## Appendix 11.5a Myocarditis/Pericarditis: Patients < 40 years of age after Dose 2 and Dose 3: Case Listings

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis, Pain in extremity, Pyrexia | 24 | Male | Recovering/Resolving | Asthma(C) | | Dose 3 | 2 | Level 1 | Confirmed | Possible | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Chest pain, Myocarditis, Palpitations, Pericarditis | 32 | Female | Not Recovered/Not Resolved | Cough(H); Nasopharyngitis(H) | COVID-19 MRNA VACCINE BNT162B2 | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Fatigue, Myocarditis, Pericarditis | 19 | Male | Recovering/Resolving | Alcohol use(H) | PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE | Dose 3 | 0 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 20 | Male | Recovering/Resolving | Cryptorchism(H) | | Dose 2 | 101 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Dizziness, Myocarditis | 29 | Male | Recovering/Resolving | Diabetes mellitus(C) | | Dose 2 | 127 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 24 | Male | Not Recovered/Not Resolved | MODERNA COVID-19 VACCINE | | Dose 2 | 48 | Level 4 | Unassessable | Unassessable | |
| | | Literature-Non-Study | Myocarditis | Serious | Chills, Myocarditis, Pyrexia | 23 | Male | Recovered/Resolved | Asthma exercise induced(C) | | Dose 2 | 2 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 25 | Male | Recovered/Resolved | | | Dose 2 | Unknown | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | COVID-19, Limb injury, Lower respiratory tract infection, Lymphadenopathy, Myocarditis | 36 | Male | Not Recovered/Not Resolved | | | Dose 3 | | Level 4 | Unassessable | Unlikely | |
| | | Spontaneous | Pericarditis | Serious | Haemoptysis, Nausea, Pericarditis, Rash | 29 | Male | Unknown | | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Arrhythmia, Pericardial effusion, Pericarditis | 38 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Angina pectoris, Dizziness, Injection site pain, Lymphadenopathy, Myocarditis | 38 | Male | Not Recovered/Not Resolved | | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Dyspnoea, Myocarditis | 28 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 35 | Male | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 32 | Male | Not Recovered/Not Resolved | SPIKEVAX(H) | | Dose 2 | 19 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations, Tachycardia | 25 | Female | Recovered/Resolved with Sequelae | | | Dose 2 | 33 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 17 | Male | Recovering/Resolving | | | Dose 2 | 2 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Arrhythmia, Pericarditis | 35 | Male | Unknown | | | Dose 3 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 35 | Male | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Pericarditis | 22 | Male | Not Recovered/Not Resolved | COVID-19(H) | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations, Pyrexia, Tachycardia | 26 | Male | Recovering/Resolving | | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 32 | Male | Recovered/Resolved | | COMIRNATY | Dose 3 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Acute coronary syndrome, Myocarditis | 27 | Male | Unknown | | | Dose 2 | 5 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Fatigue, Myocarditis, Pyrexia | 32 | Male | Recovering/Resolving | | | Dose 2 | 4 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Recovering/Resolving | | | Dose 2 | 16 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 30 | Female | Recovering/Resolving | | | Dose 3 | 13 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 13 | Male | Recovering/Resolving | | | Dose 2 | | Level 4 | Unassessable | Unlikely | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 18 | Male | Unknown | COVID-19 immunisation(H) | IBUPROFEN DH | Dose 2 | 34 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Hypoaesthesia, Myocarditis, Pericarditis, Ventricular extrasystoles | 29 | Male | Not Recovered/Not Resolved | | | Dose 2 | 4 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 38 | Male | Recovering/Resolving | | | Dose 2 | 11 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 26 | Male | Recovering/Resolving | | | Dose 2 | 57 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 24 | Male | Recovering/Resolving | | | Dose 2 | 36 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericardial effusion, Pericarditis | 25 | Female | Recovering/Resolving | Pericarditis(H) | | Dose 2 | 94 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Abdominal pain, Acute kidney injury, Colitis, Diarrhoea, Hepatic function abnormal, Hypokalaemia, Left ventricular dysfunction, Myocarditis, Pyrexia, Sepsis, Streptococcal bacteraemia, Stress cardiomyopathy, Urinary tract infection, Vomiting | 39 | Female | Unknown | Caesarean section(H); Coronary artery bypassFH | | Dose 2 | 35 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 17 | Female | Recovered/Resolved | COVID-19(H) | | Dose 2 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Headache, Myalgia, Myocarditis, Pyrexia | 26 | Male | Recovered/Resolved | | | Dose 2 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Abdominal pain upper, Back pain, Chest pain, Dyspnoea, Fatigue, Headache, Myocarditis, Neck pain, Palpitations, Tachycardia | 25 | Female | Recovering/Resolving | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Asthenia, Headache, Pericarditis, Pyrexia | 26 | Female | Not Recovered/Not Resolved | SPIKEVAX | EUTIROX | Dose 2 | | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Pericarditis | Serious | Back pain, Feeling abnormal, Interchange of vaccine products, Musculoskeletal pain, Neck pain, Pain in extremity, Pericarditis | 22 | Male | Recovered/Resolved with Sequelae | Food allergy; COVID-19 VACCINE NRVV AD26 (JNJ 78436735); Seasonal allergy | FLONASE [MOMETASONE FUROATE] | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Fatigue, Pericarditis | 35 | Unknown | Not Recovered/Not Resolved | | LEVOTHYROXINE [LEVOTHYROXINE SODIUM] | Dose 3 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Myocarditis, Nausea, Palpitations, Syncope, Tachycardia | 39 | Female | Recovering/Resolving | | | Dose 3 | 1 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Pericarditis | 22 | Female | Recovering/Resolving | | COVID-19 VACCINE ASTRAZENECA; YASMIN | Dose 3 | 2 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Myocarditis, Sinus tachycardia | 39 | Female | Recovering/Resolving | | PREGABALIN | Dose 3 | | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Chest pain, Dizziness, Dyspnoea, Fatigue, Irregular breathing, Myocarditis, Palpitations, Syncope, Tachycardia | 37 | Male | Not Recovered/Not Resolved | Suspected COVID-19(H) | | Dose 3 | 10 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Pericarditis | Non Serious | Chest pain, Pericarditis | 22 | Male | Not Recovered/Not Resolved | | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations, Pyrexia, Syncope | 21 | Male | Recovered/Resolved with Sequelae | | COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2 | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Cardiac flutter, Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations, Pyrexia | 19 | Female | Unknown | | COVID-19 MRNA VACCINE BNT162B2 | Dose 3 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 36 | Male | Not Recovered/Not Resolved | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 32 | Male | Recovered/Resolved | | | Dose 2 | 3 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Pulmonary embolism, Vaccination complication | 39 | Female | Unknown | | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 36 | Male | Recovering/Resolving | MODERNA COVID-19 VACCINE | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 36 | Male | Recovered/Resolved | | | Dose 2 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Chest pain, Dyspnoea, Myocarditis, Pain in extremity, Pain in jaw | 26 | Female | Recovering/Resolving | | | Dose 3 | 6 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Non Serious | COVID-19, Lymphadenopathy, Menstruation delayed, Myocarditis, Oligomenorrhoea | 27 | Female | Not Recovered/Not Resolved | | | Dose 3 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Pericarditis, Tachycardia | 40 | Male | Recovering/Resolving | Knee operation | | Dose 3 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Angina pectoris, Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations, Tachycardia | 28 | Male | Not Recovered/Not Resolved | Hypotension(C); Heart rate(H) | PFIZER BIONTECH COVID-19 VACCINE | Dose 3 | 18 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Cough, Dyspnoea, Fatigue, Headache, Myocarditis, Palpitations, Pyrexia, Tachycardia | 38 | Male | Not Recovered/Not Resolved | Suspected COVID-19(C) | COVID-19 MRNA VACCINE BNT162B2 | Dose 3 | 18 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 38 | Male | Not Recovered/Not Resolved | Spinal muscular atrophy(C) | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Heart rate increased, Hypertension, Myocarditis, Palpitations, Tachycardia | 32 | Male | Recovering/Resolving | | | Dose 3 | 4 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 27 | Male | Not Recovered/Not Resolved | | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Hypoaesthesia, Myocarditis, Paraesthesia | 29 | Male | Recovered/Resolved | COVID-19(H) | | Dose 2 | 74 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations, Pyrexia, Tachycardia, Troponin increased | 18 | Male | Not Recovered/Not Resolved | | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Arrhythmia, Chest pain, Dyspnoea, Exercise tolerance decreased, Heart rate irregular, Myocarditis, Pain, Stress cardiomyopathy | 30 | Female | Not Recovered/Not Resolved | | | Dose 2 | 49 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Pericarditis | Serious | Myocarditis, Pericarditis | 33 | Male | Not Recovered/Not Resolved | SPIKEVAX(H) | | Dose 2 | 0 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Arthralgia, Chest pain, Fatigue, Lethargy, Myocarditis, Syncope | 35 | Female | Recovered/Resolved | | COVID-19 VACCINE MODERNA; INFLUENZA VIRUS | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Hypertension, Malaise, Pain in extremity, Pain in jaw, Palpitations, Pericarditis, Pyrexia, Tachycardia | 39 | Female | Recovering/Resolving | Rubber sensitivity(C); Suspected COVID-19(C); Non-tobacco user(H) | COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; MIRENA; PARACETAMOL | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Palpitations, Pericarditis, Shock, Tachycardia, Tremor | 32 | Male | Not Recovered/Not Resolved | Non-tobacco user(C); Abstains from alcohol(C) | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Pericarditis, Tachycardia | 35 | Male | Recovering/Resolving | | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Malaise, Myocarditis, Palpitations, Tachyarrhythmia, Tachycardia | 33 | Female | Not Recovered/Not Resolved | | | Dose 3 | | Level 5 | Not a case | Unassessable | |
| | | Spontaneous | Pericarditis | Serious | Chest discomfort, Cough, Dyspnoea, Headache, Insomnia, Maternal exposure during pregnancy, Palpitations, Pericarditis | 35 | Female | Unknown | Mitral valve prolapse(H); Hypersensitivity; Barrett's oesophagus(C); Asthma(C); COVID-19(H) | ASPIRIN [ACETYLSALICYLIC ACID]; PRENATAL VITAMINS [MINERALS NOS;VITAMINS NOS]; PANTOPRAZOLE; FLUOXETINE; ASTHMAHALER | Dose 3 | 1 | Level 4 | Unassessable | Conditional | |
| | | Literature-Non-Study | Myocarditis | Serious | Myocarditis, Pyrexia | 20 | Male | Unknown | | | Dose 2 | 3 | Level 1 | Confirmed | Possible | |
