANIDE) (C - Product used for unknown indication - n/a - [n/a - 1mg - n/a]), ACETYL SALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [EZETIMIBE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [HYDROALAZINE] (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), [LEVOTHYROIDINE, LEVOTHYROIDINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 50ug - n/a]), [LIDOCALINE] (C - Product used for unknown indication - n/a - [n/a - 15mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 4mg - n/a]), [BIDOCARENONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	e28
EU-EC-10009181109	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009182009	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in CSRs)		e28
EU-EC-10009182426	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009183321	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac failure acute (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	SPRIKIVIA [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009183325	28/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009187160	21/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Chest discomfort (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	LANTUS (INSULIN GLARGINE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	e28
EU-EC-10009189002	26/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dehydration (1d - Fatal - Results in Death, CausedProlonged Hospitalisation), Diarhoea (1d - Fatal - Results in Death, CausedProlonged Hospitalisation), Dyskinesia (1d - Fatal - Results in Death, CausedProlonged Hospitalisation), Leishish adenitis (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Nausea (1d - Fatal - Results in Death, CausedProlonged Hospitalisation), Renal failure (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Toxicity to various agents (1d - Fatal - Results in Death, CausedProlonged Hospitalisation), Vomiting (1d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in CSRs)		e28
EU-EC-10009142827	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fall (5d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[KIEFERAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	e28
EU-EC-10009147126	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (3d - Fatal - Results in Death)	SPRIKIVIA [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2dL - Intramuscular])	ZYLIT (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - n/a - n/a - [n/a - 75mg - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM DRYHYDRATE] (C - n/a - n/a - [n/a - 20mg - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 20mg - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 200mg - Oral])	e28
EU-EC-10009147765	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (3rd - Fatal - Results in Death), Lebargy (3rd - Fatal - Results in Death), Migraine (3rd - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	LYSCA (PREGABALIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ESTROGENS CONJUGATED, ESTROGEN SODIUM SULFATE, EQUILIN SULFATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DICYCLODOL, DICYCLODOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DICYCLODOL, DICYCLODOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL, ACETYL SALICYLIC ACID, Caffeine] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	e28
EU-EC-10009151814	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009153359	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (1d - Fatal - Results in Death), Lebargy (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009153385	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009154405	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009154751	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	ELQUE (APRABAN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIPLODOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	e28
EU-EC-10009156484	25/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[CARBISOLIC] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Oral), [FLUCONAZOLE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Topical), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [HYDROCORTISONE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Oral), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Oral), [PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM, ESOMEPRAZOLE] (C - Product used for unknown indication - Unknown - [n/a - 10DF] - Unknown), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - Unknown - [n/a - 10DF] - Unknown), [HYDROXYCARBONOLINE] (C - Product used for unknown indication - Unknown - [n/a - 10DF] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - Unknown - [n/a - 10DF] - Unknown), [PLOCARPINE, PLOCARPINE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a - 10DF] - Unknown)	e28
EU-EC-10009124144	24/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Anaemia (n/a - Unknown - CausedProlonged Hospitalisation), Asthma (n/a - Unknown - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown - CausedProlonged Hospitalisation), Dizziness (n/a - Unknown - CausedProlonged Hospitalisation), HCV/HCV infection (n/a - Unknown - CausedProlonged Hospitalisation), Headache (n/a - Unknown - CausedProlonged Hospitalisation), Hypotension (n/a - Unknown - CausedProlonged Hospitalisation), Lymphadenopathy (n/a - Unknown - CausedProlonged Hospitalisation), Nausea (n/a - Unknown - CausedProlonged Hospitalisation), Neck pain (n/a - Unknown - CausedProlonged Hospitalisation), Orthostatic hypotension (n/a - Unknown - CausedProlonged Hospitalisation), Peripheral T-cell lymphoma unspecified (n/a - Fatal - Results in Death, Other Medically Important Condition), Rash (n/a - Unknown - CausedProlonged Hospitalisation), Respiratory symptom (n/a - Unknown - CausedProlonged Hospitalisation), Sepsis (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - CausedProlonged Hospitalisation), Urinary (n/a - Unknown - CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009138429	24/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Pyrexia (1d - Fatal - Results in Death), Skin desquamation (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009142526	24/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Acute thrombosis (2d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Brain herniation (2d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (2d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Death (2d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (2d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Neurological symptom (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Peripheral artery thrombosis (2d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	[ABALOPARITIDE] (C - Product used for unknown indication - n/a - [n/a - 80mg - Subcutaneous]), [COLESTIPOL] (C - Product used for unknown indication - n/a - [n/a - 3g - Unknown]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [SUBAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [HYDROMORPHINE] (C - Pain - n/a - [n/a - 4mg - Unknown]), [METOPROLOL, METOPROLOL HYDROCHLORIDE, METOPROLOL HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown)	e28
EU-EC-10009142532	24/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Inappropriate schedule of product administration (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - [n/a - 10DF] - Intramuscular - More in CSRs)		e28
EU-EC-10009113306	23/06/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	SPRIKIVIA [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009118995	23/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Loss of consciousness (1d - Fatal - Results in Death, Other Medically Important Condition), Myalgia (1d - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (1d - Fatal - Results in Death, Other Medically Important Condition)	SPRIKIVIA [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	INSULIN HUMAN (INSULIN HUMAN) (C - Product used for unknown indication - Does not changed - [n/a - 3mg - Unknown]), LYSCA (PREGABALIN) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), TRESBA (INSULIN GLARGINE) (C - Product used for unknown indication - Does not changed - [n/a - 600DF] - Unknown), [ACTOGLIC, ACTOGLIC] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown]), [ACENOCUMAROL] (C - Product used for unknown indication - Does not changed - [n/a - 1mg - Unknown]), [FLECANIDE, FLECANIDE ACETATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [GLUCAGON, GLUCAGON HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [OLYVERIL, TRINITRATE] (C - Chest pain - n/a - [n/a - 200DF] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown]), [LOMBETAPINE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - Does not changed - [n/a - 100mg - Unknown]), [PANTOPRAZOLE] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown])	e28
EU-EC-10009120747	23/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Acute kidney injury (95d - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death), Haematuria (85d - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Central thrombosis (13d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (13d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)		e28
EU-EC-10009121120	23/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Haematuria (85d - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Central thrombosis (13d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (13d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	HIMALDOL (INSULIN LISPRO) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), JARDANCE (EMPAAGLIFLOZIN) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), LANTUS (INSULIN GLARGINE) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [ACICLOVIR, ACICLOVIR] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown]), [ACENOCUMAROL] (C - Product used for unknown indication - Does not changed - [n/a - 1mg - Unknown]), [FLECANIDE, FLECANIDE ACETATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [GLUCAGON, GLUCAGON HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [OLYVERIL, TRINITRATE] (C - Chest pain - n/a - [n/a - 200DF] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown]), [LOMBETAPINE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - Does not changed - [n/a - 100mg - Unknown]), [PANTOPRAZOLE] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown])	e28
EU-EC-10009121120	23/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Haematuria (85d - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Central thrombosis (13d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (13d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	HIMALDOL (INSULIN LISPRO) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), JARDANCE (EMPAAGLIFLOZIN) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), LANTUS (INSULIN GLARGINE) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [ACICLOVIR, ACICLOVIR] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown]), [ACENOCUMAROL] (C - Product used for unknown indication - Does not changed - [n/a - 1mg - Unknown]), [FLECANIDE, FLECANIDE ACETATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown), [GLUCAGON, GLUCAGON HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [OLYVERIL, TRINITRATE] (C - Chest pain - n/a - [n/a - 200DF] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown]), [LOMBETAPINE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - Does not changed - [n/a - 100mg - Unknown]), [PANTOPRAZOLE] (C - Product used for unknown indication - Does not changed - [n/a - 20mg - Unknown])	e28
EU-EC-10009123370	23/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically			

EU Local Number	EV Emergency Review Date	Report Type	Primary Source Questionnaire	Primary Country Regulatory Procedure	Literature Reference	Patient Age Group	Patient Age Group (see report)	Patient Sex	Patient Onset Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
										Heart rate irregular (n/a - Unknown - Other Medically Important Condition).			
EU-EC-1000084761	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Pericardial swelling (n/a - Unknown - Other Medically Important Condition). COVID-19 (44 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). COVID-19 pneumonia (44 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (44 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000084763	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Drug effluvia (n/a - Unknown -). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Foaming at mouth (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000084764	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Mastitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000084797	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Back pain (765 - Unknown -). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Information (765 - Unknown - Other Medically Important Condition). Sciatica (765 - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	ELIQUIS (APIXIVAN) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). EODOLACOPERA (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). ESOCALOPRAM, ESOCALOPRAM CHLORATE (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). BIMVASTATIN (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown).	628
EU-EC-1000084840	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000084886	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-66 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000084899	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000085081	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000085083	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000085018	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000085061	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000085068	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Arrhythmia (14 - Fatal - Results in Death, Other Medically Important Condition). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Seizure (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	CARIPRAZINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]. [LONIMINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]. LISDEXAMFETAMINE DIMESYLATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown).	628
EU-EC-1000085603	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (74 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000085689	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	ALTOPHASTIN, ALTOPHASTIN CALCIUM, ALTOPHASTIN CALCIUM TRIMETHYL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]. [ULTAZIM, ULTAZIM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]. [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]. [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]. [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]. [CLONAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]. [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]. [MONTELUKAST, MONTELUKAST SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]. [ACETYLSALICYLIC ACID, ASPIRIN, BP] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]. ALTOPHASTIN, ALTOPHASTIN CALCIUM, ALTOPHASTIN CALCIUM TRIMETHYL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]. [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]. [DAZEPRAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]. [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]. [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]. [DIPYRIDOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]. [VITAMIN K3] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a].	628
EU-EC-1000087442	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in CSR)	Not reported	628
EU-EC-1000087610	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000088102	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Acute kidney injury (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Hypertension (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000088601	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Hypertension (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Death (334 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000089082	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Intracardiac thrombus (134 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Myocardial infarction (134 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Phenoxia (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Thrombolytic (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000089090	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular - More in CSR)	Not reported	628
EU-EC-1000089226	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Dizziness (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Headache (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Subdural haemorrhage (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Thrombocytopenia (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000089239	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000089284	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Atrial fibrillation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Cardiac failure chronic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Epstein-Barr virus decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Follicular lymphoma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Vaccination failure (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000090302	21/05/2021	Spontaneous	Non- Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown -). Back pain (n/a - Unknown -). Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Headache (n/a - Unknown -). Hospitalisation (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000090456	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Decreased appetite (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	LARTYLE (NOLFIN GLABRINE) (C - Product used for unknown indication - n/a - [n/a - 100mg] - Unknown). [PHENYLENE] (C - Product used for unknown indication - n/a - [n/a - 100mg] - Unknown). [QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown]. [TEMZEPRAM] (C - Product used for unknown indication - n/a - [n/a - 30mg - Unknown]. [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown]. [SIBASATININ] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown].	628
EU-EC-1000090472	21/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death). Feeling depressed (24 - Fatal - Results in Death, Other Medically Important Condition). Mastitis (24 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000090476	21/05/2021	Spontaneous	Non- Healthcare Professionals	Non- European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition). Seizure (n/a - Unknown - Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000091023	20/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	18-64 Years	Not Specified	Female	No	COVID-19 (84 - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Dyspnoea (84 - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Headache (84 - Fatal - Results in Death, Caused/Prolonged Hospitalisation). Pyrexia (84 - Fatal - Results in Death, Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	CELCEFT (ACYCLOPENCILATE MOETIL) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [ACICLOVIR, ACICLOVIR, ACICLOVIR MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [CICLOPENTIN] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [PRENOSONE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown).	628
EU-EC-1000091027	20/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	ENTRESTO (VALSARTAN, SACUBITRIL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown). [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - n/a]. [BUTIN] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [CALCIUM ACETATE] (C - Product used for unknown indication - n/a - [n/a - 2001mg - n/a]. [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown]. [FOUC ACID] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown). [HYDROMAGNESIUM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 8mg - One]. [ACETYLCISTEINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown). [ALLOPURINOL] (C - Product used for unknown indication - n/a - [n/a - 300mg - Unknown]. [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [BUDESONIDE, BUDESONIDE, MICRONISED] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [COPROLOXON, COPROLOXON HYDROCHLORIDE, COPROLOXON LACTATE] (C - Product used for unknown indication - n/a - [n/a - 500mg - Unknown). [COLCHICINE] (C - Product used for unknown indication - n/a - [n/a - 8mg - Unknown). [FURSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [SALBUTAMOL, SULFATE, [SALBUTAMOL BROMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown). [TRIMETHOPRIM LACTATE, SULFAMETHOXAZOLE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown).	628
EU-EC-1000091417	20/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Asthma (574 - Fatal - Results in Death). Death (14 - Fatal - Results in Death, Other Medically Important Condition). Decreased appetite (574 - Fatal - Results in Death). Dyspareunia (574 - Fatal - Results in Death). General physical health deterioration (574 - Fatal - Results in Death). Illness (574 - Fatal - Results in Death). Immediate post-injection reaction (574 - Fatal - Results in Death). Malnutrition (574 - Fatal - Results in Death). Staphylococcal sepsis (574 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000090725	18/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Weight decreased (574 - Fatal - Results in Death). Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition). Headache (n/a - Unknown - Caused/Prolonged Hospitalisation).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000091028	18/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Ischaemic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition). Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000090619	18/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	IRON (IRON) (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [MELATONIN, MELATONIN] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [COD-LIVER OIL] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [ERGOCALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [FENOFENACINE, FENOFENACINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [FURSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [LORATADINE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown). [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10DF] - Unknown).	628
EU-EC-1000090629	18/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	628
EU-EC-1000090736	18/05/2021	Spontaneous	Healthcare Professionals	Non- European Economic Area	Not available	65							

[illegible]

EU Local Number	EV Emergency Review Date	Report Type	Primary Source Question	Primary Country Regulatory Economic Area	Literature Reference	Patient Age Group	Patient Age Group Low risk	Patient Sex	Patient OHM Report	Reaction List PT Duration ? Outcome - Seriousness Criteria	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
										Respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition)		(ACICORIC ACES) (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), (HYDROALAME) (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), (PRYATOPRUM, SALUBITAMOL) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (ISOSORBIDE DINITRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (PANTOPRAZOLE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), (PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), (ROSEHIP SEED OIL) (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a])	C28
EU-EC-1000873461	20/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (3d - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000872452	20/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Vomiting (n/a - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000873467	20/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	(MILMOFINE BESILATE) (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), (BIOTIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (FURCISEMIDE) (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), (SULFIDIDE) (C - Product used for unknown indication - n/a - [n/a - 2.5mg - Unknown]), (LUSARTAN POTASSIUM) (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), (METOPROLOL TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), (VITAMINS NCOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000872501	20/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Condition aggravated (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	C28
EU-EC-1000872508	20/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000872504	20/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Oral (n/a - Unknown - CausedProlongedHospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (n/a - Unknown - CausedProlongedHospitalisation), Fall (n/a - Unknown - CausedProlongedHospitalisation), Gait disturbance (n/a - Unknown - CausedProlongedHospitalisation), Hypotension (n/a - Unknown - CausedProlongedHospitalisation), Muscular weakness (n/a - Unknown - CausedProlongedHospitalisation), Pyrexia (n/a - Unknown - CausedProlongedHospitalisation), Sensory disturbance (n/a - Unknown - CausedProlongedHospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000869383	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	C28
EU-EC-1000870059	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000870170	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Condition aggravated (n/a - Not Recovered/Not Resolved - CausedProlongedHospitalisation), Death (n/a - Fatal - Results in Death, CausedProlongedHospitalisation, Other Medically Important Condition), Dementia (n/a - Not Recovered/Not Resolved - CausedProlongedHospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - CausedProlongedHospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSRS)	(ATORVASTATIN) (C - Product used for unknown indication - n/a - [n/a - 40mg - Oral]), (CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]), (CYANOCOBALAMIN) (C - Product used for unknown indication - n/a - [n/a - 500mg - Unknown]), (FOLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 400mg - Oral]), (FOSPHOPRIL) (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]), (MENANTIN) (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral])	C28
EU-EC-1000870193	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000870200	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	C28
EU-EC-1000870204	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	LEVIMER (INSULIN DETEMIR) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ALPHADOLAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (QUAMPREN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (INSULIN, INSULIN HUMAN) (C - Diabetes mellitus - n/a - [n/a - n/a - Subcutaneous]), (DIYODINE, OXYCODONE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ROPANROL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28	
EU-EC-1000870238	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSRS)	Not reported	C28
EU-EC-1000870239	18/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (n/a - Fatal - Results in Death), Gait instability (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000870289	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -), Hypertension (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000870372	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000870310	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	(ATORVASTATIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (CHLORTALIDONE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (FENOFIBRATE, FENOFIBRATE MICRONISED) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (QUINAPRIL, QUINAPRIL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (BUPROFEN, BUPROFEN, BUPROFEN SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TIMOLOLOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 4mg - n/a])	C28
EU-EC-1000870467	19/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Body temperature increased (n/a - Unknown - CausedProlongedHospitalisation), Chest pain (n/a - Unknown - CausedProlongedHospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Unknown - CausedProlongedHospitalisation), Gait instability (n/a - Unknown - CausedProlongedHospitalisation), Headache (n/a - Unknown - CausedProlongedHospitalisation), Headache (n/a - Unknown - CausedProlongedHospitalisation), Mistake (n/a - Unknown - CausedProlongedHospitalisation), Nausea (n/a - Unknown - CausedProlongedHospitalisation), Oropharyngeal pain (n/a - Unknown - CausedProlongedHospitalisation), Rheumatoid arthritis (n/a - Unknown - CausedProlongedHospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - CausedProlongedHospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSRS)	(CYANOCOBALAMIN, CYANOCOBALAMINE - BP) (C - Product used for unknown indication - Not applicable - [n/a - 1DP] - Intramuscular), (LORAZEPAM) (C - Product used for unknown indication - Not applicable - [n/a - 1mg - Oral]), (MACRODOL, 3000, POTASSIUM CHLORIDE, SODIUM CARBONATE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACRODOL, 3000, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACRODOL, 3000) (C - Product used for unknown indication - Not applicable - [n/a - 1DP] - Intramuscular), (METFORMIN, ACID) (C - Product used for unknown indication - Not applicable - [n/a - 1000mg - Oral]), (METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE) (C - Product used for unknown indication - Not applicable - [n/a - 500mg - Oral]), (PARACETAMOL) (C - Product used for unknown indication - Not applicable - [n/a - 1000mg - Oral])	C28
EU-EC-1000895547	18/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Unknown - CausedProlongedHospitalisation), Cerebral ischaemia (n/a - Unknown - CausedProlongedHospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death), Food intolerance (n/a - Unknown - CausedProlongedHospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, CausedProlongedHospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - CausedProlongedHospitalisation), Nausea (n/a - Unknown - CausedProlongedHospitalisation), Terminal state (n/a - Unknown - Life Threatening, CausedProlongedHospitalisation, Other Medically Important Condition), Adverse event (n/a - Unknown - CausedProlongedHospitalisation), Death (1d - Fatal - Results in Death, CausedProlongedHospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	C28
EU-EC-1000867904	17/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, CausedProlongedHospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000867874	17/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Bradycardia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dizziness (n/a - Unknown -), Fall (n/a - Unknown -), Mistake (n/a - Unknown -), Myalgia (n/a - Unknown -), Myocardial necrosis marker increased (n/a - Unknown - Other Medically Important Condition), Pulse absent (n/a - Unknown -), Puff test (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	BUPROFEN (BUPROFEN, BUPROFEN SODIUM) (C - Product used for unknown indication - n/a - [n/a - 200mg - n/a]), (ACETYL SALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 81mg - n/a]), (GABAPENTIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (VITAMINS NCOS) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Oral)	C28
EU-EC-1000891274	17/05/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000866450	16/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000866415	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	No	Death (1d - Fatal - Results in Death, CausedProlongedHospitalisation, Hospitalisation (n/a - Unknown - CausedProlongedHospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-1000864625	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000864548	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Headache (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSRS)	Not reported	C28
EU-EC-1000864786	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000864614	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000864476	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000864913	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (1d - Not Recovered/Not Resolved - CausedProlongedHospitalisation), Death (n/a - Fatal - Results in Death), Urinary tract infection (24h - Not Recovered/Not Resolved - CausedProlongedHospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000864709	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000862464	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000862380	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000862382	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	(ALLOPURINOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (BUPROFEN HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ESICATAPRAM, ESICATAPRAM OXALATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (SABAPENTIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (HYDROCODONE BITARTRATE, PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (METOPROLOL, METOPROLOL TARTRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ROSUVASTATIN, ROSUVASTATIN CALCIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TRAZODONE, TRAZODONE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000863339	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000863352	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	SHINGRIX (RECOMBINANT VARICELLA ZOSTER VIRUS GLYCOPROTEIN E, STIMULON, MONOPHOSPHORYL LIPID A) (C - Product used for unknown indication - Not applicable - [n/a - 1DP] - Intramuscular)	C28
EU-EC-1000863357	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000863397	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000863314	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	MELATONIN (MELATONIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ACRIASTINE, DIPHEHYDROAMINE HYDROCHLORIDE, DIPHEHYDROAMINE HYDROCHLORIDE, ZINC ACETATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ALPHADOLAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (GABAPENTIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (NONFELUAST, NONFELUAST SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (SALBUTAMOL, SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000863363	14/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	No	Body temperature increased (1d - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Seizure (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable		

EU Case Number	EY Case Report Date	Report Type	Source Qualification	Primary Source Country Regulatory System Economic Area	Literature Reference	Patient Age Group	Patient Sex (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT - Duration ? Outcome - Seriousness Criteria	Supervising Drug List (Drug Char - Indication PT - Action label - Duration - Dose - Rows)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action label - Duration - Dose - Rows)	CSR Form
EU-EC-1000607278	13/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Hypertension (103 - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (106 - Not Recovered/Not Resolved - Other Medically Important Condition), Tachypnoea (176 - Not Recovered/Not Resolved - Other Medically Important Condition)		CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BISACRYL, DIOGATE SODIUM, SODIUM PHOSPHOSULFATE MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BICUCATE BESIDAC CARBON] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FINASTERIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL SUCCINATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000607306	13/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Chest pain (85 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Dizziness (205 - Unknown - Caused/Prolonged Hospitalisation), Fatigue (206 - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (206 - Unknown - Caused/Prolonged Hospitalisation), Miosis (206 - Unknown - Caused/Prolonged Hospitalisation), Somnolence (206 - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ALCOPIRINE BESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ADITHROMYCN, ADITHROMYCN DIPHOSPHATE, ADITHROMYCN HYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown])	CSR
EU-EC-1000608386	13/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Body temperature increased (n/a - Unknown -), Death (14 - Fatal - Results in Death)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[PERIDOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PILUS ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-10006083025	13/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSR)	Not reported	CSR
EU-EC-10006093572	13/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	SPINEXA [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	EGUSIS (SPINEXA) (C - Product used for unknown indication - Not applicable - [n/a - 5mg - Oral]), [FENIDOLAN, FENIDOLAN] (C - Product used for unknown indication - n/a - [n/a - 75mg - Oral]), [AMODIAZONE, AMODIAZONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 200mg - Oral]), [BISOPROLOL] (C - Product used for unknown indication - Not applicable - [n/a - 5mg - Oral]), [FENTANYL] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Transdermal]), [FLOXAMIDE] (C - Product used for unknown indication - Not applicable - [n/a - 10mg - Oral]), [EGUSIS (SPINEXA)] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [EXTRESTO (N-ALYARTAN, SALICITRIL)] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CYTODOLAMIN, VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIOXIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOPPEL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FLOXEMIDE, FLOXEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GLUCOSE, GLUCOSE MONOHYDRATE, GLUCOSE, ANHYDROUS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [NOLIN ASPART] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [NACUPITIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SCALZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MORFINUM, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SPERMOLACTONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METAZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FAMIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10006094003	13/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Cold sweat (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Confusional state (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Fall (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Head injury (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Painless electrical activity (14 - Fatal - Results in Death), Skin abrasion (14 - Not Recovered/Not Resolved -), Ventricular fibrillation (14 - Not Recovered/Not Resolved -), Blood pressure increased (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Dyspnoea (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (14 - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10006094120	13/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Blurred vision increased (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (14 - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [AMODIAZONE, AMODIAZONE BESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDROXYTONE, HYDROXYTONE, HYDROXYTONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10006097139	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Chest pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Anxiety (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSR)	Not reported	CSR
EU-EC-10006097204	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Anxiety (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSR)	EXTRESTO (N-ALYARTAN, SALICITRIL) (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), JANAVA (STAGUPTIN, STAGUPTIN PHOSPHATE, STAGUPTIN PHOSPHATE MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), XARELTO (RIVAROXAN) (C - Product used for unknown indication - n/a - [n/a - 2.5mg - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - 6.25mg - n/a]), [FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [FLOXEMIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [CLIPROLOL] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [FAMIDOL] (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), [ACN (BON)] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PRENSORONE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [PROFLAZONE (PROFLAZONE)] (C - Product used for unknown indication - Unknown - [n/a - 30mg - Unknown]), [ACETYL SALICYLIC ACID] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [AMODIAZONE, AMODIAZONE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a - 200mg - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - Unknown - [n/a - 80mg - Unknown]), [FAMOTIDINE] (C - Product used for unknown indication - Unknown - [n/a - 20mg - Unknown]), [FLOXEMIDE] (C - Product used for unknown indication - Unknown - [n/a - 40mg - Unknown]), [CABAPENTIN] (C - Product used for unknown indication - Unknown - [n/a - 300mg - Unknown]), [LISINAPRIL, LISINAPRIL DIPHOSPHATE] (C - Product used for unknown indication - Unknown - [n/a - 2.5mg - Unknown]), [METOPROLOL, METOPROLOL HYDROCHLORIDE, METOPROLOL HYDROCHLORIDE BP] (C - Product used for unknown indication - Unknown - [n/a - 1000mg - Unknown]), [METOPROLOL SUCCINATE] (C - Product used for unknown indication - Unknown - [n/a - 25mg - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [SPERMOLACTONE] (C - Product used for unknown indication - Unknown - [n/a - 25mg - Unknown]), [FAMIDOL, FAMIDOL HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a - 20mg - Unknown]), [DUTASTERIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-10006097840	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [AMODIAZONE, AMODIAZONE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a - 200mg - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - Unknown - [n/a - 80mg - Unknown]), [FAMOTIDINE] (C - Product used for unknown indication - Unknown - [n/a - 20mg - Unknown]), [FLOXEMIDE] (C - Product used for unknown indication - Unknown - [n/a - 40mg - Unknown]), [CABAPENTIN] (C - Product used for unknown indication - Unknown - [n/a - 300mg - Unknown]), [LISINAPRIL, LISINAPRIL DIPHOSPHATE] (C - Product used for unknown indication - Unknown - [n/a - 2.5mg - Unknown]), [METOPROLOL, METOPROLOL HYDROCHLORIDE, METOPROLOL HYDROCHLORIDE BP] (C - Product used for unknown indication - Unknown - [n/a - 1000mg - Unknown]), [METOPROLOL SUCCINATE] (C - Product used for unknown indication - Unknown - [n/a - 25mg - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [SPERMOLACTONE] (C - Product used for unknown indication - Unknown - [n/a - 25mg - Unknown]), [FAMIDOL, FAMIDOL HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a - 20mg - Unknown]), [DUTASTERIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-10006097856	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intracranial aneurysm (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Life support (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSR)	Not reported	CSR
EU-EC-10006097860	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Life support (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in CSR)	Not reported	CSR
EU-EC-10006097940	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[NSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10006098217	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Back pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dyspnoea (14 - Unknown - Other Medically Important Condition), Mucocutaneous rash (14 - Unknown - Other Medically Important Condition)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	HUMIRA (ADALIMUMAB) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ACN (BON)] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PRENSORONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FAMINE HYDROCHLORIDE, RETINOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FLUTICASON FURATE, FLUTEROL, TRIFENATATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL, MICROZIN, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-100060982450	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Peripheral oedema (10 - Unknown -), Pain at rest (10 - Unknown -), Respiratory arrest (14 - Unknown -), Trismus (14 - Unknown -)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[POLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDROCHLORIDHAZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-100060982462	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-65 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Vaccination failure (n/a - Fatal - Results in Death)	SPINEXA [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [METHYLPREDNISOLONE] (C - n/a - Unknown - [n/a - n/a - n/a])	XELJANZ (TOFAKITIN, TOFAKITIN CITRATE) (n/a - Unknown - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [METHYLPREDNISOLONE] (C - n/a - Unknown - [n/a - n/a - n/a])	CSR
EU-EC-100060982874	12/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Abdominal mass (n/a - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MINNA VACCINE MODERNA (CX-024414) [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[LISINAPRIL, LISINAPRIL DIPHOSPHATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a - Unknown]), [VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a - Unknown])	CSR
EU-EC-100060982890	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	SPINEXA [COVID-19 MINNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[BETAMETHASONE, BETAMETHASONE DIPROPIONATE, SALICYLIC ACID, BETAMETHASONE DIPROPIONATE, SALSALATE, BETAMETHASONE, SALICYLIC ACID] (C - Skin disorder - n/a - [n/a - 1DP] - Cutaneous), [DISULFIRAM] (C - Alcohol problem - n/a - [n/a - n/a - Oral]), [BISFAMETHIDOLE] (C - Cerebral - n/a - [n/a - 1000mg - Oral]), [ABACAVIR SULFATE, ABACAVIR SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [LAMYCONE] (C - Product used for unknown indication - n/a - [n/a - 150mg - Oral]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [CHLOROPROTHIXENE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [BISACRYL, BICUCATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]),	