| | | Literature-Non-Study | Myocarditis | Serious | Myocarditis, Pyrexia | 21 | Male | Unknown | | | Dose 2 | 3 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Dizziness, Dyspnoea exertional, Fibrin D dimer increased, Headache, Musculoskeletal pain, Pericarditis, Pyrexia | 32 | Female | Recovering/Resolving | Migraine(C) | COMIRNATY; BOTOX | Dose 3 | 13 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Body temperature increased, Chest pain, Headache, Myocarditis | 39 | Male | Recovering/Resolving | Dyslipidaemia(C); Essential hypertension(C); COMIRNATY | | Dose 3 | 5 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 39 | Male | Fatal | Gout(C); Sleep apnoea syndrome(H) | BENZBROMARONE | Dose 2 | 4 | Level 5 | Not a case | Unlikely | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Headache, Myocarditis, Palpitations, Syncope | 36 | Male | Not Recovered/Not Resolved | | COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2 | Dose 3 | 25 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 33 | Male | Unknown | MODERNA COVID-19 VACCINE | | Dose 2 | 18 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Inflammation, Myocarditis, Palpitations, Swelling, Tachycardia | 22 | Female | Not Recovered/Not Resolved | | PFIZER BIONTECH COVID-19 VACCINE; MICROGYNON [ETHINYLESTRADIOL;LEVONORGESTREL] | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Fatigue, Myocarditis | 19 | Male | Recovering/Resolving | | | Dose 2 | 0 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 26 | Male | Recovered/Resolved | Asthma(C) | | Dose 2 | 4 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Pericarditis | Serious | Pericarditis | 19 | Female | Recovering/Resolving | | | Dose 2 | | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 28 | Male | Not Recovered/Not Resolved | | | Dose 2 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 37 | Male | Recovered/Resolved | Pericarditis(H); SPIKEVAX | | Dose 2 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 31 | Male | Not Recovered/Not Resolved | Hypertension(C); Obesity(H) | | Dose 3 | 6 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 32 | Male | Recovered/Resolved | | | Dose 2 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 27 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 30 | Male | Not Recovered/Not Resolved | | DICLOFENAC SODIUM | Dose 2 | 61 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Pericarditis | 30 | Female | Recovering/Resolving | SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE(H) | | Dose 3 | 1 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Pericarditis | Serious | Chest discomfort, Chest pain, Nausea, Pericarditis | 34 | Male | Recovering/Resolving | Non-tobacco user(H); COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2 | | Dose 3 | 7 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis, Tachycardia | 23 | Male | Unknown | | | Dose 2 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 28 | Male | Recovering/Resolving | COVID-19 immunisation(H) | | Dose 2 | 96 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Headache, Myocarditis, Pyrexia, Respiration abnormal | 14 | Male | Recovering/Resolving | Food allergy(C); SPIKEVAX | | Dose 2 | 2 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Back pain, Chest pain, Depressed level of consciousness, Dizziness, Dyspnoea, Fatigue, Headache, Myocarditis, Palpitations, Seizure, Syncope, Tachycardia, Visual impairment | 40 | Female | Recovered/Resolved with Sequelae | Suspected COVID-19(H) | COVID-19 VACCINE ASTRAZENECA | Dose 3 | 18 | Level 5 | Not a case | Unlikely | |
| | | Spontaneous | Myocarditis | Serious | Illness, Myocarditis | 36 | Female | Unknown | | | Dose 3 | unknown | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Pericarditis, Pyrexia | 26 | Male | Not Recovered/Not Resolved | SARS-COV-2 VACCINE; SARS-COV-2 VACCINE | | Dose 3 | unknown | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 19 | Male | Recovered/Resolved | COVID-19 VACCINE JANSSEN | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 28 | Male | Unknown | | | Dose 2 | unknown | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 37 | Male | Recovering/Resolving | Dyspepsia(C) | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Literature-Non-Study | Myocarditis | Serious | Myocarditis | 31 | Male | Unknown | | | Dose 2 | unknown | Level 1 | Confirmed | Possible | |
| | | Literature-Non-Study | Myocarditis | Serious | Myocarditis | 30 | Male | Recovering/Resolving | Asthma(C); COVID-19(H) | | Dose 2 | 1 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | COVID-19 immunisation, Myalgia, Myocarditis | 29 | Female | Not Recovered/Not Resolved | Comirnaty; Comirnaty | | Dose 3 | 0 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 26 | Female | Unknown | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Myocarditis | 37 | Male | Not Recovered/Not Resolved | | | Dose 2 | 2 | Level 2 | Probable | Possible | [redacted] |
| | | Regulatory Authority | Myocarditis | Non Serious | Chills, Fatigue, Myocarditis | 31 | Male | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Non Serious | Influenza like illness, Myocarditis | 35 | Male | Not Recovered/Not Resolved | | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 39 | Female | Not Recovered/Not Resolved | | | Dose 3 | 9 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 29 | Male | Recovering/Resolving | | [redacted] | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Pericarditis | 33 | Male | Not Recovered/Not Resolved | | CO-AMOXICLAV [AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM] | Dose 3 | 0 | Level 3 | Acute Pericarditis | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis, Pyrexia | 29 | Male | Recovering/Resolving | Brain neoplasm(H) | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Literature-Non-Study | Myocarditis | Serious | Endocarditis, Myocarditis, Pyrexia | 20 | Male | Recovered/Resolved | | | Dose 2 | 2 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 34 | Male | Not Recovered/Not Resolved | | | Dose 3 | 4 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Recovering/Resolving | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Coronary artery dissection, Myocarditis | 21 | Female | Not Recovered/Not Resolved | SPIKEVAX(H); SPIKEVAX(H) | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 20 | Female | Not Recovered/Not Resolved | | | Dose 3 | 0 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Chills, Malaise, Myocarditis, Pyrexia | 40 | Male | Recovering/Resolving | SPIKEVAX | | Dose 2 | 3 | Level 3 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Arrhythmia, Myocarditis, Pfeiffer syndrome | 18 | Male | Not Recovered/Not Resolved | | | Dose 2 | 98 | Level 5 | Not a case | Unlikely | |
| | | Regulatory Authority | Pericarditis | Serious | COVID-19 immunisation, Pericarditis | 38 | Male | Recovering/Resolving | COMIRNATY(H); COMIRNATY(H) | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Capillary leak syndrome, Cardiogenic shock, Myocarditis, Pericardial effusion | 40 | Male | Not Recovered/Not Resolved | SARS-CoV-2 test positive(H) | | Dose 3 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Asthenia, Dyspnoea, Myocarditis, Tachycardia | 30 | Male | Not Recovered/Not Resolved | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Bedridden, Cardiac discomfort, Dissociation, Dyspnoea, Fatigue, General physical health deterioration, Pericarditis, Pyrexia | 35 | Male | Unknown | | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Cardiac failure, Myocarditis | 23 | Male | Unknown | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 29 | Male | Unknown | | | Dose 3 | 3 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Dilatation ventricular, Dizziness, Dyspnoea, Ejection fraction decreased, Hyperhidrosis, Influenza, Myocarditis, Tachycardia, Ventricular internal diameter abnormal | 31 | Male | Not Recovered/Not Resolved | | | Dose 2 | 2 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Influenza like illness, Myocarditis | 30 | Male | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 26 | Male | Recovered/Resolved | Myocarditis(H) | | Dose 2 | 3 | Level 2 | Probable | Possible | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Influenza, Myocarditis | 23 | Male | Recovering/Resolving | | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 35 | Male | Unknown | SPIKEVAX | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Myocarditis, Pyrexia | 26 | Unknown | Not Recovered/Not Resolved | | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 30 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Literature-Non-Study | Myocarditis | Serious | Myocarditis | 28 | Male | Recovered/Resolved | | | Dose 2 | 3 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 37 | Male | Recovering/Resolving | Pericarditis(H); Hodgkin's disease(H) | VAXZEVRIA | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 31 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 15 | Male | Not Recovered/Not Resolved | | | Dose 2 | 2 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Nasopharyngitis, Pericarditis, Pyrexia | 24 | Male | Recovering/Resolving | | | Dose 2 | 26 | Level 4 | Unassessable | Conditional | |
| | | Spontaneous | Pericarditis | Serious | Pericarditis | 25 | Female | Unknown | | | Dose 2 | unknown | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 32 | Female | Not Recovered/Not Resolved | | COMIRNATY | Dose 2 | 18 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 21 | Male | Recovered/Resolved with Sequelae | | | Dose 2 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Not Recovered/Not Resolved | COVID-19 VACCINE JANSSEN | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 35 | Male | Not Recovered/Not Resolved | | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 31 | Male | Not Recovered/Not Resolved | | | Dose 2 | 2 | Level 3 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Not Recovered/Not Resolved | | | Dose 3 | 8 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Influenza like illness, Myocarditis | 21 | Male | Recovered/Resolved | Obesity(C) | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 24 | Male | Recovering/Resolving | | | Dose 3 | unknown | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Pericardial effusion, Pericarditis | 19 | Female | Recovered/Resolved | | | Dose 2 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations, Tachycardia | 25 | Male | Recovering/Resolving | Suspected COVID-19(H); Immunodeficiency(H); Immune thrombocytopenia(H) | | Dose 2 | 3 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 33 | Male | Not Recovered/Not Resolved | | | Dose 3 | 10 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 29 | Male | Recovering/Resolving | Tobacco user(H) | | Dose 2 | 1 | Level 2 | Probable | Possible | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Pericarditis | Serious | Pericarditis | 24 | Male | Recovering/Resolving | | | Dose 2 | 125 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Dizziness postural, Dyspnoea, Myocarditis, Palpitations, Tachycardia | 36 | Male | Recovered/Resolved | | MODERNA COVID-19 VACCINE | Dose 2 | 43 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 33 | Male | Unknown | COMIRNATY; COMIRNATY | | Dose 3 | 9 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericardial effusion, Pericarditis | 33 | Female | Not Recovered/Not Resolved | | | Dose 3 | 14 | Level 2 | Unassessable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 31 | Female | Not Recovered/Not Resolved | | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Pericardial effusion, Pericarditis | 31 | Female | Not Recovered/Not Resolved | | | Dose 3 | 13 | Level 2 | Acute Pericarditis | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Paraesthesia, Pericardial effusion | 34 | Female | Not Recovered/Not Resolved | | | Dose 3 | 13 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 21 | Male | Recovered/Resolved | | | Dose 2 | 21 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Pericarditis | Serious | Arthralgia, Blood glucose fluctuation, Blood pressure abnormal, Chest pain, Condition aggravated, Dyspnoea, Dyspnoea at rest, Dyspnoea exertional, Fatigue, Gait disturbance, Hypoaesthesia, Impaired work ability, Menstrual disorder, Muscle twitching, Musculoskeletal chest pain, Neuralgia, Palpitations, Pericarditis, Pyrexia, Skin burning sensation, Syncope, Tachycardia, Temperature regulation disorder, Tinnitus, Tremor, Vein disorder, Vitreous floaters | 33 | Female | Unknown | Seasonal allergy(C); Seasonal allergy; Drug hypersensitivity; Allergy to chemicals | ASPIRIN [ACETYLSALICYLIC ACID]; COLCHICINE; INDOMETHACIN [INDOMETACIN]; PANTOPRAZOLE; VITAMIN D [VITAMIN D NOS]; VITAMIN K2 [MENATETRENONE]; COQ10 [UBIDECARENONE] | Dose 2 | unknown | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Angina pectoris, Chest pain, Myocarditis | 22 | Male | Recovering/Resolving | | | Dose 3 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Asthenia, Fatigue, Heart rate increased, Immune system disorder, Pericarditis | 20 | Male | Not Recovered/Not Resolved | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 23 | Female | Not Recovered/Not Resolved | | | Dose 2 | 69 | Level 4 | Unassessable | Unassessable | |