EU Case Number	EY Record Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Potency	Literature Reference	Patent Age Other	Patent Age Other per Report	Patent Sex	Patent Child Report	Reaction List PT Classification? Outcome - Seriousness Criteria	Superseding Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Adverse Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form	
EU-EC-1000623363	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	More than 10 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular	Not reported	CSR
EU-EC-1000625428	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Fatigue (19a - Unknown -), Peripheral swelling (19a - Unknown -), Pyrexia (19a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular	Not reported	CSR
EU-EC-1000623476	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	More than 10 Years	Not Specified	Female	No	Asthma (19a - Unknown -), Cough (19a - Unknown -), Death (14 - Fatal - Results in Death), Nasopharyngitis (19a - Unknown -), Oxygen saturation decreased (19a - Unknown - Other Medically Important Condition), Productive cough (19a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular - More in CSR	PROTEIN (PROTEIN) (C - Product used for unknown indication - 19a - 19a - Unknown), [ACETYL SALICYLIC ACID] (C - Product used for unknown indication - 19a - 19a - Unknown), [CLONAZEPAM] (C - Product used for unknown indication - 19a - 19a - Unknown), [DOPRENEZOL HYDROCHLORIDE] (C - Product used for unknown indication - 19a - 19a - 10mg - Unknown), [TETRAZEPAM] (C - Product used for unknown indication - 19a - 19a - Unknown), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - 19a - 19a - Unknown)	CSR
EU-EC-1000625601	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	SPRIKVA [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - 19a - 19a - Unknown)	Not reported	CSR
EU-EC-1000626360	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	More than 10 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Malaise (19a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular	METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - 19a -)	CSR
EU-EC-1000626336	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	65-85 Years	Not Specified	Female	No	Mildly decreased (19a - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Vaccination site pain (19a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular	Not reported	CSR
EU-EC-1000628423	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - 19a - 19a - 80mg - Unknown), [ATORVASTATIN] (C - Product used for unknown indication - 19a - 19a - 80mg - Unknown), [GLUCOSAMINE SULFATE, CHONDROITIN SULFATE SODIUM] (C - Product used for unknown indication - 19a - 19a - Unknown), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - 19a - 19a - 25mg - Unknown), [PARAPREL] (C - Product used for unknown indication - 19a - 19a - 5mg - Unknown), [VITAMINS MOS] (C - Product used for unknown indication - 19a - 19a - Unknown)	CSR
EU-EC-1000629195	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Myocardial infarction (14 - Unknown - Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular	[ACETYL SALICYLIC ACID, ASPIRIN BP] (C - Product used for unknown indication - 19a - 19a - 19a), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - 19a - 19a - 19a), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - 19a - 19a - 19a), [SILBENETAN, CLESAFAN MEDICATIONS] (C - Product used for unknown indication - 19a - 19a - 19a), [SIPERIDONE] (C - Product used for unknown indication - 19a - 19a - 19a), [SIPERIDONE] (C - Product used for unknown indication - 19a - 19a - 150mg - Unknown), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - 19a - 19a - 100mg - 19a)	CSR
EU-EC-1000623432	04/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anal fission (180 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Anal fission (180 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gastroscopy (180 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Dyspnoea (180 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea exertional (180 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pleural effusion (180 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary congestion (180 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (S - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Venous thrombosis (S - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular	ENTRESTO [VALSARTAN, SACUBITRIL] (C - Cardio failure - Does not change - 19a - 200mg - Unknown), [ACETYL SALICYLIC ACID] (C - Acute myocardial infarction - Does not change - 19a - 100mg - Unknown), [ATORVASTATIN, EZETIMIBE] (C - Hypercholesterolemia - Does not change - 19a - 10mg - Unknown), [CARVEDILOL] (C - Cardio failure - Does not change - 19a - 25mg - Unknown)	CSR
EU-EC-1000629309	03/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	SPRIKVA [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - 19a - 10DF) - Intramuscular	Not reported	CSR
EU-EC-1000629110	03/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (19a - Unknown - Other Medically Important Condition), Cough (19a - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Fatigue (19a - Unknown - Other Medically Important Condition), Headache (19a - Unknown - Other Medically Important Condition), Pyrexia (19a - Unknown - Other Medically Important Condition), Vomiting (19a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] - COVID-19 immunisation - Not applicable (19a - 10DF) - Intramuscular	PROGLUTAZONE [PROGLUTAZONE] (C - Product used for unknown indication - 19a - 19a - 19a), [ATENOLOL, ATENOLOL BP] (C - Product used for unknown indication - 19a - 19a - 19a), [CITALOPRAM, CITALOPRAM HYDROCHLORIDE, CITALOPRAM HYDROCHLORIDE BP] (C - Product used for unknown indication - 19a - 19a - 19a), [FLOXETIN, FLOXETIN] (C - Product used for unknown indication - 19a - 19a - 19a), [FLUPRENOL] (C - Product used for unknown indication - 19a - 19a - 19a), [LISINAPRIL, LISINAPRIL] (C - Product used for unknown indication - 19a - 19a - 19a), [METHOCARBAMOL] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 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19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown indication - 19a - 19a - 19a), [NIFEDIPINE] (C - Product used for unknown	

EU Local Number	EV Emergency Review Date	Report Type	Primary Source Questionnaire	Country Regulatory Province	Literature Reference	Patient Age Group	Patient Age Group (see report)	Patient Sex	Patient Status Report	Reaction List PT Duration ? Outcome - Seriousness Criteria	Suspect/Involved Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Her Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
										Lung opacity (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Neural status changes (15505en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mito valve incompetence (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Obesity (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pleural effusion (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Polyuria (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic shock (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septicococcal infection (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombocytopenia (15645en - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -), Productive cough (n/a - Not Recovered/Not Resolved -)			
EU-EC-1000643822	26/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -), Productive cough (n/a - Not Recovered/Not Resolved -)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Intramuscular - n/a - [n/a - n/a - n/a])	Not reported	C28
EU-EC-1000643970	26/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 5mL - Intramuscular])	Not reported	C28
EU-EC-1000644032	26/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Male	No	Asthma (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Pallor (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	PROPRANLOL HYDROCHLORIDE [PROPRANLOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ETIRIZINE DIHYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - 10mg - Oral]), [FERROUS SULFATE] (C - Iron deficiency anemia - n/a - [n/a - 325mg - Oral]), [FLUTICASON] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]), [GABAPENTIN] (C - Back pain - n/a - [n/a - 120mg - Unknown]), [GLIMETIGRONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METHOCARBAMOL] (C - Back pain - n/a - [n/a - 500mg - Oral]), [PANTOPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [SUCCALFATE] (C - Gastroesophageal reflux disease - n/a - [n/a - 2mg - Oral]), [VALACICLOVIR, VALACICLOVIR HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1mg - n/a])	C28
EU-EC-10006439145	25/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000647381	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000649030	23/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 5mL - Intramuscular])	Not reported	C28
EU-EC-1000641069	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Meningitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Retinal vascular thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sore throat (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	INSULIN GLARGINE [INSULIN GLARGINE] (C - Product used for unknown indication - n/a - [n/a - 100DP] - Unknown), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [HYDRAZINE] (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown]), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [LIVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), [ZINC ACETATE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown])	C28
EU-EC-1000641121	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular] - More in CSR)	Not reported	C28
EU-EC-1000641127	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Acute myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular] - More in CSR)	Not reported	C28
EU-EC-1000641187	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Feeling hot (n/a - Unknown -), Nervousness (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	PARACETAMOL [C - Pain in extremity - n/a - [n/a - 1300mg - Unknown])	C28
EU-EC-1000641859	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Feeling of body temperature change (n/a - Fatal - Results in Death), Hyperhidrosis (n/a - Fatal - Results in Death), Musculoskeletal stiffness (n/a - Fatal - Results in Death), Peripheral oedema (n/a - Fatal - Results in Death), Storing (n/a - Fatal - Results in Death), Tumor (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular] - More in CSR)	Not reported	C28
EU-EC-1000641870	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular] - More in CSR)	Not reported	C28
EU-EC-1000641284	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	MELATONIN [MELATONIN] (C - Product used for unknown indication - n/a - [n/a - 3mg - n/a]), [DOXUSATE] (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), [FINASTERIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-1000641480	23/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Meningitis (n/a - Fatal - Results in Death), Pallor (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	C28
EU-EC-1000639580	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Respiratory tract congestion (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -), Suspected COVID-19 (n/a - Unknown -), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639582	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Female	No	Calcitriol (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Rash (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639643	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	[ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [BUSPIRONE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [CLONAZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DOXUSATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DOPREZOL, DOPREZOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [LISINAPRIL, LISINAPRIL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [RISPERIDONE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 75mg - Unknown])	C28
EU-EC-1000639620	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular] - More in CSR)	Not reported	C28
EU-EC-1000639685	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639659	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Memory impairment (n/a - Unknown -), Body temperature increased (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Headache (n/a - Unknown -), Pain (n/a - Unknown -), Urinary tract infection (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639730	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Body temperature increased (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Headache (n/a - Unknown -), Pain (n/a - Unknown -), Urinary tract infection (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular] - More in CSR)	Not reported	C28
EU-EC-1000639780	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death, Life-Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	[GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000639807	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Conjunctivitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Exacerbation of infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639814	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	[CYPROHEPTADINE HYDROCHLORIDE, CYPROHEPTADINE HYDROCHLORIDE, ANHYDROUS] (C - Product used for unknown indication - n/a - [n/a - 20PT - Oral]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 1.0PT - Oral]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 10PT - Oral]), [METHYLPREDNISOLONE] (C - Product used for unknown indication - n/a - [n/a - 30PT - Oral])	C28
EU-EC-1000639887	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639891	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Unknown -), Chest pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Headache (n/a - Unknown -), Meningitis (n/a - Unknown -), Pain (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639910	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639950	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (n/a - Unknown -), Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Meningitis (n/a - Unknown -), Pulse absent (n/a - Unknown -), Pyrexia (n/a - Unknown -), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639975	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639977	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000640063	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]), [ALCOLOPINE, ALCOLOPINE BESILATE, ALCOLOPINE MALEATE, ALCOLOPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [IBUPROFEN] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - Not applicable - [n/a - 500mg - n/a])	C28
EU-EC-1000640076	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	85-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Testicular failure (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]), [ALCOLOPINE, ALCOLOPINE BESILATE, ALCOLOPINE MALEATE, ALCOLOPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [IBUPROFEN] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - Not applicable - [n/a - 500mg - n/a])	C28
EU-EC-10006401370	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-54 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	[ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CANABIS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CHLORPHENIRAMINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [IBUPROFEN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MOMETASONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ONDANSETRON] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TERAZOSIN, TERAZOSIN HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000640309	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000640454	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000640475	22/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639046	21/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639267	21/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chills (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639304	21/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1.0PT - Intramuscular])	Not reported	C28
EU-EC-1000639422	21/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area									

EU Local Number	EV Primary Review Date	Report Type	Primary Source Question	Primary Country Regulatory Province	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	C28 Form
EU-EC-100083904	16/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death), Nausea (n/a - Unknown -), Unresponsive to stimuli (1d - Fatal - Results in Death), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083829	16/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083792	16/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death), Feeling cold (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083793	16/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083164	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	No	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083729	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081722	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081729	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	18-64 Years	Not Specified	Male	No Chest pain (1d - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Relief of treatment by patient (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081824	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081848	15/04/2021	Spontaneous	Non-Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Body temperature decreased (n/a - Unknown -), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Salivary hypersecretion (1d - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[DEXILANSOPRAZOLE, LANSOPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 60mg - Unknown]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [RIBOFLAVIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [RIBOFLAVIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [RIBOFLAVIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown])	C28
EU-EC-100081870	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081880	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081913	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 50mg - Oral])	C28
EU-EC-100082381	15/04/2021	Spontaneous	Non-Healthcare Professional	Non-Euro- Economic Area	Not available	Not Specified	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100082400	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	18-64 Years	Not Specified	Female	No Stomach pain (n/a - Unknown -), Candida infection (n/a - Unknown -), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Dysuria (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Renal failure (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Unknown -), White blood cell disorder (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[FLUTICASON FURATE, FLUTEROL TRIFENATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 1600mg - n/a]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SPRONOLACTONE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [TIZANIDINE] (C - Product used for unknown indication - n/a - [n/a - 4mg - Unknown]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 302mg - n/a])	C28
EU-EC-100082408	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100082442	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[MIRICER METHOXY POLYETHYLENE GLYCOL-EPIDETIN BETA] (C - Product used for unknown indication - n/a - [n/a - 300mg - Intramuscular]), [DIOGLATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [GENTAMICIN, GENTAMICIN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Topical]), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 75mg - Unknown]), [LACTOBACILLUS RHANNOUS GO] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [LACTULOSE] (C - Product used for unknown indication - n/a - [n/a - 120mL - Unknown]), [DIHYDROCALCIUM, DIHYDROCALCIUM MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [PREDNISONE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [COLICALCEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FRANCOLIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GLUCOSAMINE, CHONDROITIN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MELCICAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-100082470	15/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Insomnia (n/a - Unknown -), Respiration abnormal (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular] - Note in C28)	[ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [COLICALCEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FRANCOLIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GLUCOSAMINE, CHONDROITIN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MELCICAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-100082481	15/04/2021	Spontaneous	Non-Healthcare Professional	Non-Euro- Economic Area	Not available	18-64 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death), Truncal pain (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083158	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083502	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Chronic obstructive pulmonary disease (1d - Fatal - Results in Death), Cognitive disorder (1d - Fatal - Results in Death), Condition aggravated (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083174	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083475	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death), Traumatic intracranial haemorrhage (4d - Fatal - Results in Death)	SPRIXIV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [LITHIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 450mg - n/a]), [LUTETAPINE FUMARATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [SODIUM VALPROATE] (C - Product used for unknown indication - n/a - [n/a - 1200mg - n/a]), [SODIUM VALPROATE] (C - Product used for unknown indication - n/a - [n/a - 1500mg - n/a]), [NEPPRA [LEVETIRACETAM]] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [VIMBAT [ACOSAMIDE]] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-100083184	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	18-64 Years	Not Specified	Male	No Abnormal INR (11d - Fatal - Results in Death), Decreased activity (11d - Fatal - Results in Death), Gout attacks (11d - Fatal - Results in Death), Increased upper urinary secretion (11d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083966	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083966	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083987	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[PANTOPRAZOLE, PANTOPRAZOLE SODIUM BESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ALCOLOPHOL, ALCOLOPHOL MESILATE, ALCOLOPHOL MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BENZEPHOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BENZONATE, FORMOTEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CARBOLIC] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CHLOROBALAMINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GLYCERYL TRINITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LIDOCANE, LIDOCANE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FAMSILOLEN, FAMSILOLEN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TERBINAFIN, TERBINAFIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TIZANIDINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMIN, VITAMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PANTOPRAZOLE, PANTOPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NADOLOL] (C - Hyperlipidemia - n/a - [n/a - n/a - Unknown])	C28
EU-EC-100083716	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Altered amylase/creatinine increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Aspartate aminotransferase increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dysphagia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Topiram increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100083184	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081182	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081175	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	18-64 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081191	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081186	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081205	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100081207	14/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100082874	13/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100082916	13/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100082887	13/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	Not Specified	Not Specified	Male	No Abdominal pain (n/a - Fatal - Results in Death), Arrhythmia (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Episodes (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Feeling abnormal (n/a - Fatal - Results in Death), Mouth haemorrhage (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[PENTAMIN, PENTAMIN, CITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Transdermal]), [PHENETHAZINE, PHENETHAZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-100082836	13/04/2021	Spontaneous	Healthcare Professional	Non-Euro- Economic Area	Not available	Not Specified	Not Specified	Male	No Vomiting (n/a - Fatal - Results in Death) Death (1d - Fatal - Results in Death), Feeling abnormal (1d - Unknown - Other Medically Important Condition), Nausea (1d - Unknown - Other Medically Important Condition), Pyrexia (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	C28
EU-EC-100082830	13/04/2021	Spontaneous	Healthcare Professional									