| | | Literature-Non-Study | Myocarditis | Serious | Myocarditis | 25 | Male | Recovered/Resolved | | | Dose 2 | | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 22 | Male | Recovered/Resolved | | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 31 | Male | Not Recovered/Not Resolved | COVID-19(H); PFIZER BIONTECH COVID-19 VACCINE | | Dose 2 | 6 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Influenza like illness, Pericarditis | 32 | Female | Recovered/Resolved | Silent thyroiditis(H); Polycystic ovaries(H); Gestational diabetes(H); Pericarditis(H) | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 38 | Male | Fatal | Hypertension(C); End stage renal disease(H); Congenital cystic kidney disease(C); Bone fissure(H); Inguinal hernia(H); Peritoneal dialysis; Cranial operation | | Dose 3 | 5 | Level 4 | Unassessable | Unlikely | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Headache, Myocarditis | 21 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Muscular weakness, Myocarditis, Pyrexia | 25 | Male | Recovering/Resolving | | | Dose 2 | 4 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Endocarditis, Heavy menstrual bleeding, Myocarditis | 25 | Female | Recovering/Resolving | SPIKEVAX; SPIKEVAX | [redacted] | Dose 3 | 40 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 29 | Male | Recovering/Resolving | | | Dose 3 | 11 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Recovering/Resolving | COVID-19 immunisation(H); Asthma exercise induced(C) | MONTELUKAST EG | Dose 2 | 80 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericardial effusion, Pericarditis | 40 | Male | Not Recovered/Not Resolved | | | Dose 2 | 11 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 39 | Female | Not Recovered/Not Resolved | | | Dose 3 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 32 | Female | Recovering/Resolving | | | Dose 2 | 89 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis, Tachycardia | 33 | Male | Recovered/Resolved | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 31 | Male | Recovering/Resolving | | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Pericarditis | 19 | Male | Recovering/Resolving | | | Dose 3 | 7 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 12 | Male | Not Recovered/Not Resolved | | | Dose 2 | 2 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 37 | Female | Not Recovered/Not Resolved | | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Cardiac failure chronic, Dyspnoea exertional, Pericarditis, Ventricular tachycardia | 29 | Female | Not Recovered/Not Resolved | SPIKEVAX | | Dose 2 | 84 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 31 | Male | Not Recovered/Not Resolved | | | Dose 3 | 1 | Level 2 | Probable | Conditional | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 37 | Male | Unknown | Comirnaty(H); Comirnaty(H) | | Dose 3 | 21 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 23 | Male | Recovering/Resolving | COVID-19(H); Spikevax(H); Spikevax(H); Tobacco user(C) | | Dose 3 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 40 | Male | Not Recovered/Not Resolved | COMIRNATY; SPIKEVAX | | Dose 3 | 12 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Arrhythmia, Dyspnoea, Myocarditis | 35 | Female | Not Recovered/Not Resolved | | | Dose 2 | 28 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Cardiovascular disorder, COVID-19 immunisation, Impaired work ability, Myocarditis | 19 | Male | Recovering/Resolving | Comirnaty; Comirnaty; Tobacco user(C) | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 38 | Male | Unknown | Muscle atrophy(C); Myocarditis(H) | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Recovering/Resolving | | | Dose 2 | 4 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Arrhythmia, Chest discomfort, Dyspnoea exertional, Myocarditis, Somnolence, Supraventricular extrasystoles | 21 | Male | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Myocarditis | 33 | Male | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 22 | Male | Recovering/Resolving | Comirnaty(H); Comirnaty(H) | | Dose 3 | 4 | Level 3 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 38 | Female | Not Recovered/Not Resolved | | | Dose 3 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 35 | Male | Not Recovered/Not Resolved | COMIRNATY; COMIRNATY | | Dose 3 | 5 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 39 | Male | Not Recovered/Not Resolved | | | Dose 3 | 5 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Pericarditis | Serious | Chest discomfort, Chest pain, Dyspnoea, Fatigue, Pain in extremity, Palpitations, Pericarditis, Tachycardia | 24 | Male | Recovered/Resolved with Sequelae | | | Dose 3 | 1 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 21 | Male | Unknown | SPIKEVAX(H); SPIKEVAX(H) | | Dose 3 | 12 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Pleuropericarditis | Serious | Pleuropericarditis | 34 | Male | Unknown | Hospitalisation; Abdominal pain upper(H) | COLCHICINE | Dose 3 | 349 | Level 3 | Probable | Unlikely | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 27 | Male | Not Recovered/Not Resolved | | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Palpitations, Pericarditis, Tachycardia | 33 | Male | Not Recovered/Not Resolved | Suspected COVID-19(H) | | Dose 3 | 11 | Level 1 | Acute Pericarditis | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 27 | Male | Recovering/Resolving | | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dizziness, Dyspnoea, Feeling abnormal, Myocarditis, Palpitations | 30 | Male | Not Recovered/Not Resolved | | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 16 | Male | Not Recovered/Not Resolved | COMIRNATY(H); COMIRNATY(H) | | Dose 3 | 1 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Asthenia, COVID-19 immunisation, Dyspnoea, Myalgia, Myocarditis, Pleuritic pain, Pyrexia | 29 | Female | Recovering/Resolving | | VAXZEVRIA | Dose 3 | 12 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Cardiovascular disorder, COVID-19 immunisation, Myocarditis | 19 | Male | Recovering/Resolving | COMIRNATY; COMIRNATY | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, COVID-19 immunisation, Fatigue, Myocarditis, Pyrexia | 32 | Male | Recovering/Resolving | | | Dose 3 | 0 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 13 | Male | Not Recovered/Not Resolved | COMIRNATY; COMIRNATY | | Dose 3 | 2 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 20 | Male | Unknown | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Axillary pain, Bedridden, Chest pain, Costochondritis, Discomfort, Dyspnoea, Exercise tolerance decreased, Fatigue, Heart rate increased, Hyperhidrosis, Impaired work ability, Insomnia, Loss of personal independence in daily activities, Lymphadenopathy, Malaise, Musculoskeletal chest pain, Myocarditis, Palpitations, Pericarditis, Swelling | 37 | Female | Not Recovered/Not Resolved | | | Dose 3 | | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 39 | Male | Recovering/Resolving | COVID-19 immunisation(H); COVID-19 immunisation(H) | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Spontaneous | Pericarditis | Serious | Pericarditis, Pregnancy | 30 | Female | Recovering/Resolving | COMIRNATY; COMIRNATY; Pregnancy(C) | | Dose 3 | 2 | Level 2 | Acute Pericarditis | Possible | [redacted] |
| | | Spontaneous | Myocarditis | Serious | Chest pain, Myocarditis, Pyrexia | 25 | Male | Not Recovered/Not Resolved | | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Cardiovascular disorder, COVID-19 immunisation, Myocarditis | 18 | Male | Recovering/Resolving | COMIRNATY; COMIRNATY | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 35 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 21 | Female | Not Recovered/Not Resolved | | | Dose 3 | 24 | Level 1 | Confirmed | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 21 | Female | Recovered/Resolved | | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Tachycardia | 40 | Male | Recovered/Resolved | | | Dose 3 | 11 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Dyspnoea, Fatigue, Myocarditis, Tachycardia | 34 | Male | Not Recovered/Not Resolved | | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Palpitations | 35 | Female | Not Recovered/Not Resolved | | | Dose 3 | 25 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myalgia, Myocarditis | 31 | Female | Recovered/Resolved | | | Dose 3 | 19 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 31 | Male | Not Recovered/Not Resolved | SPIKEVAX; SPIKEVAX | | Dose 3 | 14 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Arthralgia, COVID-19 immunisation, Fatigue, Injection site reaction, Malaise, Myalgia, Pericarditis, Pyrexia | 31 | Female | Recovering/Resolving | COMIRNATY; COMIRNATY | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 39 | Female | Unknown | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Chills, Dyspnoea, Myocarditis, Pyrexia | 21 | Male | Not Recovered/Not Resolved | COMIRNATY; COMIRNATY | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 17 | Female | Recovering/Resolving | Polyarthritis(H); Autoinflammatory disease(H) | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Amenorrhoea, Amnesia, Confusional state, COVID-19 immunisation, Pain in extremity, Paraesthesia, Pericarditis | 40 | Female | Unknown | Barrett's oesophagus(C); Iron deficiency anaemia(C); Autoimmune hypothyroidism(C); BRCA2 gene mutation assay(C); COVID-19(H); Mastectomy | EUTIROX; EUTIROX; COMIRNATY; OVITRELLE; [redacted] FERO GRADUMET | Dose 3 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 32 | Male | Not Recovered/Not Resolved | | VAXZEVRIA; COMIRNATY | Dose 3 | 24 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 36 | Male | Recovered/Resolved | | | Dose 3 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Pericarditis | Serious | Myocarditis, Pericarditis | 19 | Male | Recovering/Resolving | Pulmonary valve stenosis(H); Myopia(C); Intellectual disability(C); Haematuria(H); Meniere's disease(H); Sudden hearing loss(H); COMIRNATY; COMIRNATY | | Dose 3 | 1 | Level 1 | Acute Pericarditis | Probable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Spontaneous | Myocarditis | Serious | Myocarditis | 22 | Male | Unknown | | | Dose 3 | 1 | Level 3 | Probable | Possible | [redacted] |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 31 | Male | Recovering/Resolving | Pleuropericarditis(C) | | Dose 3 | 11 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Headache, Myocarditis, Pain in extremity | 35 | Male | Not Recovered/Not Resolved | | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Recovering/Resolving | Tobacco user(C) | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 26 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 26 | Male | Recovering/Resolving | | | Dose 3 | 50 | Level 1 | Probable | Unlikely | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Chest pain, Myocarditis | 22 | Female | Recovering/Resolving | | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 34 | Male | Recovering/Resolving | | | Dose 3 | 12 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 23 | Male | Recovering/Resolving | COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2 | | Dose 3 | 0 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Cardiovascular disorder, COVID-19 immunisation, Myocarditis, Respiratory disorder, Troponin increased | 18 | Male | Recovering/Resolving | COVID-19(H); COMIRNATY; COMIRNATY; Asthma(C) | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 39 | Male | Recovering/Resolving | | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis, Pericarditis | 18 | Male | Recovered/Resolved | COVID-19(H); Oropharyngeal pain(H) | | Dose 3 | 7 | Level 3 | Probable | Possible | |
| | | Spontaneous | Myocarditis | Serious | Anxiety disorder, Diabetes mellitus, Myocarditis, Thyroiditis subacute | 21 | Female | Recovered/Resolved | COMIRNATY; COMIRNATY; Atopy; Fracture | | Dose 3 | 2 | Level 5 | Not a case | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 30 | Male | Not Recovered/Not Resolved | | | Dose 3 | 15 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Apathy, Arrhythmia, Dyspnoea, Hypoaesthesia, Insomnia, Loss of consciousness, Memory impairment, Monoplegia, Myocarditis | 31 | Female | Not Recovered/Not Resolved | | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Angina pectoris, Chest pain, Myocarditis | 37 | Male | Not Recovered/Not Resolved | | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Fatigue, Myalgia, Myocarditis, Palpitations, Tachycardia | 30 | Male | Not Recovered/Not Resolved | | | Dose 3 | 11 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Acute stress disorder, Myocarditis | 34 | Male | Not Recovered/Not Resolved | COMIRNATY; COMIRNATY | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 25 | Male | Unknown | | | Dose 3 | 1 | Level 2 | Probable | Possible | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 23 | Male | Recovering/Resolving | Underweight(H) | | Dose 3 | 2 | Level 1 | Probable | Conditional | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Arthralgia, Chest pain, Cough, COVID-19 immunisation, Dizziness, Dyspnoea exertional, Headache, Heart rate increased, Malaise, Myocarditis, Pyrexia, Vaccination site oedema | 35 | Female | Not Recovered/Not Resolved | | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Spontaneous | Pericarditis | Serious | Arthralgia, Headache, Pericarditis, Pyrexia | 19 | Male | Unknown | | | Dose 3 | 10 | Level 1 | Acute Pericarditis | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | COVID-19 immunisation, Myocarditis | 20 | Male | Recovering/Resolving | | COMIRNATY | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 27 | Male | Recovering/Resolving | | | Dose 3 | 1 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Chest pain, Myocarditis | 25 | Male | Recovering/Resolving | | | Dose 3 | 16 | Level 5 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Chest pain, Myocarditis | 19 | Male | Recovering/Resolving | | | Dose 3 | 4 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | COVID-19 immunisation, Myocarditis | 25 | Male | Recovered/Resolved | | COMIRNATY | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | COVID-19 immunisation, Myocarditis | 37 | Male | Recovering/Resolving | Tobacco user(C); Hypertension(C); Obesity(C) | COMIRNATY | Dose 3 | 22 | Level 4 | Unassessable | Unlikely | |