EU Local Number	EV Emergency Review Date	Report Type	Primary Question	Primary Country Regulatory Procedure	Literature Reference	Patient Age Group	Patient Sex	Patient Age Group	Patient Sex	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-1000620360	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dysphagia (n/a - Unknown -), Hypertonia (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown -).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	SENNA (BENKOSIDE 448) [BENKOSIDE 448] (C - n/a - Dose not changed - [n/a - n/a - n/a])	C28
EU-EC-1000620370	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Ventricular arrhythmia (n/a - Unknown - Other Medically Important Condition).	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620379	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Unstable event (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY MAGNESIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FLUTICASONIC PROPIONATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BENNA ALEXANDRIAN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-1000620397	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620399	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620399	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ATORVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [BISOPROLOL FLUMARATE] (C - Product used for unknown indication - n/a - [n/a - 2.5mg - Unknown - More in ICSP]), [DILTIAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 180mg - Unknown]), [PHENPROLOLUMIN] (C - Product used for unknown indication - n/a - [n/a - 3mg - Unknown])	C28
EU-EC-1000620318	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620325	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620347	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620328	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Intentional dose omission (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620313	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620315	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[CARVEDILOL] (C - n/a - n/a -), [FUROSEMIDE] (C - n/a - n/a -)	C28
EU-EC-1000620389	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620430	13/04/2021	Spontaneous	Non-Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute left ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Peripheral ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Skin swelling (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620550	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Apnoea (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Heart rate irregular (n/a - Unknown -), Hypophagia (n/a - Unknown -), Irras (n/a - Unknown -), Lethargy (n/a - Unknown -), Mabise (n/a - Unknown -), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	[CARBOHYDRATES NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CHOLESTEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DOCUISATE SODIUM CASSIA] (C - n/a - n/a -), [FAT] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GENTAMICIN GENTAMICIN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GUARANTERIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HALOPERIDOL, HALOPERIDOL, DECANATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LOPERAMIDE HYDROCHLORIDE, LOPERAMIDE OXIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MACRODOL 355S] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MELNOLAL NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NIVESTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [RISPERIDONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ENALAPRIL, ENALAPRIL, MALEATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [DMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), [SPRONOLACTONE] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a])	C28
EU-EC-1000620630	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSP)	Not reported	C28
EU-EC-1000620637	13/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620642	12/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620678	10/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Recovered/Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Recovered/Resolved - Life-Threatening - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-1000620680	12/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620617	12/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	C28
EU-EC-1000620627	10/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620627	10/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LANTIDOL (NIDULIN GLANDRE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MELANOLAN (MELANOLAN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SUBOXONE (BUPRENORPHINE, NALOXONE, NALOXONE HYDROCHLORIDE, DIPHENATE, BUPRENORPHINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ALCOLOPINE, ALCOLOPINE BESILATE, ALCOLOPINE MALEATE, ALCOLOPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LUPRODOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-1000620628	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620636	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620681	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	SPRIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	C28
EU-EC-1000620624	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	14-64 Years	Not Specified	Male	No	Adrenia (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Productive cough (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	NEPRA [LEVETIRACETAM] (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), [CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-1000620628	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Adrenia (n/a - Unknown -), Crying (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Gait disturbance (n/a - Unknown -), General physical health deterioration (n/a - Unknown -), Halegallid use (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	[DONPEZOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-1000620423	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620482	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	C28
EU-EC-10006205174	09/04/2021	Spontaneous	Non-Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	SPRIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620547	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - n/a)	GLYCOPHYRUM BROMIDE (GLYCOPHYRUM BROMIDE) (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Nasal]), MELANOLAN (MELANOLAN) (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Oral]), [ALCOLOPINE MESILATE] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Oral]), [COLICAPICOL] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Oral]), [VITAMINS NOS] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Oral])	C28
EU-EC-10006205529	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28
EU-EC-1000620526	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ABILEY (BIPRAZOLE) (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), KARELTO (BIVARODAN) (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [BILATAPRIN] (C - Product used for unknown indication - n/a - [n/a - 1mg - n/a]), BUPRENORPHINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BUPROPION HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 300mg - Unknown]), [DILTIAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 180mg - Unknown]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]), [MCCOLAMIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [MORONOLIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-10006205817	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSP)	Not reported	C28
EU-EC-10006205943	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ALLOPURINOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [COLICAPICOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-10006207196	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Constitutional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ALDOXIA, DIETHYLENE GLYCOL, MONOMETHYL ETHER, MAGNESIUM SEARATE, WOOD ALCOHOL, CETHYL ACETATE, SODIUM DEHYDROCATATE, ZEA MAYE] (C - Immunodeficiency - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID] (C - Immunodeficiency - n/a - [n/a - n/a - Unknown]), [BUDESONIDE, FORMOTEROL, FLUMARATE, FORMOTEROL, FLUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - Unknown]), [FORMOTEROL, FLUMARATE, DIPHENATE] (C - Asthma - n/a -), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - n/a - Unknown]), [PARACETIN] (C - Immunodeficiency - n/a -), [SALBUTAMOL, SALBUTAMOL, SULFATE] (C - Asthma - n/a -), [ZINC] (C - Immunodeficiency - n/a - [n/a - n/a - Unknown])	C28
EU-EC-10006207474	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	C28	
EU-EC-10006207488	09/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	CLOPIDOGREL HYDROGEN SULFATE (CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BILATAPRIN] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ASCORBIC ACID] (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - 12.5mg - n/a]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - 200mg - n/a]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 30mg - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), [SALBUTAMOL, SULFATE, IPATROPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a])	C28
EU-EC-1000620778													

EU Local Number	EV Primary Review Date	Report Type	Primary Source Question	Primary Country Regulatory Authority	Literature Reference	Patient Age Group	Patient Age Group (see ref)	Patient Sex	Patient Onset Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Her Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	C2B Form
EU-EC-1000240439	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	ACETYSALICYLIC ACID (C - Product used for unknown indication - n/a - [30d - 80mg - n/a]), ATORVASTATIN (C - Product used for unknown indication - n/a - [30d - n/a - n/a]), CETAZEDINE, CETAZEDINE PENTAHYDRATE, CETAZEDINE PENTAHYDRATE SODIUM BUTYRATE (C - Product used for unknown indication - n/a - [30d - 1000mg - n/a]), [EPOETIN ALFA] (C - Product used for unknown indication - n/a - [30d - 16000DU - n/a]), [FLUCONAZOLE] (C - Product used for unknown indication - n/a - [30d - 150mg - n/a]), [CODEXTRINE] (C - Product used for unknown indication - n/a - [30d - 2500mL - n/a]), [MINERALS NOS, VITAMINS NOS] (C - Product used for unknown indication - n/a - [30d - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [30d - 20mg - n/a]), [VITAMIN C] (C - Product used for unknown indication - n/a - [30d - 1000mg - n/a])	C2B
EU-EC-1000240466	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (5d - Fatal - Results in Death), [Diarrhoea (5d - Unknown - Other Medically Important Condition), Hypertension (5d - Unknown - Other Medically Important Condition)]	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular - More in C2B)	Not reported	C2B
EU-EC-1000241020	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Hypertension (5d - Unknown - Other Medically Important Condition) Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000241167	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (30d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000241511	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Confusional state (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mental impairment (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pancreatitis (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	METHOTREXATE [METHOTREXATE] (C - n/a - n/a -), ALUMINOSILICATE SODIUM, ALUMINOSILICATE SODIUM PHOSPHATE, ALUMINOSILICATE SODIUM PHOSPHATE (C - n/a - n/a -), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - n/a - n/a -), [DOLZOLAMIDE, DOLZOLAMIDE HYDROCHLORIDE] (C - n/a - n/a -), [FOLIC ACID] (C - n/a - n/a -), [LACTACIPROST] (C - n/a - n/a -), [NAPROXEN, NAPROXEN SODIUM] (C - n/a - n/a -), [DIBENAZOLE] (C - n/a - n/a -)	C2B
EU-EC-1000241543	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Confusional state (30d - Unknown -), Death (30d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Lethargy (n/a - Unknown -), Memory impairment (n/a - Unknown -), Nightmare (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	ELIQUIS [APIXABAN] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a -), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a -), [FURCEMIDE] (C - n/a - n/a -), [GABAPENTIN] (C - n/a - n/a -), [LISINAPRIL, LISINAPRIL HYDRATE] (C - n/a - n/a -), [POTASSIUM CHLORIDE] (C - n/a - n/a -)	C2B
EU-EC-1000242428	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000242407	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	ELIQUIS [APIXABAN] (C - Product used for unknown indication - n/a - [30d - n/a - n/a])	C2B
EU-EC-1000242446	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal discomfort (30d - Unknown -), Death (1d - Fatal - Results in Death), Pain in extremity (30d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000242712	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000242720	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	[DIBENAZOLE, DIBENAZOLE MAGNESIUM] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown])	C2B
EU-EC-1000242780	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Bowel movement irregularity (4d - Unknown -), Death (1d - Fatal - Results in Death), Decreased appetite (4d - Unknown -), Delusional disorder (4d - Unknown -), Dyspnoea (n/a - Unknown -), Nausea (4d - Unknown -), Pain (4d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000242851	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (30d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000242869	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Arrhythmia (30d - Unknown - Caused/Prolonged Hospitalisation), Cerebral ischaemia (30d - Unknown - Caused/Prolonged Hospitalisation), Chills (30d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Dyspnoea (30d - Unknown - Caused/Prolonged Hospitalisation), Nausea (30d - Unknown - Caused/Prolonged Hospitalisation), Pain (30d - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	[ATEMOLOL, ATEMOLOL BP] (C - Product used for unknown indication - n/a -), [CALCIUM] (C - Product used for unknown indication - n/a -), [COLICACALFERRIC] (C - Product used for unknown indication - n/a -), [CYANOCOBALAMIN, FOLIC ACID] (C - Product used for unknown indication - n/a -), [FURCEMIDE, POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a -)	C2B
EU-EC-1000243004	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	SPINRYVA [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000243404	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Adverse (30d - Unknown -), Cold sores (30d - Unknown -), Death (1d - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Pain (30d - Unknown -), Parosmia (n/a - Unknown -), Unresponsive to stimuli (30d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - n/a - [30d - 40mg - n/a]), [CETIRIZINE, DIPHENHYDRAMINE] (C - Product used for unknown indication - n/a - [30d - 10mg - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [30d - 800mg - n/a]), [METHOCARBAMOL] (C - Product used for unknown indication - n/a - [30d - 500mg - n/a]), [PROPRANLOLOL, PROPRANLOLOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [30d - 40mg - n/a]), [SUCRALFATE] (C - Product used for unknown indication - n/a - [30d - 1g - n/a])	C2B
EU-EC-1000243421	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (4d - Fatal - Results in Death), Decreased appetite (4d - Fatal - Results in Death), Dyspnoea (4d - Fatal - Results in Death), Fatigue (4d - Fatal - Results in Death), Myocardial infarction (4d - Fatal - Results in Death), Nausea (4d - Fatal - Results in Death), Pain (4d - Fatal - Results in Death), Pyrexia (4d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	ACETYSALICYLIC ACID (C - Product used for unknown indication - n/a - [30d - 80mg - n/a]), [ESICLOPRIM, ESCILOPRIM OXALATE] (C - Product used for unknown indication - n/a - [30d - 10mg - n/a]), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [30d - 12.5mg - n/a]), LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [30d - 100mg - n/a]), [FAMBUSOLIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [30d - 4mg - n/a])	C2B
EU-EC-1000243465	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1440min - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000243708	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cough (30d - Unknown - Caused/Prolonged Hospitalisation), Death (17d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000244118	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Feeding tube user (1d - Fatal - Results in Death), General physical health deterioration (1d - Fatal - Results in Death), Hypertension (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	[ATORVASTATIN] (C - Product used for unknown indication - n/a - [30d - 20mg - n/a]), [FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - n/a - [30d - 20mg - n/a]), [FLUCONAZOLE, FLUCONAZOLE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [30d - n/a - n/a]), [LORAZEPAM] (C - Product used for unknown indication - n/a - [30d - n/a - n/a]), [MEGESTROL ACETATE] (C - Product used for unknown indication - n/a - [30d - n/a - n/a]), [PENTOPHYLLINE] (C - Product used for unknown indication - n/a - [30d - 800mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [30d - 200mg - n/a]), [TENZAPAM] (C - Product used for unknown indication - n/a - [30d - 20mg - n/a])	C2B
EU-EC-1000244473	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Adverse (30d - Unknown -), Death (1d - Fatal - Results in Death), Eye movement disorder (30d - Unknown -), Feeling abnormal (30d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [30d - 1DP] - Intramuscular)	CINACALCET [CINACALCET] (C - Product used for unknown indication - n/a - [30d - 30mg - Unknown]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Dipeptide - n/a - [30d - 20mg - Unknown]), BEVELAMER [BEVELAMER, BEVELAMER CARBONATE] (C - Product used for unknown indication - n/a - [30d - 2400mg - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [30d - 5mg - Unknown]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [30d - 25mg - Unknown]), [FURCEMIDE] (C - Product used for unknown indication - n/a - [30d - 100mg - Unknown]), [FENICLOLOL, FENICLOLOL HYDROCHLORIDE, FENICLOLOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [30d - 2mg - Unknown]), [BEPOTASTINE BESILATE] (C - Product used for unknown indication - n/a -), [BETAHALOL, BETAHALOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a -), [BRANDONINE, BRANDONINE TARTRATE] (C - Product used for unknown indication - n/a -), [KETOTIFEN] (C - Product used for unknown indication - n/a -), [LACTACIPROST, LACTACIPROST MESILATE] (C - Product used for unknown indication - n/a -), [PROPYLENE GLYCOL, MACROGOL, PROPYLENE GLYCOL, MACROGOL, 400] (C - Product used for unknown indication - n/a -), [PROPYLENE GLYCOL] (C - Product used for unknown indication - n/a -), [TOTOPIRAM, TOTOPIRAM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - n/a -)	C2B
EU-EC-1000244746	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000244813	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [30d - n/a - n/a]), PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - n/a - n/a - [30d - n/a - n/a]), ACETYSALICYLIC ACID (C - n/a - n/a - [30d - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - n/a - n/a - [30d - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [30d - n/a - n/a]), [PROPRANLOLOL] (C - n/a - n/a - [30d - n/a - n/a]), [LUMESARTAN, LUMESARTAN MEDICINUM] (C - n/a - n/a - [30d - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - n/a - [30d - n/a - n/a]), [LUBECARBONATE] (C - n/a - n/a - [30d - n/a - n/a])	C2B
EU-EC-1000244916	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chest pain (30d - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Headache (30d - Unknown -), Nausea (30d - Unknown -), Pain (30d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000244921	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000244919	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	[EPINEPHRINE] (C - Adrenaline - n/a - [30d - n/a - Unknown])	C2B
EU-EC-1000244921	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chronic obstructive pulmonary disease (2d - Unknown -), Condition aggravated (2d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000244942	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Brain haemorrhage (1d - Fatal - Results in Death), Cerebral haemorrhage (1d - Fatal - Results in Death), Central mass effect (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Neurological symptoms (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	ELIQUIS [APIXABAN] (C - Product used for unknown indication - n/a -), [AMODIUM, AMODIUM HYDROCHLORIDE] (C - Product used for unknown indication - n/a -), [DIAZEPAM] (C - Product used for unknown indication - n/a -), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a -), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a -), [PRACETAMOL] (C - Product used for unknown indication - n/a -), [PRIMOSON] (C - Product used for unknown indication - n/a -), [TRIMETHOPRIM] (C - Product used for unknown indication - n/a -)	C2B
EU-EC-1000244912	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal distension (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute kidney injury (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Dehydration (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (30d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	BRANCO [PULMONOL] (C - Product used for unknown indication - Not applicable -), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - Not applicable -), [BETHELOL] (C - Product used for unknown indication - Not applicable -), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - Not applicable -), [VITAMIN D] (C - Product used for unknown indication - Not applicable -)	C2B
EU-EC-1000244904	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Adverse (30d - Unknown -), Chills (30d - Unknown -), Death (30d - Fatal - Results in Death), Dry throat (30d - Unknown -), Dyspnoea (30d - Unknown - Caused/Prolonged Hospitalisation), Eye movement disorder (30d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (30d - Unknown -), Headache (30d - Unknown - Caused/Prolonged Hospitalisation), Neurological symptoms (30d - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (30d - Unknown -), Pulver (30d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (30d - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (30d - Unknown - Caused/Prolonged Hospitalisation), Rhinorrhoea (30d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000244917	08/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Death (30d - Fatal - Results in Death), Diarrhoea (30d - Unknown -), Hypertension (30d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [30d - 1DP] - Intramuscular)	ACETYSALICYLIC ACID (C - Product used for unknown indication - n/a - [30d - 80mg - Unknown]), [AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a - [30d - 5mg - Unknown]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [30d - 25mg - Unknown]), [COLICACALFERRIC] (C - Product used for unknown indication - n/a - [30d - n/a - n/a]), [NOT AVAILABLE] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [OXYBUTYRIN, OXYBUTYRIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [CETILININ] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [OTAPRANAL, OTAPRANAL HYDROCHLORIDE, OTAPRANAL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [COLICACALFERRIC] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [DIBENAZOLE] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [LACTOBACILLUS ACIDOPHILUS] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [30d - n/a - Unknown])	C2B
EU-EC-1000244905	07/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000244905	07/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [30d - 1DP] - Intramuscular)	Not reported	C2B
EU-EC-1000244905	07/04/2021												