| | | Regulatory Authority | Myocarditis | Serious | Bradycardia, Cardiac dysfunction, Dizziness exertional, Dyspnoea, Fatigue, Myocarditis, Palpitations, Pyrexia, Syncope, Tachycardia | 29 | Male | Not Recovered/Not Resolved | Suspected COVID-19(C); TETRACYCLINE(H); DOXYCYCLINE(H); MINOCYCLINE(H); COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA(H) | | Dose 3 | 1 | Level 5 | Unassessable | Unassessable | |
| | | Spontaneous | Pericarditis | Serious | Pericarditis | 20 | Male | Recovering/Resolving | | | Dose 3 | 1 | Level 2 | Acute Pericarditis | Possible | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 29 | Male | Unknown | | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Arthralgia, Chest pain, COVID-19 immunisation, Headache, Heart rate increased, Injection site reaction, Myalgia, Palpitations, Pericarditis, Pyrexia | 25 | Female | Not Recovered/Not Resolved | COVID-19(H); COMIRNATY; COMIRNATY | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 26 | Male | Unknown | | | Dose 3 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 30 | Male | Recovering/Resolving | Nicotine dependence(C) | | Dose 3 | 7 | Level 1 | Acute Pericarditis | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 19 | Male | Not Recovered/Not Resolved | | | Dose 3 | 56 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Palpitations, Pericarditis, Tachycardia | 35 | Female | Recovered/Resolved | | | Dose 3 | 20 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 30 | Male | Recovering/Resolving | | | Dose 3 | 0 | Level 1 | Acute Pericarditis | Possible | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis, Vaccination site pain, Vaccination site swelling | 30 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 2 | Probable | Possible | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis, Pericarditis | 24 | Male | Unknown | | | Dose 3 | 10 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 35 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Spontaneous | Myocarditis | Serious | Myocarditis | 24 | Female | Recovering/Resolving | Comirnaty; Comirnaty | | Dose 3 | 5 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Non Serious | Influenza, Injection site pain, Myocarditis | 30 | Male | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Pain, Palpitations, Pericarditis | 31 | Male | Recovered/Resolved with Sequelae | PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Arrhythmia, Myalgia, Pericarditis | 32 | Male | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 28 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Diarrhoea, Dyspnoea, Fatigue, Headache, Loss of consciousness, Myocarditis, Polyuria, Pyrexia, Syncope, Tachycardia, Thrombosis | 40 | Male | Unknown | INFLUENZA VIRUS; COVID-19 MRNA VACCINE BNT162B2; COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA; Complex regional pain syndrome(C); Epilepsy(C); Deep vein thrombosis(H); Myocardial infarction(H) | EPILIM CHRONO; ETHOSUXIMIDE; SULPHASALAZINE | Dose 4 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 26 | Male | Unknown | | | Dose 2 | 8 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 12 | Male | Not Recovered/Not Resolved | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 30 | Male | Unknown | | | Dose 2 | 21 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis, Pain | 19 | Male | Recovering/Resolving | COMIRNATY; COMIRNATY; COMIRNATY; COMIRNATY | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Pulmonary embolism | 31 | Male | Recovered/Resolved | Comirnaty; Comirnaty | | Dose 3 | 36 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Carditis | Serious | Abdominal discomfort, Abdominal pain upper, Angina pectoris, Autonomic nervous system imbalance, Back pain, Carditis, Chest discomfort, Chest pain, Chills, Cognitive disorder, Dizziness, Dyspnoea, Erythema, Feeling abnormal, Gait disturbance, Head discomfort, Headache, Inner ear inflammation, Lymphadenopathy, Muscular weakness, Nausea, Neck pain, Pain in extremity, Pallor, Palpitations, Peripheral coldness, Presyncope, Sneezing, Spinal pain, Thirst, Throat tightness, Tremor | 31 | Male | Recovered/Resolved with Sequelae | Autonomic nervous system imbalance(C); COVID-19(H) | GARLIC ODOURLESS; VITAMIN D3 | Dose 3 | 5 | Level 5 | Not a case | N/A | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 34 | Male | Recovering/Resolving | | | Dose 3 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | COVID-19 immunisation, Myocarditis | 23 | Male | Recovering/Resolving | COMIRNATY; COMIRNATY | | Dose 3 | 22 | Level 5 | Not a case | N/A | |
| | | Regulatory Authority | Myopericarditis | Serious | Abdominal pain upper, Chest pain, Dizziness, Dyspnoea, Myopericarditis, Palpitations | 29 | Male | Not Recovered/Not Resolved | | PFIZER BIONTECH COVID-19 VACCINE | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Arrhythmia, Chills, Fatigue, Feeling hot, Influenza like illness, Myalgia, Myocarditis, Paraesthesia, Tachycardia | 34 | Male | Unknown | Seasonal allergy; Asthma(C); Depression(C) | PAROXETINE; PANTOPRAZOLE; CORTISONE | Dose 3 | 7 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 24 | Male | Not Recovered/Not Resolved | COMIRNATY; COMIRNATY | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 33 | Male | Unknown | | | Dose 2 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Arthralgia, Axillary mass, Chills, COVID-19 immunisation, Dyspnoea, Extensive swelling of vaccinated limb, Fatigue, Headache, Injection site reaction, Malaise, Myalgia, Myocarditis, Nausea, Palpitations, Pyrexia, Skin disorder, Vomiting | 34 | Male | Recovered/Resolved with Sequelae | COMIRNATY; COMIRNATY | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Chest pain, Fatigue, Myocarditis | 23 | Male | Recovered/Resolved | COMIRNATY; COMIRNATY | | Dose 3 | 22 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Non Serious | Myopericarditis | 33 | Female | Not Recovered/Not Resolved | COVID-19(H) | | Dose 2 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Breast pain, Chest discomfort, Myocarditis, Tachycardia | 32 | Female | Not Recovered/Not Resolved | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Chest pain, Cold sweat, Dyspnoea, Fatigue, Hyperhidrosis, Influenza, Migraine, Myalgia, Myocarditis, Nasal discomfort, Palpitations, Pyrexia, Somnolence, Tachycardia, Throat irritation, Tinnitus | 25 | Male | Recovered/Resolved with Sequelae | | COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2 | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis, Pericarditis, Pulmonary oedema | 21 | Male | Recovering/Resolving | Lung neoplasm malignantFH; Breast cancerFH; COVID-19(H) | | Dose 3 | 1 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 27 | Male | Recovering/Resolving | SPIKEVAX | | Dose 2 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Serious | Myopericarditis, Skin reaction, Urticaria | 34 | Male | Not Recovered/Not Resolved | Hypersensitivity(C) | COVID-19 Vaccine Moderna; COVID-19 Vaccine Moderna | Dose 3 | 27 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 20 | Female | Recovering/Resolving | | | Dose 3 | 3 | Level 3 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Chills, Myocarditis, Nausea, Pyrexia, Vomiting | 21 | Male | Recovering/Resolving | ASTRAZENECA COVID-19 VACCINE; COVID-19 MRNA VACCINE BNT162B2 | | Dose 3 | 2 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Dyspnoea, Myocarditis | 17 | Female | Recovered/Resolved | COVID-19 MRNA VACCINE BNT162B2 | | Dose 2 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 21 | Male | Recovering/Resolving | COVID-19 VACCINE MRNA (BNT162B2); COVID-19 VACCINE MRNA (BNT162B2); Diarrhoea(H) | | Dose 3 | 0 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Feeling cold, Headache, Myocarditis, Pyrexia | 26 | Male | Recovering/Resolving | | | Dose 2 | 4 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Recovering/Resolving | BNT162B2; BNT162B2 | | Dose 3 | 0 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Hepatomegaly, Lung consolidation, Myocarditis | 36 | Male | Not Recovered/Not Resolved | | | Dose 2 | 14 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Dyspnoea, Fatigue, Pericarditis | 20 | Male | Not Recovered/Not Resolved | | | Dose 2 | 0 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Unknown | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 21 | Male | Recovered/Resolved | COVID-19 immunisation(H) | ALVEDON | Dose 2 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 22 | Female | Recovered/Resolved with Sequelae | | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Female | Recovering/Resolving | | | Dose 2 | 4 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Myocarditis | 22 | Male | Recovering/Resolving | | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 18 | Female | Recovering/Resolving | | | Dose 3 | 2 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Chest pain, Cold sweat, Myocarditis, Pyrexia | 22 | Male | Recovering/Resolving | COVID-19 VACCINE MRNA (BNT162B2); COVID-19 VACCINE MRNA (BNT162B2) | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 20 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 26 | Female | Recovering/Resolving | | | Dose 3 | 4 | Level 1 | Probable | Possible | |
| | | Spontaneous | Pericarditis | Serious | Chest pain, Pericarditis | 22 | Male | Unknown | | | Dose 3 | 4 | Level 5 | Not a case | N/A | |
| | | Regulatory Authority | Myocarditis | Serious | Abdominal discomfort, Cardiac discomfort, Influenza, Myocarditis | 32 | Male | Unknown | PFIZER BIONTECH COVID-19 VACCINE(H); PFIZER BIONTECH COVID-19 VACCINE(H) | | Dose 3 | 1 | Level 1 | Probable | Unlikely | |
| | | Regulatory Authority | Myopericarditis | Non Serious | Erythema, Myopericarditis, Pruritus, Skin reaction | 30 | Male | Not Recovered/Not Resolved | SPIKEVAX | | Dose 2 | 91 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Fatigue, Myocarditis, Pericarditis | 32 | Female | Not Recovered/Not Resolved | Suspected COVID-19(H) | | Dose 3 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Chest pain, Myocarditis | 27 | Female | Recovered/Resolved | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 25 | Male | Recovering/Resolving | Obesity(C) | | Dose 2 | 151 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | COVID-19 immunisation, Dyspnoea, Myocarditis | 33 | Male | Not Recovered/Not Resolved | COVID-19 immunisation; Irritable bowel syndrome(C); COVID-19 immunisation | | Dose 3 | 28 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest discomfort, Dyspnoea, Fatigue, Myocarditis | 29 | Male | Not Recovered/Not Resolved | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 20 | Male | Recovering/Resolving | Viral myocarditis(H); COMIRNATY; COMIRNATY | | Dose 3 | 3 | Level 1 | Confirmed | Possible | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 21 | Male | Unknown | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 21 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 1 | Probable | Possible | |
| | | Spontaneous | Myocarditis | Serious | Cardio-respiratory arrest, Headache, Loss of consciousness, Malaise, Myocarditis, Pyrexia, Ventricular fibrillation | 37 | Male | Fatal | Seasonal allergy | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 39 | Female | Not Recovered/Not Resolved | MODERNA COVID-19 VACCINE | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Spontaneous | Myocarditis | Serious | Chest pain, Myocarditis | 18 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 2 | Probable | Possible | [redacted] |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 20 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 2 | Probable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Recovering/Resolving | | | Dose 3 | 1 | Level 2 | Probable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Pyrexia | 20 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 40 | Male | Recovering/Resolving | | | Dose 3 | 5 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 32 | Male | Recovering/Resolving | Hypertension(C); Dyslipidaemia(C); Dermatitis atopic(H); Rhinitis allergic | | Dose 3 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Fatigue, Myocarditis, Pyrexia | 38 | Female | Recovering/Resolving | Colitis ulcerative(H); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE; MESALAZINE(H) | | Dose 3 | 5 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | COVID-19 immunisation, Myocarditis | 23 | Male | Not Recovered/Not Resolved | | COMIRNATY | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Pericarditis | Serious | Interchange of vaccine products, Pericarditis | 35 | Female | Not Recovered/Not Resolved | Rhinitis(C); Seasonal allergy; Asthma(C); Drug hypersensitivity; Drug hypersensitivity; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; COVID-19(H) | BELLOZAL | Dose 3 | 65 | Level 4 | Unassessable | Unlikely | |
| | | Regulatory Authority | Myocarditis | Serious | Arrhythmia, Chest pain, Myocarditis | 27 | Male | Recovered/Resolved with Sequelae | | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Dyspnoea, Myocarditis, Palpitations, Somnolence | 40 | Male | Not Recovered/Not Resolved | Autoimmune pancreatitis(H) | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis, Pyrexia | 12 | Male | Recovering/Resolving | PFIZER BIONTECH COVID-19 VACCINE | | Dose 2 | 2 | Level 4 | Unassessable | Conditional | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 25 | Male | Recovering/Resolving | | | Dose 3 | 12 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 20 | Male | Recovering/Resolving | PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Arrhythmia(H) | | Dose 3 | 1 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 25 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations | 20 | Male | Recovering/Resolving | Acne(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE | ADAPALENE; DOXYCYCLINE; BENZOYL PEROXIDE | Dose 3 | 1 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Pericarditis | Serious | Pain in extremity, Pericarditis | 38 | Male | Not Recovered/Not Resolved | Psychiatric investigation(H); Tobacco user(H) | COVID-19 VACCINE JANSSEN | Dose 2 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Circulatory collapse, Myocarditis, Ventricular fibrillation | 22 | Male | Not Recovered/Not Resolved | | | Dose 3 | 1 | Level 1 | Confirmed | Possible | |
| | | Spontaneous | Myocarditis | Serious | Bundle branch block right, Myocarditis | 21 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Pyrexia | 29 | Unknown | Unknown | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocardial necrosis marker increased, Myocarditis | 24 | Unknown | Unknown | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 19 | Male | Recovered/Resolved | Mitral valve prolapse(H) | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 25 | Male | Recovering/Resolving | | | Dose 3 | 4 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 20 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Non Serious | Pericarditis | 30 | Female | Recovering/Resolving | Von Willebrand's disease(H); COVID-19(H); Pericarditis(H) | COMIRNATY | Dose 2 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 27 | Female | Not Recovered/Not Resolved | Chest discomfort(H) | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 18 | Male | Not Recovered/Not Resolved | COMIRNATY; COMIRNATY | | Dose 3 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Dyspnoea, General physical health deterioration, Mitral valve prolapse, Myocarditis, Pyrexia, Vomiting | 40 | Male | Unknown | | | Dose 3 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Literature-Non-Study | Myocarditis | Serious | Myocarditis | 17 | Male | Recovered/Resolved | | | Dose 2 | 3 | Level 1 | Confirmed | Possible | |
| | | Regulatory Authority | Myopericarditis | Serious | Myopericarditis | 16 | Male | Not Recovered/Not Resolved | | | Dose 3 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 27 | Male | Recovering/Resolving | COVID-19 immunisation(H) | | Dose 2 | 77 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Recovered/Resolved | COVID-19(H); Colitis ulcerative(C); COVID-19 immunisation(H) | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 19 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 30 | Male | Recovering/Resolving | | | Dose 2 | 371 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Serious | Myopericarditis | 35 | Male | Recovered/Resolved with Sequelae | | | Dose 2 | 1 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Not Recovered/Not Resolved | | | Dose 2 | 190 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 35 | Male | Recovered/Resolved with Sequelae | | | Dose 2 | 84 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 21 | Male | Recovered/Resolved | | | Dose 2 | 117 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Serious | Myopericarditis | 21 | Male | Recovering/Resolving | Tobacco user(C) | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 31 | Female | Not Recovered/Not Resolved | | | Dose 2 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Arrhythmia, Myocarditis | 40 | Female | Recovered/Resolved | | | Dose 2 | 34 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 23 | Male | Not Recovered/Not Resolved | | | Dose 2 | 2 | Level 1 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 31 | Male | Recovered/Resolved | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Recovering/Resolving | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Myocarditis | 24 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 26 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Cardiac discomfort, Chest discomfort, Myocarditis | 32 | Male | Unknown | | | Dose 2 | 26 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | COVID-19 immunisation, Pericarditis, Pneumonia | 38 | Male | Not Recovered/Not Resolved | COMIRNATY | | Dose 2 | 119 | Level 4 | Unassessable | Unlikely | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 24 | Male | Recovered/Resolved | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 29 | Male | Recovering/Resolving | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 20 | Female | Recovering/Resolving | COVID-19 immunisation(H); Myocarditis(C) | FLUOXETINE EG | Dose 2 | 50 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 32 | Female | Recovering/Resolving | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 29 | Male | Recovering/Resolving | | | Dose 2 | 27 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 38 | Male | Recovering/Resolving | Migraine(H); Psoriasis(H) | | Dose 2 | 10 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Serious | Myopericarditis | 17 | Male | Not Recovered/Not Resolved | | | Dose 2 | 4 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Cardiovascular disorder, Fatigue, Hot flush, Hyperhidrosis, Hypotension, Myocarditis, Tremor | 24 | Female | Not Recovered/Not Resolved | Mite allergy; Allergy to arthropod sting; Seasonal allergy | | Dose 2 | 1 | Level 4 | Unassessable | Unlikely | |
| | | Regulatory Authority | Pericarditis | Serious | Chest pain, Costochondritis, Dyspnoea, Fatigue, Palpitations, Pericarditis | 32 | Male | Recovered/Resolved with Sequelae | Gastroocsophageal reflux disease(H) | LANSOPRAZOLE | Dose 2 | 3 | Level 4 | Unassessable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 26 | Male | Recovering/Resolving | COVID-19 immunisation(H) | | Dose 2 | 144 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Serious | Myopericarditis | 31 | Male | Not Recovered/Not Resolved | Myocarditis(H); Tobacco user(C) | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Serious | Myopericarditis | 25 | Male | Recovering/Resolving | | | Dose 2 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Abdominal pain upper, Chest discomfort, Chest pain, Dyspnoea, Fatigue, Menstruation irregular, Pericarditis | 36 | Female | Recovered/Resolved with Sequelae | Contraceptive implant | | Dose 2 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Abdominal pain, Muscular weakness, Myocarditis | 22 | Male | Not Recovered/Not Resolved | Tobacco user(H) | | Dose 2 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Immunisation reaction, Pericarditis, Swelling | 16 | Male | Recovered/Resolved | | | Dose 2 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 29 | Female | Recovered/Resolved | Asthma(C) | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 22 | Male | Recovering/Resolving | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Exercise tolerance decreased, Myocarditis, Pyrexia | 19 | Female | Recovering/Resolving | | | Dose 2 | 197 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Arrhythmia, Pericarditis | 27 | Male | Not Recovered/Not Resolved | | | Dose 2 | 14 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Serious | Myopericarditis | 39 | Male | Unknown | | | Dose 2 | 5 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Regulatory Authority | Myocarditis | Serious | Myocarditis | 21 | Male | Recovered/Resolved | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | [redacted] |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 32 | Female | Not Recovered/Not Resolved | Raynaud's phenomenon(H) | | Dose 2 | 38 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 31 | Male | Recovering/Resolving | COVID-19(H) | | Dose 2 | 16 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis, Pyrexia | 24 | Male | Recovering/Resolving | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myopericarditis | Non Serious | Influenza like illness, Myopericarditis | 33 | Female | Recovering/Resolving | Myopericarditis(H) | | Dose 2 | 17 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 35 | Male | Recovering/Resolving | | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Asthma, Choking, Lymphadenitis, Lymphadenopathy, Myocarditis, Odynophagia | 28 | Male | Recovering/Resolving | MODERNA COVID-19 VACCINE | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Non Serious | Pericarditis | 37 | Female | Not Recovered/Not Resolved | | | Dose 2 | 130 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Chest pain, Myocarditis | 19 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Decreased appetite, Dizziness, Dyspepsia, Dyspnoea, Malaise, Myalgia, Myocarditis, Paraesthesia, Splenomegaly, Tachycardia | 27 | Male | Recovering/Resolving | | | Dose 2 | 7 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Chills, Dyspnoea, Headache, Heart rate increased, Myalgia, Pericarditis | 33 | Male | Unknown | | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Cardiac discomfort, Cardiomyopathy, Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations, Syncope, Tachycardia | 21 | Male | Not Recovered/Not Resolved | Suspected COVID-19(H) | | Dose 2 | 2 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 38 | Female | Recovering/Resolving | Drug hypersensitivity; Tobacco user(C) | | Dose 2 | 31 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Pericarditis | 32 | Male | Recovering/Resolving | Seasonal allergy | | Dose 2 | 84 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Acute kidney injury, Atrioventricular block complete, Chills, Headache, Hypersensitivity, Inappropriate schedule of product administration, Myocarditis, Pulmonary embolism, Pyrexia | 22 | Male | Recovering/Resolving | | | Dose 2 | 66 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Pericarditis | Serious | Neck pain, Pericarditis | 38 | Female | Recovered/Resolved | | | Dose 2 | 16 | Level 4 | Unassessable | Unlikely | |
| | | Regulatory Authority | Myocarditis | Serious | Chills, Myocarditis, Pyrexia | 21 | Female | Recovered/Resolved | COVID-19(H); Seasonal allergy | | Dose 2 | 3 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 33 | Male | Recovering/Resolving | | | Dose 2 | 5 | Level 4 | Unassessable | Unassessable | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 23 | Male | Recovering/Resolving | | | Dose 2 | 2 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Anaemia, Chest discomfort, Dizziness, Heart rate increased, Myocarditis | 40 | Female | Not Recovered/Not Resolved | Abstains from alcohol(C); SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE(H) | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 29 | Male | Recovering/Resolving | COVID-19 immunisation; Pneumothorax(H) | | Dose 2 | 30 | Level 4 | Unassessable | Unassessable | |