EU Local Number	EV Emergency Review Date	Report Type	Primary Source Questionnaire	Primary Country Regulatory Procedure	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List PT - Duration ? Outcome - Seriousness Criteria	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Her Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	C2SR Form	
			Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	immunosup - Not applicable - [n/a - 1Df] - Intramuscular]		
EU-EC-1000628246	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	SPINEVIA COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	HYDROCHLOROTHIAZIDE, ALDOPRINE BESILATE, CLMESARTAN, CLMESARTAN MEDDOXIMIL, ALDOPRINE, HYDROCHLOROTHIAZIDE) (C - Product used for unknown indication - Dose not changed - [n/a - n/a - 1d])	C2SR Form
EU-EC-1000628281	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mental status changes (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000628355	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Mabixie (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000628349	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac failure congestive (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Oedema (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	NOURISE ELUPITA [UNELCULINUM BROWIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PLUTICADINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FLUCIDONE, POTASSIUM CHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 1200mg - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 20mg - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), [NAPROXEN] (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [SALMETEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C2SR
EU-EC-1000629207	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000632124	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000632313	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Anaesthesia (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dysphagia (1d - Fatal - Results in Death), Oxygen saturation decreased (1d - Fatal - Results in Death), Productive cough (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000632276	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000627052	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Dyspnoea (3d - Fatal - Results in Death), Pyrexia (3d - Fatal - Results in Death)	SPINEVIA COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000638180	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	[METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C2SR
EU-EC-1000638435	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000638475	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000638512	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000638361	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000638574	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000638576	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000638917	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000639788	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000639816	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000639865	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Confusional state (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Decubitus ulcer (n/a - Unknown -), Disorientation (n/a - Unknown -), General physical health deterioration (n/a - Unknown -), Hypophagia (n/a - Unknown -), Lethargy (n/a - Unknown -), Mental status changes (n/a - Unknown -), Wound dehiscence (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	[CARBIDOPA, LEVODOPA, LEVODOPA, ANHYDROUS CARBIDOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a -), [DONEPEZIL] (C - n/a - n/a -), [FAMOTIDINE] (C - n/a - n/a -), [MIRTAZAPINE] (C - n/a - n/a -), [PROCHETAMINE] (C - n/a - n/a -), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a -), [SINNA ALEXANDRIAN] (C - n/a - n/a -), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - n/a - n/a -)	C2SR
EU-EC-1000670564	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	ALDOPRINE, ALDOPRINE BESILATE) (C - Product used for unknown indication - n/a -), [DONEPEZIL, HYDROCHLORIDE] (C - Product used for unknown indication - n/a -), [ESICATOLPRAM, ESICATOLPRAM OXALATE] (C - Product used for unknown indication - n/a -), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a -), [METOPROLOL, SUCCINATE] (C - Product used for unknown indication - n/a -), [TIMOLOLOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a -), [VITAMIN B2] (C - Product used for unknown indication - n/a -)	C2SR
EU-EC-1000670665	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	ALDOPRINE, ALDOPRINE BESILATE, ALDOPRINE MALEATE, ALDOPRINE MESILATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BUPROPION HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ESTROGENS CONJUGATES, ESTRONE SODIUM SULFATE, EQUIN SULFATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FLUTICASON FURCATE, VILANTEROL, TRIFENATATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [NIFEDILUMAT, NIFEDILUMAT SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIMPRAZOLE, OMEPRAZOLE, MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C2SR
EU-EC-1000670675	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000671074	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Abdominal pain upper (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Diarrhoea (1d - Fatal - Results in Death), Vomiting (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Unknown - [n/a - 1Df] - Unknown)	[AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [BUPROPION] (C - Product used for unknown indication - n/a - [n/a - 150mg - n/a]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - n/a])	C2SR
EU-EC-1000671121	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000671143	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	[ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C2SR
EU-EC-1000671363	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Aphasia (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Lip swelling (n/a - Fatal - Results in Death), Paresthesia distal activity (n/a - Fatal - Results in Death), Swollen tongue (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	[EPINEPHRINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [EPINEPHRINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C2SR
EU-EC-1000671389	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebral haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Incontinent (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	AREDS (ASCORBIC ACID, TOCOPHERYL ACETATE, XANTHOPYL, ZEAXANTHIN, ZINC) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [IRON] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ASCORBIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [COLECALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DONEPEZIL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ESICATOLPRAM, ESICATOLPRAM OXALATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NEMANTINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C2SR
EU-EC-1000671547	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000671549	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Menstr (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000671767	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	[ALENDRONATE SODIUM, ALENDRONATE SODIUM TRIHYDRATE, ALENDRONIC ACID] (C - n/a - Not applicable - [n/a - n/a - n/a]), [CHLORTALIDONE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [CLONIDINE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - Not applicable - [n/a - n/a - n/a]), [METOPROLOL, SUCCINATE] (C - n/a - Not applicable - [n/a - n/a - n/a])	C2SR
EU-EC-1000671345	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (1440m - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000672000	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000672020	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	[BIVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C2SR
EU-EC-1000672603	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (3d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (3d - Fatal - Results in Death), Dyspnoea exertional (3d - Fatal - Results in Death), Heart rate increased (3d - Fatal - Results in Death), Hyperhidrosis (3d - Fatal - Results in Death), Pyrexia (3d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000672752	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Respiratory rate increased (3d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000672855	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	Not reported	C2SR
EU-EC-1000673025	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) (COVID-19 MRNA VACCINE MODERNA (CX-020414) (S - COVID-19 immunisation - Not applicable - [n/a - 1Df] - Intramuscular]	[LANTUS [INSULIN GLARGINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PIOGLITAZONE [PIOGLITAZONE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FLUTICASON FURCATE, VILANTEROL, TRIFENATATE] (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 900mg - Unknown]), [LOSARTAN] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [OMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [DIPYRIDOL, DIPHENOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1.2mg - Unknown]), [PAROXETINE, PAROXETINE HYDROCHLORIDE, HEMIHYDRATE, PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - Product used for unknown indication - n/a - [n/a - 30mg - Unknown]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 40mg - Unknown]), [THEOPHYLLINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMIN B2] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C2SR
EU-EC-1000673201	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area</									

EU Local Number	EV Primary Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List PT Duration ? Outcome - Seriousness Criteria	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-10008198130	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10008198139	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10008198326	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death), Fall (y/a - Fatal - Results in Death), Feeling abnormal (y/a - Fatal - Results in Death), Head injury (y/a - Fatal - Results in Death), Muscular weakness (y/a - Fatal - Results in Death), Respiratory arrest (y/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	MULTAQ (DROVEDARONE) (C - Anti bradycardia - y/a - [y/a] - n/a - Unknown), ATORVASTATIN (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown), EZETIMIBE (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown), LISINAPRIL LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown), LOPERAMIDE HYDROCHLORIDE (LOPERAMIDE OXIDE) (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown), METFORMIN METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown), METOPROLOL METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [y/a] - n/a - Unknown)	C28
EU-EC-10008198369	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	Not reported	C28
EU-EC-10008198405	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Burning sensation (12d - Fatal - Results in Death), Cardiorespiratory arrest (12d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Fatigue (12d - Fatal - Results in Death), Hepes 2000r (5d - Fatal - Results in Death), Hypoaesthesia (1d - Fatal - Results in Death), Loss of consciousness (12d - Fatal - Results in Death), Myalgia (12d - Fatal - Results in Death), Nose pain (y/a - Fatal - Results in Death), Pain in extremity (1d - Fatal - Results in Death), Pyrexia (12d - Fatal - Results in Death), Rash pruritic (12d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	ALLOPURINOL (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), AMLODIPINE, AMLODIPINE MESILATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), ACEINIB (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), FUROSEMIDE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), LUTANOPROST (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), LORATADINE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), MESALAZINE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), NOMETAZONE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), DMEPRAZOLE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), PARACETAMOL (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), LUCQUE (APRABAN) (C - Product used for unknown indication - n/a - [y/a] - 5mg - n/a), FUROSEMIDE (C - Product used for unknown indication - n/a - [y/a] - 40mg - n/a), MORPHINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [y/a] - 5mg - n/a), PARACETAMOL (C - Product used for unknown indication - n/a - [y/a] - 1300mg - n/a), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [y/a] - 10mg - n/a), SPRINDOLACTONE (C - Product used for unknown indication - n/a - [y/a] - 12.5mg - n/a), DOLIPRIN, ZOLPIDINE TARTRATE (C - Product used for unknown indication - n/a - [y/a] - 5mg - n/a), CHLORPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, BUPROPION, BUPROPION (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), FUROSEMIDE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), LACTULOSE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), DIBENZYLANTHRACEN-9-YL HYDROCHLORIDE, DIBENZYLANTHRACEN-9-YL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), SPRINDOLACTONE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), TETRACYCLINE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), BIPHENACETAM, BIPHENACETAM (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), SAMOTRINE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a)	C28
EU-EC-1000820040	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Female	No Back pain (4d - Unknown -), Condon aggravated (4d - Unknown -), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular - More in CSR)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008201172	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death), Mental status changes (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Thrombocytopenia (2d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008201409	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	SPRIVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008201549	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death), Obesity (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008201674	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008201995	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008202137	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (y/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008202165	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008202166	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008202250	05/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008170003	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (y/a - Fatal - Results in Death), Ronal pain (y/a - Unknown -)	SPRIVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - n/a)	IRRESANTAN 75 MG - TABLET (C - n/a - n/a - [y/a] - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - [y/a] - n/a - n/a), PREGABALIN/PREGABALIN (C - n/a - n/a - [y/a] - n/a - n/a), PREGABALIN/PREGABALIN (C - n/a - n/a - [y/a] - n/a - n/a), SEVEXAMER HYDROCHLORIDE 80MG TABLET - FILM COATED TABLET (C - n/a - n/a - [y/a] - n/a - n/a), BULEMATE, CITRATE BULEMATE, CITRATE (C - n/a - n/a - [y/a] - n/a - n/a), INSULIN, INSULIN HUMAN (C - n/a - n/a - [y/a] - n/a - n/a), METOPROLOL TARTRATE (C - n/a - n/a - [y/a] - n/a - n/a), NIFEDIPINE (C - n/a - n/a - [y/a] - n/a - n/a), OMEPRAZOLE (C - n/a - n/a - [y/a] - n/a - n/a), ATORVASTATIN (C - Hyperlipidemia - n/a - [y/a] - 20mg - n/a), COLICACALFEROL (C - Product used for unknown indication - n/a - [y/a] - 2000mg - n/a), FAMCICLOVIR (C - Product used for unknown indication - n/a - [y/a] - 250mg - n/a), GLUCOSAMINE HYDROCHLORIDE, CHONDROITIN SULFATE SODIUM, SODIUM (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), MELNOCAM (C - Product used for unknown indication - n/a - [y/a] - 7.5mg - n/a), EMPAFLIZON (EMPAFLIZON) (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), STADILPTIN (STADILPTIN) (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), ACETYL SALICYLIC ACID (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALFEROL, CALCIUM (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), ATORVASTATIN (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), OMEPRAZOLE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), PREGABALIN/PREGABALIN (C - Product used for unknown indication - n/a - [y/a] - 5mg - n/a), INSULIN LISPRO (INSULIN LISPRO) (C - Product used for unknown indication - n/a - [y/a] - 75mg - n/a), ATENOLOL, ATENOLOL BP (C - Product used for unknown indication - n/a - [y/a] - 60mg - n/a), ATORVASTATIN (C - Product used for unknown indication - n/a - [y/a] - 60mg - n/a), COLISTHYMALINE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a), ESCALFALIN, ESCALFALIN (C - Product used for unknown indication - n/a - [y/a] - 25mg - n/a), FERROUS SULFATE (C - Product used for unknown indication - n/a - [y/a] - 300mg - n/a), FUROSEMIDE (C - Product used for unknown indication - n/a - [y/a] - 10mg - n/a), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [y/a] - 10mg - n/a), PARACETAMOL (C - Product used for unknown indication - n/a - [y/a] - 650mg - n/a), SALBUTAMOL, SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [y/a] - n/a - n/a)	C28
EU-EC-10008172916	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death), Dyspnoea (y/a - Unknown -), Fatigue (y/a - Unknown -), Headache (y/a - Unknown -), Respiration abnormal (y/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008173134	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008173171	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Acute respiratory failure (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Blood glucose increased (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Cardiac failure acute (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation), Metabolic encephalopathy (2d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008173326	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	18-64 Years	Not Specified	Female	No Acute abdomen (y/a - Fatal - Results in Death), Cardiogenic shock (y/a - Fatal - Results in Death), Death (y/a - Fatal - Results in Death), Gastrostomy (y/a - Fatal - Results in Death), Hypoglycemia (y/a - Fatal - Results in Death), Hypertension (y/a - Fatal - Results in Death), Sepsis (y/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - n/a - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - n/a - Intramuscular)	C28
EU-EC-10008173994	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	C28
EU-EC-10008174000	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Death (2d - Fatal - Results in Death), Multiple organ dysfunction syndrome (2d - Fatal - Results in Death), Pulse absent (2d - Fatal - Results in Death), Pulseless electrical activity (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	C28
EU-EC-10008174051	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Death (y/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - n/a)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - n/a)	C28
EU-EC-10008174421	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (y/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008174681	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death), Mebase (3d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008174862	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008175135	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (y/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008175359	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (y/a - Fatal - Results in Death), Diarrhoea (y/a - Unknown -), Mebase (y/a - Unknown -), Pyrexia (y/a - Unknown -), Vomiting (y/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Unknown)	C28
EU-EC-10008175531	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008175533	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Female	No Arrhythmia (7d - Fatal - Results in Death), Death (7d - Fatal - Results in Death), Influenza like illness (7d - Fatal - Results in Death), Pain intensity (7d - Fatal - Results in Death), Syncope (7d - Fatal - Results in Death, Other Medically Important Condition), Tremor (7d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008175807	02/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death), Unresponsive to stimuli (y/a - Fatal - Results in Death), Vomiting (y/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008157046	01/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	SPRIVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	SPRIVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [y/a] - [D/F] - Intramuscular)	C28
EU-EC-10008157241	01/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-65 Years	Not Specified	Female	No Cerebellar stroke (y/a - Fatal - Results in Death), Death (y/a - Fatal - Results in Death)	SPRIVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 prophylaxis - Not applicable - [y/a] - 5mL - n/a)	SPRIVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 prophylaxis - Not applicable - [y/a] - 5mL - n/a)	C28
EU-EC-10008157369	01/04/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	18-64 Years	Not Specified					

Local Number	EY Country Report Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Program	Literature Reference	Patient Age Group	Patient Age Group (see per report)	Patient Sex	Parent Child Report	Reaction List PT - Duration ? Outcome - Seriousness Criteria	Supplementing Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Cocoon/other Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	KSR Form
EUEC-10006185104	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	[NARSARIN, NARSARIN SODIUM] (C - Product used for unknown indication - n/a - jva - n/a - n/a)	KSR
EUEC-10006185104	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	[ASCORBIC ACID] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [COLCALKALCIOL] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [CHVANDOCILAMIN, FOLIC ACID] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [DROSEPH SEED OIL] (C - Product used for unknown indication - n/a - jva - n/a - n/a)	KSR
EUEC-10006185163	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006185173	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cough (n/a - Unknown - Life Threatening), Death (14 - Fatal - Results in Death), Dysgeusia (n/a - Unknown - Life Threatening), Exposure to SARS-CoV-2 (n/a - Unknown - Life Threatening), Feeling abnormal (n/a - Unknown - Life Threatening), Gastrointestinal tract irritation (n/a - Unknown - Life Threatening), Headache (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Mountain urgency (n/a - Unknown - Life Threatening), Pain (n/a - Unknown - Life Threatening), Poliakutia (n/a - Unknown - Life Threatening), Resuscitation (n/a - Unknown - Life Threatening), SARS-CoV-2 test negative (n/a - Unknown - Life Threatening), Symptoms (n/a - Unknown - Life Threatening), Syncope (n/a - Unknown - Life Threatening), Upper respiratory tract infection (n/a - Unknown - Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	[HYDROCHLOROTHIAZIDE, THIAMETERNE] (C - n/a - n/a -), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a -)	KSR
EUEC-10006185204	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No		COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	[METOPROLOL SUCCINATE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [MEPRADAZOLE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [PREMEDIACONE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown)	KSR
EUEC-10006185209	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006185609	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area		65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	CANNABIDIOL, CANNABIDIOL] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [ATENOLOL, ATENOLOL BP] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [VALIETAMINE, AZELASTINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [CASBII] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [HALOPERIDOL] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [HYDROLAZINE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [HYDROXYMARE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [EUGENOLBUTANOL, TARTARATE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [DORAZEPAM] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [METHAZAPINE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [NIFEDIPINE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [DIHYDRE] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [FLURIDEC] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [FAMELONIAL, VULANTEROL] (C - Product used for unknown indication - n/a - jva - n/a - Unknown), [VITAMINS NOS] (C - Product used for unknown indication - n/a - jva - n/a - Unknown)	KSR
EUEC-10006185939	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186272	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cardio arrest (14 - Unknown - Life Threatening), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186289	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Cheerless (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalization), Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalization), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalization), Pulse absent (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalization)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186382	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalization) Death (14 - Fatal - Results in Death), Fatigue (n/a - Unknown -), Myalgia (26 - Unknown -)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	BIVACT [BRUVACTAM] (C - Product used for unknown indication - Does not changed - jva - 100mg - Oral), PANTOZOL CONTROL (PANTOZOLAC) (C - Product used for unknown indication - Does not changed - jva - 20mg - Oral), [EPROSANTAN MESILATE, HYDROCHLOROTHAZIDE, EPROSANTAN, HYDROCHLOROTHAZIDE] (C - Product used for unknown indication - Does not changed - jva - 600mg - Oral), [LAMOTRIGINE] (C - Product used for unknown indication - Does not changed - jva - n/a - Oral), [POLYPHENOL ZALPHEM TARTARATE] (C - Product used for unknown indication - Does not changed - jva - n/a - Oral), [COLCALKALCIOL] (C - Product used for unknown indication - n/a - jva - 10mg - n/a), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - jva - 325mg - n/a), [NOSLIN HUMAN, INSULIN HUMAN ZINC, ISOPHANE INSULIN, INSULIN HUMAN] (C - Diabetes mellitus - n/a - jva - 20U/ml - n/a), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - hypertension - n/a - jva - 2.5mg - n/a), BRIVACTAM (C - Product used for unknown indication - n/a - jva - 20mg - n/a)	KSR
EUEC-10006186673	01/04/2021	Sponaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Lethargy (n/a - Unknown -), Respiration abnormal (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186276	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186816	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-100061867139	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Eye contusion (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-100061867175	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-100061867208	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (24 - Fatal - Results in Death), Massive (28 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-100061867224	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-100061867256	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	EUGENOL, EUGENOL] (C - n/a - n/a - jva - n/a - Unknown), [AM, DOXIFINE, AMOXICAPINE MESILATE, AMOXICAPINE MESILATE] (C - n/a - n/a - jva - n/a - Unknown), [CARVEDILOL] (C - n/a - n/a - jva - n/a - Unknown), [ENALAPRIL, MALEATE] (C - n/a - n/a - jva - n/a - Unknown), [OMEPRAZOLE, OMEPRADOLE MAGNESIUM] (C - n/a - n/a - jva - n/a - Unknown), [PARACETAMOL] (C - n/a - n/a - jva - n/a - Unknown)	KSR
EUEC-100061867487	01/04/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Bronchitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalization), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006184287	01/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (34 - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - jva - 5ml - Intramuscular)	SEVELAMER [SEVELAMER, SEVELAMER CARBONATE] (C - n/a - n/a - jva - n/a - n/a), [BISOPROLOL, FUMARATE] (C - n/a - n/a - jva - n/a - n/a), [CEFTAZIDIME] (C - n/a - n/a - jva - n/a - n/a), [PAROSIMOX] (C - n/a - n/a - jva - n/a - n/a), [METHYLPREDNISOLONE, METHYLPREDNISOLONE ACETATE, METHYLPREDNISOLONE SODIUM HEMISULFONATE] (C - n/a - n/a - jva - n/a - n/a)	KSR
EUEC-10006184551	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006184989	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - jva - n/a - n/a)		KSR
EUEC-10006185345	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006183945	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	XARELTO [RIVAROXABAN] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [COLCALKALCIOL] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [PROGEMIDE] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [MEPRADAZOLE] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [PROPRANOLOL, PROPRANOLOL, HYDROCHLORIDE] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [SPRONOLACTONE] (C - Product used for unknown indication - n/a - jva - n/a - n/a), [SUCRALFATE] (C - Product used for unknown indication - n/a - jva - n/a - n/a)	KSR
EUEC-1000618498	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006184716	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006185628	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006185884	31/03/2021	Sponaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Genetic cancer stage IV (n/a - Unknown - Other Medically Important Condition), Phonemia (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186200	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalization)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186305	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186345	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186455	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-10006186458	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown -), Respiratory distress (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)		KSR
EUEC-1000618666	31/03/2021	Sponaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable (jva - IDP) - Unknown)	[ACETILSALICYLIC ACID, ASPIRIN BP] (C - n/a - n/a -), [ALLULOSIDAMINE] (C - n/a - n/a -), [HALDOXIFINE, AMOXICAPINE MESILATE, AMOXICAPINE MESILATE] (C - n/a - n/a -), [ATORVASTATIN] (C - n/a - n/a -), [BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL, FUMARATE, BUDESONIDE] (C - n/a - n/a -), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a -), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - n/a - n/a -), [BUPROPION] (C - n/a - n/a -), [ACETILSALICYLIC ACID] (C - n/a - n/a -),	

Number	Evidence Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex	Patient Age Group (at report)	Patient Sex	Parent Child Report	Reaction List PT Duration? Outcome: Seriousness Criteria	Supplementing Drug List (Drug Class - Indication PT Action taken - [Duration - Dose - Route])	Concomitant/Adverse Drug List (Drug Class - Indication PT Action taken - [Duration - Dose - Route])	CSR Form
EUEC-10008125619	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular]	SOLIDAGO VIRGAUREA (C - Product used for unknown indication - n/a - (10a - n/a) - Unknown), [THIMUS VULGARIS] (C - Product used for unknown indication - n/a - (10a - n/a) - Unknown), [VACCINIUM MACROCARPON] (C - Product used for unknown indication - n/a - (10a - n/a) - Unknown), [ZEA MAYS] (C - Product used for unknown indication - n/a - (10a - n/a) - Unknown)	C2R
EUEC-10006000064	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Dry mouth (n/a - Unknown -), Dyspnoea (14 - Unknown -), Fatigue (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Pain (n/a - Unknown -), Unresponsive to stimuli (14 - Unknown - Other Medically Important Condition), Weighting (n/a - Unknown -)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	GALVUS (NADAGLUPITIN) (C - Product used for unknown indication - n/a - (10a - 50mg - n/a), LEVETIRACETAM ACTAVIS (LEVETIRACETAM) (C - Product used for unknown indication - n/a - (10a - 500mg - n/a), SPRINAPRIDE (BIPHENOLACIDINE ENDOXYBATE) (C - Product used for unknown indication - n/a - (10a - 25mg - n/a), [ESICLOPRIMAN] (C - Product used for unknown indication - n/a - (10a - 10mg - n/a), [HALOPERIDOL DECANOATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MACRODOL SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACRODOL 3350] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - 1000mg - n/a), [NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [OXAZEPIN] (C - Product used for unknown indication - n/a - (10a - 10mg - n/a), [POTASSIUM] (C - Product used for unknown indication - n/a - (10a - 10mg - n/a)	C2R
EUEC-10008000024	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	Not reported	C2R
EUEC-10008000021	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - (10a - n/a) - Intramuscular)	Not reported	C2R
EUEC-10008000050	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	COVID-19 pneumonia (14 - Unknown -), COVID-19 pneumonia (14 - Unknown -), Cough (n/a - Unknown -), Death (14 - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Emotional distress (n/a - Unknown -), Mildness (n/a - Unknown -), Pyrexia (n/a - Unknown -), Rales (n/a - Unknown -)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	Not reported	C2R
EUEC-10008000057	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death), Pyrexia (14 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular - More in CS25)	[AMOXICILIN, AMOXICILIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CLONAZEPAM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [DIPYRIDAMOLE, ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ETIDRABATE, PROPRABATE, INDOXIDINE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [FURSEMIDE, FURSEMIDE SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-10008000748	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death), One infected (20a - Unknown -), Refusal of treatment by patient (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	Not reported	C2R
EUEC-100080001287	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Insomnia (n/a - Unknown -), Lethargy (n/a - Unknown -), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	Not reported	C2R
EUEC-100080001510	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[HYDROCHLOROTHIAZIDE, TRAMETRENE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [KOPRACOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-10008000166	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[COLICAPROFOL, CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - 20mg - n/a), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MAGNESIUM, ALPHACIPROFOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - (10a - 40mg - n/a), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - (10a - 40mg - n/a), [TIMULOSIN, TIMULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - 4mg - n/a)	C2R
EUEC-10008000265	24/03/2021	Spontaneous	Not Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death), Fatigue (n/a - Unknown -), Mildness (n/a - Unknown -), Musculoskeletal stiffness (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	Not reported	C2R
EUEC-100080003127	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	Not reported	C2R
EUEC-100080006318	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	Not reported	C2R
EUEC-100080007257	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080001217	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007346	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007354	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007388	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007437	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007454	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007388	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007437	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death), Epilepsy (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007388	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007388	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [MORPHINUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a)	C2R
EUEC-100080007388	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-65 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - (10a - 10b) - Intramuscular)	[DALOINETHE, DALOINETHE, DALOINETHE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [BUPROPION, BUPROPION, BUPROPION SODIUM] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ACETYSALICYLIC ACID] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [GABAPENTIN] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - (10a - n/a - n/a), [ORATOPRIN] (C - Product used for unknown indication - n/a - (10a - n/a - n	