| Case ID | Country | Report Type | PT | Event Seriousness | ALL PTs | Age | Gender | Event Outcome | Medical History | Concomitant Medications | Dose # | TTO | Brighton | CDC | WHO | WW Identifier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [redacted] | [redacted] | Spontaneous | Myocarditis | Serious | Myocarditis | 21 | Male | Recovering/Resolving | COMIRNATY; COMIRNATY | | Dose 3 | 2 | Level 2 | Probable | Possible | [redacted] |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 36 | Male | Recovering/Resolving | | | Dose 3 | 4 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 21 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Myocarditis | Non Serious | Myocarditis | 22 | Male | Recovering/Resolving | | | Dose 3 | 0 | Level 4 | Unassessable | Unassessable | |
| | | Regulatory Authority | Myocarditis | Serious | Myocarditis | 18 | Male | Recovering/Resolving | | | Dose 2 | 3 | Level 2 | Probable | Possible | |
| | | Regulatory Authority | Pericarditis | Non Serious | Pericarditis | 21 | Male | Recovering/Resolving | | | Dose 3 | 2 | Level 2 | Probable | Possible | |
| | | Spontaneous | Myocarditis | Serious | Myocarditis | 18 | Male | Recovering/Resolving | | | Dose 3 | 3 | Level 2 | Probable | Possible | |
| | | Spontaneous | Myocarditis | Serious | Chronic fatigue syndrome, Condition aggravated, Dizziness, Gait disturbance, Impaired work ability, Loss of consciousness, Myocarditis, Respiratory distress, Thrombosis | 36 | Male | Not Recovered/Not Resolved | Non-tobacco user(C) | IBUPROFEN; PANTOPRAZOLE | Dose 2 | 84 | Level 2 | Probable | Possible | |

## Appendix 11.5b Myocarditis/Pericarditis: Patients < 40 years of age after Dose 2 and Dose 3: Case Narratives

| Case ID | Narrative | MAH Comment | WW Identifier |
|---|---|---|---|
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted], on 02-Jan-2022. The most recent information was received on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest Pain), PYREXIA (Fever) and PAIN IN EXTREMITY (Pain in arm) in a 24-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>Concurrent medical conditions included Asthma (Since childhood. well controlled, takes no inhalers).<br><br>On 27-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced PYREXIA (Fever) (seriousness criteria hospitalization and medically significant). On 29-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest Pain) (seriousness criteria hospitalization and medically significant). 29-Dec-2021, the patient experienced PAIN IN EXTREMITY (Pain in arm) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving and CHEST PAIN (Chest Pain), PYREXIA (Fever) and PAIN IN EXTREMITY (Pain in arm) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 30-Dec-2021, Blood creatinine: 70 70.<br>On 30-Dec-2021, Blood potassium: 4.2 4.2.<br>On 30-Dec-2021, Blood sodium: 138 138.<br>On 30-Dec-2021, Blood urea: 5.8 5.8.<br>On 30-Dec-2021, Full blood count: wcc 7.26 WCC 7.26.<br>On 30-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On 30-Dec-2021, Troponin: 6324, 8650 (High) 6324, 8650 and serial values - 8650 ng/l (High) 8650 ng/L.<br>On an unknown date, Chest X-ray: normal (normal) Normal.<br>On an unknown date, Ejection fraction (55-77): 55% (normal) 55%.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Widespread concave ST changes in keeping with pericarditis.<br>On an unknown date, Left ventricular end-diastolic pressure: 209 ml 209 ml.<br>On an unknown date, Magnetic resonance imaging heart: inconclusive (Inconclusive) Results not provided.<br>On an unknown date, Stroke volume (82-154): 114 ml (normal) 114 ml.<br>On an unknown date, Troponin: serial values - 6324ng/l (High) 6324 ng/L.<br>On an unknown date, Ventricular internal diameter (68-112): 114 ml/m2 (abnormal) 114 ml/m2 and 52 ml/m2 (abnormal) 52 ml/m2.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. | 24 years old male with medical history of asthma as a child, well control, and unknown concomitant medications, who had two doses of Cominarty as primary series vaccination for COVID-19, and who experienced fever next day after the 3rd dose of Spikevax. The following day the patient experienced chest pain and pain in his arm. Patient was hospitalized and was diagnosed with myopericarditis. Laboratory and diagnostic imaging results showed elevated creatinine, elevated WBC, elevated Troponin, abnormal EKG, abnormal cMRI (Myocardial oedema and late gadolinium enhancement pattern). SARS-CoV-2 test was negative. Nonsteroidal anti-inflammatory treatment was administered, however, as they caused him to vomit, they were changed to colchicine. Patient was admitted for 3 days. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and cMRI results; a causal relationship cannot be excluded. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
|---|---|---|---|
| | For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient has not tested positive for COVID-19 since having the vaccine.<br>Patient is not enrolled in clinical trial.<br>The report of the patient related to possible myocarditis or pericarditis. The patient was admitted to hospital and was hospitalized for 3 days. The patient was seen by a cardiologist and was diagnosed with Myo-pericarditis.<br><br>Patient received 1st and 2nd dose of Pfizer dates not provided.<br>Re-challenge was reported as unknown.<br>Company comment:<br>This regulatory case concerns a 24-year-old, male patient with no relevant medical history, who experienced the unexpected, serious (Hospitalization/Medically significant) events of chest pain, pyrexia, pain in extremity and expected, serious (Hospitalization/Medically significant) and AESI of myocarditis. The patient developed pyrexia 1 day after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient COVID-19 vaccination schedule. Evolved with pain in extremity and chest pain. Cardiac magnetic resonance evidenced Myocardial oedema and late gadolinium enhancement pattern consistent with myocarditis and Troponin result was 8650ng/l, the diagnosis was myo-pericarditis, for what he was admitted for 3 days to the hospital. Nonsteroidal anti-inflammatory treatment was administered, however, as they caused him to vomit, they were changed to colchicine. The patient received as first and second dose of his COVID-19 vaccination schedule two doses Pfizer's COVID-19 vaccine.<br>The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 11-Jan-2022: Significant follow up received on 11-Jan-2022. Relevant lab details were added. Start date of event 'fever' was added. Medical history added. | | |
| [redacted] | This case was initially received via [redacted] (Reference number [redacted] on 02-Jan-2022. The most recent information was received on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations), CHEST DISCOMFORT (Chest discomfort), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 32-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>The patient's past medical history included Cough and Cold symptoms.<br>Concomitant products included TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for an unknown indication. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 16-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 20-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant) and CHEST DISCOMFORT (Chest discomfort) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations) and CHEST DISCOMFORT (Chest discomfort) outcome was unknown and MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>Patient experienced Chest pain and heart palpitations.<br>Patient was ill 2-3 weeks before booster (heavy cold symptoms with cough) but had tested negative for covid on both PCR and multiple LTF tests. patient had booster Thursday 16th Dec and did not really have any side effects the day after. She ran 5000 on 19th Dec (patient run often so this was not new or overly strenuous exercise for her) and then the following day or so started experiencing discomfort in my chest which was like a heavy pushing sensation in the centre and to the left of my chest.<br>Patient had not tested positive for COVID-19 since having the vaccine. Patient hadno symptoms associated with COVID-19 .Patient is not pregnant, Patient is not currently breastfeeding<br>Patient reported that his report relates to possible inflammation of the heart (myocarditis or pericarditis).<br>Patient would be having an chest X-ray, echocardiogram, cardiac MRI, chest computerised tomography (CT) and other tests in the next few days. Patient reported that symptoms do not lead to a hospital stay. And her diagnosis was made by a medical professional. And the healthcare professional had mentioned the specific details of the diagnosis as an unnamed surgery.<br>Patient had been booked in for ECG and other tests.<br>No treatment information was provided.<br><br>Company comment: This regulatory authority case concerns a 32-year-old female patient, with no medical history reported, who experienced the serious (medically significant) expected AESI of MYOCARDITIS and PERICARDITIS. The events occurred on an unknown date after receiving a booster dose of mNRA-1273. Patient previous vaccination schedule included two doses of Tozinameran. According to source document narrative, patient started experiencing chest discomfort after vaccination with mRNA-1273. Patient states that the reports relate to | | |

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| | possible inflammation of the heart (myocarditis or pericarditis), but no investigations or tests have been conducted at the time of the rep<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Jan-2022: Follow up received contain significant information. Medical history , Action taken, Concomitant product details, New event chest discomfort added. Deleted event verbatim cold symptoms. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 02-Jan-2022. The most recent information was received on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myocarditis), FATIGUE (Fatigue), CHEST PAIN (Chest Pain) and PERICARDITIS (Pericarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>The patient's past medical history included Alcohol use (social).<br>Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 25-Jun-2021 to 08-Aug-2021 and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 25-Jun-2021 to an unknown date for COVID-19 vaccination.<br><br>On 20-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 20-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 22-Dec-2021, the patient experienced CHEST PAIN (Chest Pain) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). On 24-Dec-2021, CHEST PAIN (Chest Pain) outcome was unknown. At the time of the report, MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) was resolving and FATIGUE (Fatigue) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 22-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On 23-Dec-2021, Angiocardiogram: normal NAD.<br>On 24-Dec-2021, C-reactive protein: 16 16.<br>On 24-Dec-2021, Full blood count: 7.4 NAD, WCC 7.4.<br>On 24-Dec-2021, Urine electrolytes: egfr >90 (normal) NO abnormality detected Egfr >90.<br>On an unknown date, Blood creatine phosphokinase: 269 269.<br>On an unknown date, Echocardiogram: results not reported Results not reported and Impression of systolic lv function - normal no significant valve abnormalities pericardium at the lv posterior wall appears echogenic and mildly thickened no significant lv diastolic dysfunction.<br>On an unknown date, Electrocardiogram: results not reported Results not reported.<br>On an unknown date, Troponin: 4065 4065 and 3045 3045. | 19-year-old male patient with no reported medical history and who completed primary vaccination with COVID 19 Pfizer vaccine and 2 days after the 3 rd dose of Spikevax experienced Fatigue, right sided chest pain, throbbing in nature with occasional sharp pain, not pleuritic in nature with no radiation into arms or neck and was hospitalized for four days. Laboratory results showed high troponin, Echocardiogram showed pericardium at the lv posterior wall echogenic and mildly thickened with no significant lv diastolic dysfunction and no other abnormalities. There were no signs of heart failure or arrhythmia. No abnormalities were detected on angiogram. ECG was done, results were not provided. Treatment medications included Colchicine at a dose of 500 micrograms daily for 6 weeks. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded. | [redacted] |