EU Local Number	EV Entry Review Date	Report Type	Primary Source Question	Primary Country Regulatory Province	Literature Reference	Patient Age Group	Patient Group (see last report)	Patient Sex	Patient Onset Report	Reaction List PT Duration ? Outcome - Seriousness Criteria	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
			Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Death (1d - Fatal - Results in Death), Feeling abnormal (n/a - Unknown -), Vaccination site pain (n/a - Unknown -). Vomiting (n/a - Unknown -)	immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)		
EU-EC-100080417	23/03/2021	Spontaneous	Non-Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-1000799524	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007998183	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007996439	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007997149	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007997059	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007997987	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Aphasia (n/a - Unknown -), Communication disorder (n/a - Unknown -), Correlation (n/a - Unknown -), Death (1d - Fatal - Results in Death), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007998926	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007998647	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown -), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10008001109	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - (n/a - 1[PT] - Intramuscular)	[SALBUTAMOL SULFATE] (C - Asthma - n/a -)	628
EU-EC-10008001401	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10008001828	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10008001906	19/03/2021	Spontaneous	Non-Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Illness (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10008002200	18/03/2021	Spontaneous	Non-Healthcare Professional	Non-Euro Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10008002204	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Pyrexia (n/a - Unknown -), Tense (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10008002370	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	16-84 Years	Not Specified	Male	No	Cyanosis (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Unresponsive to stimuli (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - (n/a - 1[PT] - Intramuscular)	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a)), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (n/a - n/a)), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a)), [DOLICERONE] (C - Product used for unknown indication - n/a - (n/a - n/a)), [HYDROALANINE] (C - Product used for unknown indication - n/a - (n/a - n/a)), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - (n/a - n/a)), [INSULIN HUMAN] (C - Product used for unknown indication - n/a - (n/a - n/a)), [LEVOSALBUTAMOL] (C - Product used for unknown indication - n/a - (n/a - n/a)), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [MELGICICAM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPS] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [POLYCARBOPHIL CALCIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	628
EU-EC-10008002389	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007979386	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	16-84 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Asthma (n/a - Unknown -), Asterixis (n/a - Unknown - Other Medically Important Condition), Ataxia (n/a - Unknown -), Cholelithiasis (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Depression (n/a - Unknown -), Emetia (n/a - Unknown -), Hypoglycemia (n/a - Unknown -), Ictus (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown -), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Parest. diffusion (n/a - Unknown -), Proctitis (n/a - Unknown -), Rash (n/a - Unknown -), Varices oesophageal (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	[BUPIROPION, BUPIROPION, BUPIROPION SODIUM] (C - Product used for unknown indication - n/a -), [TESTOSTERONE] (C - Product used for unknown indication - n/a -), [ATROPINE, DIPHEXYLATE] (C - Product used for unknown indication - n/a -), [CALCIUM CARBONATE] (C - Product used for unknown indication - n/a -), [COLECALCIFEROL] (C - Product used for unknown indication - n/a -), [FLURIDEMER] (C - Product used for unknown indication - n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a -), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a -), [MAGNESIUM CHLORIDE] (C - Product used for unknown indication - n/a -), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a -), [DIMEPRIZOLE] (C - Product used for unknown indication - n/a -), [PARACETAMOL] (C - Product used for unknown indication - n/a -), [SIMASTATIN] (C - Product used for unknown indication - n/a -), [SUCRALFATE] (C - Product used for unknown indication - n/a -)	628
EU-EC-10007979394	18/03/2021	Spontaneous	Non-Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest (n/a - Recovering/Resolving -), Death (n/a - Fatal - Results in Death), Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007980135	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	[METOPROLOL SUCCINATE] (C - Product used for unknown indication - n/a - (n/a - 50mg - n/a))	628
EU-EC-10007981895	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007982054	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007993262	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007982803	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007983355	19/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007983908	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007985206	18/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (1d - Fatal - Results in Death), Dyspnoea (2d - Fatal - Results in Death), Pyrexia (2d - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (1d - n/a - n/a))	Not reported	628
EU-EC-10007987792	17/03/2021	Spontaneous	Non-Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthma (n/a - Fatal - Results in Death), Constitutional state (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007988795	17/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	16-84 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - n/a - Unknown))	Not reported	628
EU-EC-10007989177	17/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	[ALENDRONIC ACID] (C - Product used for unknown indication - n/a - (n/a - Unknown)), [ANASTROZOLE] (C - Product used for unknown indication - n/a - (n/a - Unknown)), [DOLICERONE SODIUM] (C - Product used for unknown indication - n/a - (n/a - Unknown)), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - Unknown)), [LYNASTATIN] (C - Product used for unknown indication - n/a - (n/a - Unknown)), [NIFEDIPINE] (C - Product used for unknown indication - n/a - (n/a - Unknown))	628
EU-EC-100079972159	17/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - n/a - Intramuscular))	Not reported	628
EU-EC-10007994487	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - n/a - (n/a - n/a - n/a))	Not reported	628
EU-EC-10007944984	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - n/a - (n/a - n/a - n/a))	Not reported	628
EU-EC-10007946234	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Malaise (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - (n/a - 1[PT] - Intramuscular)	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown))	628
EU-EC-10007946230	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007946307	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007947194	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007950940	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (17d - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	[RITIGOTINE [RITIGOTINE]] (C - Product used for unknown indication - n/a - (n/a - 6mg - n/a)), [ACETYL SALICYLIC ACID] (C - Product used for unknown indication - Unknown - (n/a - n/a - n/a)), [BAMATEXON HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - 100mg - n/a)), [FLUTICASON PROPRIONATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [HEPARIN SODIUM] (C - Product used for unknown indication - n/a - (n/a - 100000U) - n/a)), [MAGNESIUM OXIDE] (C - Product used for unknown indication - n/a - (n/a - 400mg - n/a)), [METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [NEDISALICIC ACID, NEDISALICIC ACETATE, NEDISALICIC ACETATE, NEDISALICIC ACID, NEDISALICIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [BIOTIN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [COLECALCIFEROL] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [DIPYRIDAMOLE, ASPIRIN SALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [GABAPENTIN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [OXANDETROXON, OXANDETROXON HYDROCHLORIDE, OXANDETROXON HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [SMITICONE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [TRIMETHOPRIM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	628
EU-EC-10007952187	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007954444	16/03/2021	Spontaneous	Non-Healthcare Professional	Non-Euro Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	Not reported	628
EU-EC-10007954947	16/03/2021	Spontaneous	Healthcare Professional	Non-Euro Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), SARS-CoV-2 test positive (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 1[PT] - Intramuscular)	[ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - 10mg - n/a)), [DEXTRAMETHORPHAN, GUAFENESIN] (C - Product used for unknown indication - n/a - (n/a - 60ml - n/a)), [DULPIDE] (C - Product used for unknown indication - n/a - (n/a - 10mg - n/a)), [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - 1000mg - n/a))	628
EU-EC-10007954963	16/03												

Case Number	Evidence Recd Date	Report Type	Primary Source Qualification	Primary Source Regulatory Purpose	Literature Reference	Patient Age Other	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT Discontinuation / Outcome - Seriousness Criteria	Supplementing Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	CGR Form
EUEC-1000786440	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Immobility (n/a - Unknown -),	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - Unknown -), [DOVASTATIN] (C - Product used for unknown indication - Unknown -), [NACRODOL 3500 IC] (C - Product used for unknown indication - Unknown -), [METOPROLOL TARTARATE] (C - Product used for unknown indication - Unknown -), [NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown -), [DIKEMIPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - Product used for unknown indication - Unknown -), [PARACETAMOL] (C - Product used for unknown indication - Unknown -), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - Unknown -), [BENNA ALEXANDRIAN] (C - Product used for unknown indication - Unknown -), [SODIUM POLYSTYRENE SULPHONATE] (C - Product used for unknown indication - Unknown -), [WARFARIN SODIUM] (C - Product used for unknown indication - Unknown -)	CGR
EUEC-1000786440	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Pruritus (n/a - Unknown -), Swelling (n/a - Unknown -),	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[BISACODYL] (C - Product used for unknown indication - Unknown - n/a - (n/a - Unknown)), [HYSCRYAMINE SULFATE] (C - Product used for unknown indication - Unknown - n/a - (n/a - Unknown)), [PARACETAMOL] (C - Product used for unknown indication - Unknown - n/a - (n/a - Unknown))	CGR
EUEC-10007865182	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007865322	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[DULCINETE, DULCINETE, DULCINETE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a)), [ELIGUS (APROMAB)] (C - Product used for unknown indication - n/a - (n/a - n/a)), [PIRACASILUM (PIRACASILUM)] (C - Product used for unknown indication - n/a - (n/a - n/a)), [ASCORBIC ACID, CYNOCOBALAMIN, FOLIC ACID, LACTIC ACID, FERROSUS FLUMINATE, IRON] (C - Product used for unknown indication - n/a - (n/a - n/a)), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - n/a - (n/a - n/a)), [FUROSEMIDE] (C - Product used for unknown indication - n/a - (n/a - n/a)), [LATANOPROST] (C - Product used for unknown indication - n/a - (n/a - n/a)), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - (n/a - n/a)), [METOPROLOL, SACCHARIN] (C - Product used for unknown indication - n/a - (n/a - n/a)), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - (n/a - n/a))	CGR
EUEC-10007865259	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Myocardial infarction (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007865649	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Head injury (n/a - Unknown -), Injection site ulcer (n/a - Unknown -), Miosis (n/a - Unknown -), Neck pain (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007866013	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[ACETYLSALICYLIC ACID, ASPIRIN BPS] (C - Product used for unknown indication - n/a - (n/a - 8mg - n/a)), [MAGNESIUM, MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - n/a - (n/a - 10mg - n/a)), [MAGNESIUM, ALUMINIUM BESILATE, ALUMINIUM MESILATE] (C - Product used for unknown indication - n/a - (n/a - 2.5mg - n/a)), [BUDESONIDE, FORMOTEROL, FLUMASTER, FORMOTEROL, FLUMASTER, BUDESONIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [CALCIOTROL] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [CARVEDILOL] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [PRATIPILOL, SALBUTAMOL] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	CGR
EUEC-10007866256	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007866235	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007866335	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[CARBIDOPA, LEVODOPA (CARBIDOPA, LEVODOPA)] (C - Product used for unknown indication - n/a - (n/a - n/a - Oral)), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - (n/a - n/a - Oral)), [FINASTERIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [FISH OIL, ALPHA TOCOPHEROL] (C - Product used for unknown indication - n/a - (n/a - n/a - Oral)), [PARACETAMOL] (C - Product used for unknown indication - n/a - (n/a - 500mg - Oral)), [TAMSULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - 4mg - Oral)), [TIMOLOL, TIMOLOL MALEATE] (C - Product used for unknown indication - n/a - (n/a - 20mg - n/a))	CGR
EUEC-10007866558	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007866660	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Hypertension (n/a - Unknown -), Muscle rigidity (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007867199	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007867240	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - (n/a - Unknown))	CGR
EUEC-10007867264	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	CGR
EUEC-10007867264	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007867368	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[DOUGASTE SODIUM, CASSIA] (C - Product used for unknown indication - n/a - (n/a - n/a - Oral)), [COXIMATEZOLINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - Nasal))	CGR
EUEC-10007868058	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute respiratory distress syndrome (204 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (204 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007868532	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Respiratory failure (203 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007867240	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007867356	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Chest pain (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pericarditis (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007868665	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007868374	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Respiratory arrest (n/a - Unknown - Other Medically Important Condition),	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007868264	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	14-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Fatigue (n/a - Unknown -),	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007869068	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Pain in extremity (14 - Unknown -),	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007869458	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Unresponsive to stimuli (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007869810	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cardiomy failure congestive (24 - Fatal - Results in Death), Cardomyopathy (24 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Feeling hot (24 - Fatal - Results in Death), Haematemesis (24 - Fatal - Results in Death), Myocardial infarction (24 - Fatal - Results in Death), Leukocytosis (24 - Fatal - Results in Death), Pleural effusion (24 - Fatal - Results in Death), Pulmonary oedema (24 - Fatal - Results in Death), Pulmonary vascular disorder (24 - Fatal - Results in Death), Renal failure (24 - Fatal - Results in Death), Spontaneous fracture (24 - Fatal - Results in Death), Urinary tract infection (24 - Fatal - Results in Death), Vomiting (24 - Fatal - Results in Death), White blood cell disorder (24 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007869592	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[ELIGUS (APROMAB)] (C - Product used for unknown indication - n/a -), [PROTEINEN NOT AVAILABLE] (C - Product used for unknown indication - n/a -), [ACETIC ACID] (C - Bacterial contamination - n/a -), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a -), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a -), [COLESTYRAMINE] (C - Product used for unknown indication - n/a -), [FINASTERIDE] (C - Product used for unknown indication - n/a -), [FINASTERIDE] (C - Product used for unknown indication - n/a -), [FLAVOXATE] (C - Product used for unknown indication - n/a -), [LACTOBACILLUS] (C - Product used for unknown indication - n/a -), [LORATADINE] (C - Product used for unknown indication - n/a -), [NACRODOL 3500] (C - Product used for unknown indication - n/a -), [MAGNESIUM OXIDE] (C - Product used for unknown indication - n/a -), [METOPROLOL, METOPROLOL TARTARATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [DIKEMIPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a -), [PARACETAMOL] (C - Product used for unknown indication - n/a -), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a -), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a -) [ELIUM TAMEZ (BUTETAMIDE)] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	CGR
EUEC-10007869898	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [ELIUM TAMEZ (BUTETAMIDE)] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE)] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [CANDESARTAN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [CARVEDILOL] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [GABAPENTIN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [METILDONIC] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	CGR
EUEC-100078691048	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-100078691073	05/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	14-64 Years	Not Specified	Female	No	Abdominal distension (34 - Unknown -), Cardio-respiratory arrest (34 - Unknown - Life Threatening), Death (34 - Fatal - Results in Death), Decreased appetite (34 - Unknown -), Fatigue (34 - Unknown -), Feeling abnormal (34 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[ASCORBIC ACID] (C - Product used for unknown indication - n/a - (n/a - 500mg - n/a)), [BISACODYL] (C - Product used for unknown indication - n/a - (n/a - 10mg - n/a)), [CLOMIFRAME] (C - Product used for unknown indication - n/a - (n/a - 200mg - n/a)), [LEVOTHYROIDINE, LEVOTHYROIDINE SODIUM] (C - Product used for unknown indication - n/a - (n/a - 200mg - n/a)), [LENDOPRIL, LENDOPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - 20mg - n/a)), [METOPROLOL, SACCHARIN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [NALPHEDIC ACID] (C - Product used for unknown indication - n/a - (n/a - 200mg - n/a)), [VITAMIN D, CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	CGR
EUEC-10007869429	04/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	14-64 Years	Not Specified	Male	No	Acute respiratory failure (64 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-10007869602	04/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	14-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[INSULIN DETEMER (INSULIN DETEMER)] (C - Diabetes mellitus - n/a - (n/a - n/a - Unknown)), [BEVILAMIN (BEVILAMIN, BEVILAMIN CARBONATE)] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [MELGULINE AMIDOTRIZATE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [MODURINE] (C - n/a - n/a - (n/a - n/a - Unknown)), [PARACETAMOL] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [SODIUM POLYSTYRENE SULPHONATE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown))	CGR
EUEC-10007869328	04/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	14-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - n/a - Not applicable - (n/a - n/a - n/a))	Not reported	CGR
EUEC-10007869065	04/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac failure (30en - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Fatigue (30n - Unknown -), Feeling cold (30n - Unknown -), Hypohidrosis (30n - Unknown -), Hypotension (30en - Fatal - Results in Death), Itches (n/a - Unknown -), Mobility decreased (n/a - Unknown -), Tinnitus (30n - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[WARFARIN SODIUM] (C - Cardiac failure congestive, Prophylaxis - n/a - (n/a - n/a - Unknown))	CGR
EUEC-100078694748	04/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	CLOPGOGREL (CLOPGOGREL, CLOPGOGREL BESILATE) (C - Product used for unknown indication - n/a -),	CGR
EUEC-10007869167	04/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-100078693219	04/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-100078693731	04/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma pain (24 - Not Reviewed/Not Reviewed -), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	[LEVOTHYROIDINE, LEVOTHYROIDINE SODIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	CGR
EUEC-100078691233	04/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a -) [DPT] - Intramuscular)	Not reported	CGR
EUEC-100078694002	04/03/202												

EU Local Number	EV Summary Review Date	Report Type	Primary Question	Primary Country Regulatory Procedure Economic Area	Literature Reference	Patent Group	Patent Group (see report)	Patent Sex	Patent EM Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - (Duration - Dose - Route))	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - (Duration - Dose - Route))	CSR Form
												[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a -) [ACOSAPRINE ACID, ACOSAPRINE ACID, HEAVY AMMONIUM] (C - Product used for unknown indication - n/a -) [CARVEDILOL] (C - Product used for unknown indication - n/a -) [CYCLOBENZAPRINE] (C - Product used for unknown indication - n/a -) [DOXUSATE SODIUM] (C - Product used for unknown indication - n/a -) [FERROUS SULFATE] (C - Product used for unknown indication - n/a -) [GLYCERYL TRINERATE] (C - Product used for unknown indication - n/a -) [GUARANTERIN] (C - Product used for unknown indication - n/a -) [HYDROCODONE SULFATE, PAINCIZ 1400] (C - Product used for unknown indication - n/a -) [INSULIN BOVINE (SOPHANE)] (C - Product used for unknown indication - n/a -) [LEVOTHYROIDINE, LEVOTHYROIDINE SODIUM] (C - Product used for unknown indication - n/a -) [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a -) [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a -) [SPRINOLACTONE] (C - Product used for unknown indication - n/a -) [TAMOXIFEN, TAMOXIFEN HYDROCHLORIDE] (C - Product used for unknown indication - n/a -) [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a -)	
EU-EC-1000779215	04/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779393	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Aspiration (n/a - Fatal - Results in Death), Asthma (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Erythema (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Left sided dilation (n/a - Fatal - Results in Death), Lung consolidation (n/a - Fatal - Results in Death), Lung opacity (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Orchitis (n/a - Fatal - Results in Death), Orchitis (n/a - Fatal - Results in Death), Pulmonary granuloma (n/a - Fatal - Results in Death), Pulmonary tumour mass (n/a - Fatal - Results in Death), Pulmonary mass (n/a - Fatal - Results in Death), Respiratory tract congestion (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [FUROSEMIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [GLUCOSAMINE, CHONDROITIN] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [OXANDEFOSFATE, OXANDEFOSFATE DIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [PARACETAMOL] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [TAMOXIFEN, TAMOXIFEN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [THIAMINE HYDROCHLORIDE, RETINOL] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	628
EU-EC-1000779372	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779350	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthenia (d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (d - Fatal - Results in Death), Food refusal (d - Fatal - Results in Death), Memory impairment (d - Fatal - Results in Death), Mobility decreased (d - Fatal - Results in Death), Somnolence (d - Fatal - Results in Death), Visual impairment (d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779356	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), General physical health deterioration (1d - Fatal - Results in Death), Malaise (d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[RENEVA, BEVELAMER CARBONATE] (C - Product used for unknown indication - n/a - (n/a - 80mg - n/a)), [ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - 81mg - n/a)), [AMLODIPINE BESILATE, ATORVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - (n/a - 5mg - n/a)), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (n/a - 20mg - n/a)), [COLECALCIFEROL] (C - Product used for unknown indication - n/a - (n/a - 1000U - n/a)), [CYANOCOBALAMIN, VITAMIN B12] (C - Product used for unknown indication - n/a - (n/a - 1000ug - n/a)), [FUROSEMIDE] (C - Product used for unknown indication - n/a - (n/a - 80mg - n/a)), [METOPROLOL, METOPROLOL TARTRATE PH. EUR.] (C - Product used for unknown indication - n/a - (n/a - 25mg - n/a))	628
EU-EC-1000779345	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779349	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Menstrual status changes (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[ANDRO, MILECLOLUMIN BROMIDE, VILANTEROL] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [MELATONIN, MELATONIN] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [PROGLUTAZONE, PROGLUTAZONE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [SIMPLIXA, SIMPLIXA, TENIPROVIR, ALFAPIRAMIDE, FUMARATE, DARUNAVIR, ETHANOLATE, COBICISTAT, EMTRICITABINE, TENIPROVIR, ALFAPIRAMIDE, DARUNAVIR, COBICISTAT] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [VICTOZA, VICTOZA] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [ATORVASTATIN] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [GABAPENTIN] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [INSULIN, INSULIN] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [RISPERIDONE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [VITAMINE MCE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown))	628
EU-EC-1000779316	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779340	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779345	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[ACETYL SALICYLIC ACID] (C - Product used for unknown indication - n/a -), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a -), [COLECALCIFEROL] (C - Product used for unknown indication - n/a -), [DOXUSATE SODIUM] (C - Product used for unknown indication - n/a -), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a -), [MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL, 3300] (C - Product used for unknown indication - n/a -), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a -), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a -)	628
EU-EC-1000779379	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (d - Fatal - Results in Death, Other Medically Important Condition), Chills (d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (d - Fatal - Results in Death), Headache (d - Fatal - Results in Death), Nausea (d - Fatal - Results in Death), Pneumonia (d - Fatal - Results in Death), Pyrexia (d - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination site pain (d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779316	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Respiratory tract congestion (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - (n/a - 10PT) - Intramuscular)	[MELATONIN, MELATONIN] (C - n/a - n/a -), [CLONAZEPAM] (C - n/a - n/a -), [FLUNISOLIDE] (C - n/a - n/a -), [MACROGOL, 3300] (C - n/a - n/a -), [MAGNESIUM HYDROXIDE] (C - n/a - n/a -), [NIFEDIPINE] (C - n/a - n/a -), [PARACETAMOL] (C - n/a - n/a -), [TAMOXIFEN, TAMOXIFEN HYDROCHLORIDE] (C - n/a - n/a -)	628
EU-EC-1000779324	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Ibuprofen (1d - Fatal - Results in Death), Syncope (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[ALEXANDER, ALEXANDER] (C - Product used for unknown indication - n/a - (n/a - 10PT) - Oral), [ACOSAPRINE ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - (n/a - 10PT) - Oral)	628
EU-EC-1000779326	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[AZOT, BRENDAZOLAM] (C - Product used for unknown indication - n/a - (n/a - 10mg - Oral)), [BRIVACT, BRIVACTAMINE] (C - Product used for unknown indication - n/a - (n/a - 100mg - Oral)), [BACTRACIN, ZINC, NEOMYCIN SULFATE, POLYMYXIN B SULFATE] (C - Product used for unknown indication - n/a - (n/a - n/a - Topical)), [CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - (n/a - 800mg - Oral))	628
EU-EC-1000779337	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779370	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779347	03/03/2021											[COLECALCIFEROL] (C - Product used for unknown indication - Unknown -), [GLUTAMIC ACID, GLUTAMIC ACID] (C - Product used for unknown indication - Unknown -), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - Unknown - (n/a - n/a - n/a)), [HYDROXYZINE] (C - Product used for unknown indication - Unknown -), [LEVONORGESTREL, LEVONORGESTREL, MICRONISED] (C - Product used for unknown indication - Unknown -), [PREDNISONE] (C - Product used for unknown indication - Unknown -), [TRAMACLOLONE] (C - Product used for unknown indication - Unknown -), [VALACLOLIVIR HYDROCHLORIDE] (C - Product used for unknown indication - Unknown -)	628
EU-EC-1000779347	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779344	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779306	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779307	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[FENTANYL, FENTANYL, FENTANYL CITRATE] (C - Product used for unknown indication - n/a - (n/a - n/a - Unknown)), [HYDROCODONE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a)), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - (n/a - n/a - n/a))	628
EU-EC-1000779345	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779348	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-10007793815	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Breastfeeding (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation), Cardio-respiratory arrest (1d - Fatal - Results in Death, Caused Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Dermatological reaction (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation), Hypersensitivity to stimuli (1d - Fatal - Results in Death, Caused Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[HYDROXYCORTISONE, HYDROXYCORTISONE, HYDROXYCORTISONE SODIUM SUCCINATE] (C - n/a - Unknown - (n/a - n/a - n/a)), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - Unknown - (n/a - n/a - n/a)), [DANABES] (C - n/a - Unknown - (n/a - n/a - n/a)), [GLUCOCORTICOID] (C - n/a - Unknown - (n/a - n/a - n/a)), [FAMOTIDINE] (C - n/a - Unknown - (n/a - n/a - n/a)), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - Unknown - (n/a - n/a - n/a)), [MIRTAPAZINE] (C - n/a - Unknown - (n/a - n/a - n/a)), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - Unknown - (n/a - n/a - n/a)), [DIPHENHYDRAZINE] (C - n/a - Unknown - (n/a - n/a - n/a)), [EMULSIFER] (C - n/a - Unknown - (n/a - n/a - n/a))	628
EU-EC-10007793816	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-10007793840	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular - More in CSRS)	Not reported	628
EU-EC-10007793905	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[ACETYL SALICYLIC ACID] (C - n/a - n/a - (n/a - n/a - n/a - n/a)), [ALLOPURINOL] (C - n/a - n/a - (n/a - n/a - n/a - n/a)), [ATORVASTATIN] (C - n/a - n/a - (n/a - n/a - n/a - n/a)), [CARVEDILOL] (C - n/a - n/a - (n/a - n/a - n/a - n/a)), [HALOPERIDOL] (C - n/a - n/a - (n/a - n/a - n/a - n/a)), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - (n/a - n/a - n/a - n/a)), [VALPROIC ACID] (C - n/a - n/a - (n/a - n/a - n/a - n/a)), [ZEPRAZOLAM] (C - n/a - n/a - (n/a - n/a - n/a - n/a))	628
EU-EC-10007793941	03/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[ATRO, SPERGALIN] (C - Product used for unknown indication - Unknown - (n/a - 200mg - Unknown)), [ATORVASTATIN CALCIUM] (C - Product used for unknown indication - Unknown - (n/a - n/a - Unknown)), [FLUCONAZOLE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - (n/a - n/a - Unknown)), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - Unknown - (n/a - n/a - Unknown)), [MAGNESIUM SULFATE] (C - Product used for unknown indication - Unknown - (n/a - 25mg - Unknown)), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - Unknown - (n/a - 25mg - Unknown)), [NIFEDIPINE] (C - Product used for unknown indication - Unknown - (n/a - n/a - Unknown)), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - Unknown - (n/a - 20mg - Unknown))	628
EU-EC-10007793025	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chronic kidney disease (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Pneumonia (1d - Fatal - Results in Death), Septic shock (1d - Fatal - Results in Death), Urinary tract infection (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Unknown - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-1000779384	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (10d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-10007793718	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-10007793199	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Mebel (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	[ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - 40mg - n/a)), [CARVEDILOL] (C - Product used for unknown indication - n/a - (n/a - 25mg - Oral)), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - (n/a - 20mg - Oral)), [LEVOTHYROIDINE, LEVOTHYROIDINE SODIUM] (C - Product used for unknown indication - n/a - (n/a - 25mg - Oral)), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - 25mg - Oral)), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - (n/a - 40mg - Oral)), [PHENOBARBITAL, PHENOBARBITAL SODIUM] (C - Product used for unknown indication - n/a - (n/a - 10mg - Oral)), [TERAZOSIN, TERAZOSIN HYDROCHLORIDE, TERAZOSIN HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - (n/a - 10mg - Oral))	628
EU-EC-10007793170	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiogenic shock (1d - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation), Sepsis (1d - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-020414) [COVID-19 MRNA VACCINE MODERNA (CX-020414)] (S - COVID-19 immunisation - Not applicable - (n/a - 10PT) - Intramuscular)	Not reported	628
EU-EC-10007793172	02/03/2021	Spontaneous	Healthcare Professional	Non-Eurozone Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Abdominal pain (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Diarrhoea (1d - Fatal - Results in Death), Injection			

EU Local Number	EV Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Province	Literature Reference	Patient Age Group	Patient Age Group (by sex)	Patient Sex	Patient OHM Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Other Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form
												MAGNESIUM OXIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). MONTELUKAST MONTELUKAST SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). DIMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). POTASSIUM POTASSIUM CHLORIDE POTASSIUM GLYCEROPHOSPHATE POTASSIUM HYDROGEN CARBONATE POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). SALBUTAMOL SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]). TERAZOSIN TERAZOSIN HYDROCHLORIDE DIFRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]).	
EU-EC-1000757551	10/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Other Medically Important Condition), Dyspnoea (4d - Fatal - Results in Death, Other Medically Important Condition), Renal failure (4d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-1000757591	10/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Aphasia (n/a - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Endotracheal intubation (1d - Fatal - Results in Death), Hemiparesis (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-1000757584	10/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-1000757584	10/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute respiratory failure (8d - Fatal - Results in Death, Cause of Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Cause of Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (8d - Fatal - Results in Death, Cause of Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	CELICEPT (HYPOCHLORITE MOFETIL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ZYPEREX (DANAZAPINE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ATOVASTATIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DILESONIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Respiratory (inhalation)), EZEITIMBE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FENEMISATE, FENEMISATE (ANALOGUE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LEVOSALBUTAMOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Respiratory (inhalation)), MACROGOL 3350 (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DIMEPRAZOLE, DIMEPRAZOLE MAGNESIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PAROXETINE, PAROXETINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PREDNISONE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), TRAZODONE, TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), UMECLOFINUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-10007575901	10/03/2021	Spontaneous	Not Healthcare Professionals	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007575903	10/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Exposure to SARS-CoV-2 (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	CARBIDOPA, LEVODOPA (CARBIDOPA, LEVODOPA) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FENIBAM, FENIBAM, FENIBAM, CITRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), NOLISE ELIPTA (LUMELINUM BROMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MALICHO HYDROCHLORIDE, HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM DIALATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYRONE, LEVOTHYRONE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METHYLDOPA] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-10007575713	10/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007575928	10/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-1000759032	08/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	KETOCONAZOLE (KETOCONAZOLE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LEVEMIR (INSULIN DETEMIR) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LIVETRACTAM (LIVETRACTAM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PROLIS (PROLIS) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), VIMPT (LACOSAMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [AMINO ACIDS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ANASTROZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CARBONYLATES NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOLACALOPRAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOLACALOPRAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOLACALOPRAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FATS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FIBRE, DIETARY] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FLUOXIMINE MALEATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [INSULIN ASPART] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MACROGOL 3350] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MINERALS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [POLYCARBONYL CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SELENIUM SULFIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TITANINE NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-10007590010	08/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Syncope (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007590041	08/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	OXYBUTYRIN (OXYBUTYRIN, OXYBUTYRIN HYDROCHLORIDE) (C - Product used for unknown indication - n/a -), [AMLODIPINE, AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a -), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a -), [BENIDOLIPINE BESILATE] (C - Product used for unknown indication - n/a -), [HYDROCHLOROTHIAZIDE, TRIAMTERENE] (C - Product used for unknown indication - n/a -), [LITHIUM] (C - Product used for unknown indication - n/a -), [PALIPERIDONE PALMITATE] (C - Product used for unknown indication - n/a -), [PENTAMYL, PENTAMYL, PENTAMYL, CITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MERTAZAPINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	C28
EU-EC-10007590139	08/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007590300	08/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007590308	08/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	ACEPILSALICYLIC ACID (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), FLUCIDEMOL FLUCIDEMOL SODIUM (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [SPRONOLACTONE] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [TOTOPIUM, TOTOPIUM BROMIDE, TOTOPIUM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a])	C28
EU-EC-10007590297	08/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007591665	08/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	RANOLAZINE (RANOLAZINE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BIOTIN] (C - Product used for unknown indication - n/a - [n/a - 250mg - n/a]), [CLODOPORIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [EZEITIMBE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [FISH OIL] (C - Product used for unknown indication - n/a - [n/a - 1000mg - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 200mg - n/a]), [LYME HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1000mg - n/a]), [METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), [DIMEPRAZOLE, DIMEPRAZOLE MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), [ZINC, CALCIUM, MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-10007591110	05/03/2021	Spontaneous	Not Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007591445	05/03/2021	Spontaneous	Not Healthcare Professionals	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Anxiety (n/a - Unknown -), Death (1d - Fatal - Results in Death), Pyrexia (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007591483	05/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	PARACETAMOL (C - Product used for unknown indication - Unknown -)	C28
EU-EC-10007593099	05/03/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007488513	01/02/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intervaccinal)	ACEPILSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CLODOPORIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [EZEITIMBE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [FISH OIL] (C - Product used for unknown indication - n/a - [n/a - 1000mg - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 200mg - n/a]), [LYME HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1000mg - n/a]), [METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), [DIMEPRAZOLE, DIMEPRAZOLE MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), [ZINC, CALCIUM, MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	C28
EU-EC-10007471020	29/01/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Blood creatinine increased (n/a - Unknown - Other Medically Important Condition), Blood urea increased (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Erythema (n/a - Unknown -), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Lack of appetite (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -), Respiratory rate increased (n/a - Unknown - Other Medically Important Condition)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007450386	28/01/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown -)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007450382	28/01/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28
EU-EC-10007418556	24/01/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (0d - Fatal - Results in Death)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 3mc - Intervaccinal)]	ESCITALOPRAM (C - n/a - n/a - [n/a - 1DP] - Unknown), [FAMOTIDINE] (C - n/a - n/a - [n/a - 20mg - Unknown]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 800mg - Unknown]), [PHENOBARBITAL] (C - n/a - n/a - [n/a - 1DP] - Unknown)	C28
EU-EC-10007416328	23/01/2021	Spontaneous	Healthcare Professionals	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Erythema (n/a - Unknown -), Feeling hot (n/a - Unknown -), Swelling (n/a - Unknown -)	SPKIVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intervaccinal)	Not reported	C28