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| | For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient presented on the 22-Dec-2021 at ED with right sided chest pain since 06:00, throbbing in nature, occasional sharp pains, not pleuritic in nature, no radiation into arms or neck. No dyspnoea, no fevers, Patient had COVID booster.<br><br>Past medical history: Nil, no FHx of ischemic heart disease (IHD).<br>Non-smoker and social alcohol drinker, no recreational drug use.<br><br>Patient was diagnosed with post covid vaccine myocarditis.<br><br>Patient has not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. Patient had not had any symptoms associated with COVID-19.<br>It was reported that MRI was not performed.<br><br>Company comment: This regulatory authority case concerns a 19-year-old male patient with no relevant medical history and no family history of ischemic heart disease; who experienced events of Fatigue, Chest pain, Myocarditis (AESI) and Pericarditis (AESI) (seriousness criteria hospitalization and medically significant). It was reported that two days after the third dose of mRNA-1273 vaccine, the patient presented to the ED with right sided chest pain, throbbing in nature with occasional sharp pain, not pleuritic in nature with no radiation into arms or neck and was hospitalized for four days. Laboratory results showed high troponin with the peak troponin value of 4065. Echocardiogram showed pericardium at the lv posterior wall echogenic and mildly thickened with no significant lv diastolic dysfunction and no other abnormalities. There were no signs of heart failure or arrhythmia. No abnormalities were detected on angiogram. ECG was done, results were not provided. Treatment medications included Colchicine at a dose of 500 micrograms daily for 6 weeks. At the time of the report Myocarditis and Pericarditis were resolving. Patient completed primary vaccination with COVID.19 Pfizer vaccine on 25-Jun-2021 and on 08-Aug-2021. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 11-Jan-2022: Follow-up document received contain lab data added. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 03-Jan-2022 and was forwarded to Moderna on 03-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214017 and 3004234) for COVID-19 vaccination.<br><br>The patient's past medical history included Ectopic testis. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On 06-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 27-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 06-Dec-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Acute myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 09-Aug-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medication of the patient was not reported.<br>No treatment information was provided by the reporter.<br><br>Company Comment - This regulatory authority case concerns a 20 year old male patient with no relevant medical history, who experienced the serious (hospitalization) expected event of myocarditis. The event occurred approximately 3 months after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 03-Jan-2022 and was forwarded to Moderna on 03-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of DIZZINESS (dizziness) and MYOCARDITIS (myocardium inflammation) in a 29-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Diabetes mellitus.<br><br>On 28-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Jul-2021, the patient experienced DIZZINESS (dizziness) (seriousness criterion medically significant). On 02-Oct-2021, the patient experienced MYOCARDITIS (myocardium inflammation) (seriousness criterion medically significant). At the time of the report, DIZZINESS (dizziness) and MYOCARDITIS (myocardium inflammation) was resolving.<br><br>No allergies known Information on risk factors or pre-existing conditions Diabetes, Syrix/ cold symptoms in summer, but severe dizziness and shortness of breath in late summer, quickly out | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | of breath. At routine check made ECG and irregularities detected by doctor. clarification was carried out by a cardiologist. He found a decaying myocarditis and suspects vaccination as the cause. No further, worthy of treatment, declining. But booster vaccination is not recommended at the moment.<br><br>This case concerns a 29-year-old male patient with no relevant medical history, who experienced the unexpected serious events of Dizziness, and adverse event of special interest, Myocarditis, all events were reported as medically significant by the regulatory authority. The event of Dizziness occurred approximately 2 months after receiving the second dose of mRNA-1273 Vaccine the event Myocarditis occurred approximately 5 months later. The rechallenge was reported as not applicable by the regulatory authority. No clinical or treatment details were given. It was reported that the outcome of the events was resolving. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 03-Jan-2022 and was forwarded to Moderna on 03-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003610) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: Moderna vaccine (Left arm, Intramuscular injection and Lot N :3002184) on 20-May-2021.<br>Past adverse reactions to the above products included No adverse event with Moderna vaccine.<br><br>On 28-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 15-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 17-Aug-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant product was provided.<br>No treatment information was provided.<br><br>Company Comment - This regulatory authority case concerns a 24 year old male patient with no relevant medical history, who experienced the serious (hospitalization) expected event of myocarditis. The event occurred 48 days after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| [redacted] | This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (peri-myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>LITERATURE REFERENCE:<br>McCullough J, McCullough JP, Korlipara G, Kaell A. Myocarditis post moderna vaccination: review of criteria for diagnosis. Cureus. 2021;13(11):e19633<br><br>Concurrent medical conditions included Exercise induced asthma.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (peri-myocarditis) (seriousness criteria hospitalization and medically significant), CHILLS (chills) and PYREXIA (Fever). The patient was hospitalized for 3 days due to MYOCARDITIS. The patient was treated with ACETYLSALICYLIC ACID for Perimyocarditis, at a dose of 325 milligram once a day; INDOMETHACIN SODIUM for Perimyocarditis, at a dose of 50 milligram twice a day and COLCHICINE for Perimyocarditis, at a dose of .6 milligram once a day. At the time of the report, MYOCARDITIS (peri-myocarditis), CHILLS (chills) and PYREXIA (Fever) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Angiogram: negative for pulmonary embolism CT angiography (CTA) of the chest was negative for pulmonary embolism (PE).<br>On an unknown date, Antinuclear antibody: negative (Negative) negative.<br>On an unknown date, Blood thyroid stimulating hormone: normal (normal) normal.<br>On an unknown date, C-reactive protein: 11.6mg/l (High) 11.6mg/L Normal less than 4.0mg/L.<br>On an unknown date, Echocardiogram: abnormal Transthoracic echo (TTE) revealed abnormal motion and increased thickening of the septal wall with preserved ejection fraction (EF) of 65% and normal diastolic function. Trace pericardial effusion was also noted. and resolution At his 60-day follow-up visit, TTE confirmed resolution of the wall motion abnormality and pericardial effusion and he remains completely symptom free at 128 days.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Initial electrocardiogram (ECG) showed right axis deviation with left posterior fascicular block without any ST elevations as well as premature atrial contractions (PACs) in trigeminy and normal (normal) normalization of ECG was demonstrated within two weeks during follow up.<br>On an unknown date, Neutrophil count: 8.09 k/ul 8.09 K/uL.<br>On an unknown date, Physical examination: normal (normal) On physical examination the patient was in no distress, with normal vital signs, normal S1/S2 heart sounds without any murmurs, rubs, or gallops and no jugular vein distention (JVD). There was no palpable tenderness of the chest wall. The lungs were clear to auscultation. There was no pitting edema in the lower extremities..<br>On an unknown date, Red blood cell sedimentation rate (0-15): 37mm/hr (High) 37mm/hr.<br>On an unknown date, Respiratory viral panel: negative (Negative) negative. | Literature report for a 23-year-old Caucasian male with a history of exercise-induced asthma presented to the emergency department complaining of left-sided chest pain which started two days after receiving the second dose Spikevax. The patient described the pain as sharp, intermittent with radiation to the left upper back and left arm with 10/10 severity and worsening with deep inspiration. Fever and chills were also present. Patient was in no distress, normal vital signs, no rubs, lungs normal, laboratory results showed elevated troponin, abnorla ECG with right axis deviation with left posterior fascicular block without any ST elevations as well as premature atrial contractions (PACs) in trigeminy. Abnormal echo showed traced pericardial effusion. No pulmonary embolism. Leukocytosis, elevated ESR, elevated CSR, positive for [redacted] Transthoracic echo (TTE) revealed abnormal motion and increased thickening of the septal wall with preserved ejection fraction (EF) of 65% and normal diastolic function. Patient was diagnosed with myopericarditis. cMRI was not done since the patient had clinically improved within 48 hrs. He received aspirin 325 mg once followed by indomethacin 50mg twice a day and discharged on day three to complete a total of two weeks indomethacin and three months of colchicine 0.6mg daily. Complete resolution of his symptoms, normalization of troponins and ECG, was demonstrated within two weeks during follow up. At his 60-day follow-up visit, TTE confirmed resolution of the wall motion abnormality and pericardial effusion and he remains completely symptom free at 128 days. According to the WHO causality assessment this report is considered probable. | [redacted] |

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| | On an unknown date, Serology test: negative (Negative) negative.<br>On an unknown date, Toxicologic test: positive for recreational marijuana Urine toxicology was positive for recreational marijuana drug use but negative for cocaine use..<br>On an unknown date, Troponin T (Unknown-<22ng/l): 475ng/l, peak of 910ng/l (abnormal) Diagnostic testing revealed elevated troponin T of 475ng/L (<22ng/L) which trended upward reaching a peak of 910ng/L (<22ng/L). and normal (normal) normalization of troponins was demonstrated within two weeks during follow up.<br>On an unknown date, Ultrasound scan: pericardial effusion A bedside ultrasound showed trace pericardial effusion..<br>On an unknown date, White blood cell count (3.8-10.5): 11.09 k/ul (High) 11.09 K/ul.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MYOCARDITIS (peri-myocarditis), CHILLS (chills) and PYREXIA (Fever) to be related.<br><br>Patient presented to the emergency department complaining of left-sided chest pain which started two days after receiving the second dose of the mRNA-1273 Moderna vaccine. The patient described the pain as sharp, intermittent with radiation to the left upper back and left arm with 10/10 severity and worsening with deep inspiration. Fever and chills were also present. The patient did not report any recent history of tick bites, upper respiratory symptoms, paroxysmal nocturnal dyspnea (PND), orthopnea, arthralgias or rashes.<br><br>Based on the patient's clinical presentation, ECG, cardiac markers and TTE findings a presumptive diagnosis of peri-myocarditis was made.<br><br>Authors did not pursue cardiac MRI since the patient had clinically improved within 48 hrs.<br><br>Company comment:<br>This case concerns a 23-year-old male patient with no medical history provided who experienced serious expected event of special interest Myocarditis. As per SD, the event occurred several days after the second dose of mRNA-1273. At the time of the report, the event resolved. It was reported that follow-up at 128 days revealed no residual sequelae. No further information was provided. No information regarding laboratory nor diagnostic tests was provided. The Reporter assessed the event as related to the suspect product. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 06-Jan-2022: Follow up received by safety 06-Jan-2022 included an Email with [redacted] received from [redacted] team and contains significant information. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Jan-2022 and was forwarded to Moderna on 04-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (NA) in a 25-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No Medical History information was reported.<br><br>On 08-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (NA) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (NA) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br><br>No treatment medications were reported.<br><br>Company comment: This is a regulatory case concerning a 25-year-old male patient with no medical history reported who experienced the AESI pericarditis. The event occurred on an unknown day after a second dose of mRNA-1273 vaccine was administered. No further details were reported. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 04-Jan-2022 and was forwarded to Moderna on 04-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis), COVID-19 (SARS-CoV-2 infection), LIMB INJURY (Arm injury), LOWER RESPIRATORY TRACT INFECTION (Chest infection) and LYMPHADENOPATHY (Swollen glands) in a 36-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000050a) for COVID-19 vaccination.<br><br>Patient has not had symptoms associated with COVID-19.<br><br>On 30-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 30-Dec-2021, the patient experienced LIMB INJURY (Arm injury). On 31-Dec-2021, the patient experienced LYMPHADENOPATHY (Swollen glands). On 02-Jan-2022, the patient experienced LOWER RESPIRATORY TRACT INFECTION (Chest infection). On 03-Jan-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced COVID-19 (SARS-CoV-2 infection). On an unknown date, the patient experienced MYOCARDITIS (myocarditis). At the time of the report, MYOCARDITIS (myocarditis), COVID-19 (SARS-CoV-2 infection), LIMB INJURY (Arm injury) and LOWER RESPIRATORY TRACT INFECTION (Chest infection) had not resolved and LYMPHADENOPATHY (Swollen glands) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-Jan-2022, SARS-CoV-2 test: yes - positive covid-19 test and positive (Positive) Positive. | Patient diagnosed with COVID-19 5 days after the 3rd dose of Spikevax and with myocarditis at an unknown date after his positive SARS-CoV-2 test | [redacted] |

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| | The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br>Concomitant product usage were not provided.<br>Treatment details were not provided.<br><br>Patient was not enrolled in clinical trial. Patient had no symptoms associated with COVID-19.<br><br>Company Comment: This case concerns a 36 year-old male patient with no reported medical history who experienced the unexpected adverse event of special interest of COVID-19 which occurred 5 days after the third dose and myocarditis which occurred on an unknown date relative to vaccination with mRNA-1273 vaccine administered as a booster third dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Jan-2022: Follow up received with non significant information. | | |
| [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of HAEMOPTYSIS (Coughing up some blood in his mucus) and PERICARDITIS (Heart was bumping/nausea/felt like heart was beating 1000 beats a minute/felt like it was going to beat out ofhis chest, and he was going to die/phone feels heavy to hold/wakes up with pain/diagnosed pericarditis) in a 29-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 071S21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 17-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Nov-2021, the patient experienced HAEMOPTYSIS (Coughing up some blood in his mucus) (seriousness criterion medically significant), PERICARDITIS (Heart was bumping/nausea/felt like heart was beating 1000 beats a minute/felt like it was going to beat out ofhis chest, and he was going to die/phone feels heavy to hold/wakes up with pain/diagnosed pericarditis) (seriousness criterion medically significant), RASH (Had random sandpaper type rash on upper leg and also left and right thigh) and NAUSEA (Bad nausea). The patient was treated with IBUPROFEN at a dose of 1 dosage form. At the time of the report, HAEMOPTYSIS (Coughing up some blood in his mucus), PERICARDITIS (Heart was bumping/nausea/felt like heart was beating 1000 beats a minute/felt like it was going to beat out ofhis chest, and he was going to die/phone feels heavy to hold/wakes up with pain/diagnosed pericarditis), RASH (Had random sandpaper type rash on upper leg and also left and right thigh) and NAUSEA (Bad nausea) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In 2021, Electrocardiogram: results not reported Results not reported.<br>In 2021, Investigation: results not reported Results not reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No concomitant medications were reported.<br><br>The patient reported, beginning18-Nov-2021 his heart was bumping and bumping. It felt like his heart was beating 1000 beats a minute. His heart felt like it was going to beat out of his chest, and he was going to die. He was also coughing up some blood in his mucus and also had bad nausea. He further stated the phone feels heavy to hold. He had random sandpaper type rash on upper leg and also left and right thigh. He further stated he woke up with pain. Patient went to ER and at first was diagnosed with pericarditis, however he stated he has no history of heart related conditions, acid reflux etc.<br>Patient had EKGs and other tests done and a different doctor said patient did not have pericarditis. Doctors don't seem to know what was wrong with patient. Patient was still under doctor's care.<br>Company comment: This is a spontaneous case concerning a 29-year-old male patient with no medical history reported who experienced the AESI pericarditis and the serious and unexpected event of hemoptysis. The events occurred the following day a booster dose of mRNA-1273 vaccine was administered. Patient´s heart was bumping and bumping; he felt like his heart was beating 1000 beats a minute. He stated he woke up with pain. Patient went to ER and at first was diagnosed with pericarditis, he had EKGs and other tests done and a different doctor said patient did not have pericarditis. Patient was treated with ibuprofen. Doctors don't seem to know what was wrong with patient. Patient was still under doctor's care. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ARRHYTHMIA (Pericarditis after Moderna vaccination, secured in the back wall), PERICARDIAL EFFUSION (pericardial effusion) and PERICARDITIS (Pericarditis after Moderna vaccination, secured in the back wall) in a 38-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005690) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 02-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Dec-2021, the patient experienced ARRHYTHMIA (Pericarditis after Moderna vaccination, secured in the back wall) (seriousness criterion medically significant), PERICARDIAL EFFUSION (pericardial effusion) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis after Moderna vaccination, secured in the back wall) (seriousness criterion medically significant). At the time of the report, ARRHYTHMIA (Pericarditis after Moderna vaccination, secured in the back wall), PERICARDIAL EFFUSION (pericardial effusion) and PERICARDITIS (Pericarditis after Moderna vaccination, secured in the back wall) was resolving. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Concomitant medications details were not reported by the reporter.<br><br>Treatment details was not reported by the reporter.<br><br>Patient had allergy of pollinosis, none medi-allergy.<br><br>Patient taking NSAIDs, control echo for pericardial effusion with puncture worthiness.<br><br>This case concerns a 38-year-old male patient with no medical history, who experienced the unexpected serious adverse events of special interest, ARRHYTHMIA and PERICARDIAL EFFUSION and expected serious adverse events of special interest PERICARDITIS, all of the events were medically significant as reported by the regulatory authority. The events occurred 3 days after receiving the third dose of mRNA-1273. The rechallenge was reported as not applicable by the regulatory authority. No clinical or treatment details were given. It was reported that the outcome of the events was resolving. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ANGINA PECTORIS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness), DIZZINESS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness), INJECTION SITE PAIN (Injection site pain), LYMPHADENOPATHY (Swollen lymph nodes) and MYOCARDITIS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness) in a 38-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000109A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 04-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Dec-2021, the patient experienced INJECTION SITE PAIN (Injection site pain) (seriousness criterion medically significant) and LYMPHADENOPATHY (Swollen lymph nodes) (seriousness criterion medically significant). On 05-Dec-2021, the patient experienced ANGINA PECTORIS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness) (seriousness criterion medically significant), DIZZINESS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness) (seriousness criterion medically significant) and MYOCARDITIS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness) (seriousness criterion medically significant). On 06-Dec-2021, INJECTION SITE PAIN (Injection site pain) outcome was unknown. On 13-Dec-2021, LYMPHADENOPATHY (Swollen lymph nodes) outcome was unknown. At the time of the report, ANGINA PECTORIS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness), | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | DIZZINESS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness) and MYOCARDITIS (pain in the left chest area, according to doctor suspected heart muscle inflammation, dizziness) had not resolved.<br><br>No Concomitant medication was reported.<br>No treatment medications were reported.<br><br>This case concerns a 38-year-old male patient with no medical history, who experienced the unexpected serious events of Injection Site Pain, Lymphadenopathy, Angina Pectoris, Dizziness, and adverse event of special interest, Myocarditis, all events were reported as medically significant by the regulatory authority. The events occurred 1-3 days after receiving the third dose of mRNA-1273 Vaccine. The rechallenge was reported as not applicable by the regulatory authority. No clinical or treatment details were given. It was reported that the outcome of the events was not resolving and unknown. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (heart muscle inflammation, determined by a specialist) and MYOCARDITIS (heart muscle inflammation, determined by a specialist) in a 28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 26-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 29-Jul-2021, the patient experienced DYSPNOEA (heart muscle inflammation, determined by a specialist) (seriousness criterion hospitalization) and MYOCARDITIS (heart muscle inflammation, determined by a specialist) (seriousness criteria hospitalization and medically significant). At the time of the report, DYSPNOEA (heart muscle inflammation, determined by a specialist) and MYOCARDITIS (heart muscle inflammation, determined by a specialist) was resolving.<br><br>Concomitant medication use was not reported.<br>Treatment information was not reported.<br>Patient had no allergies.<br><br>Patient had shortness of breath, chest pressure pain, sweats and high blood pressure. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | This case concerns a 28-year-old male patient with no medical history, who experienced the unexpected serious event of Dyspnea, and adverse event of special interest, Myocarditis, all events led to the hospitalization of the patient as reported by the regulatory authority. The events occurred 4 days after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was reported as unknown by the regulatory authority. No clinical or treatment details were given. It was reported that the outcome of the event was resolving. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocardium inflammation) in a 35-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216044) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Dec-2021, the patient experienced MYOCARDITIS (myocardium inflammation) (seriousness criterion hospitalization). On 13-Dec-2021, MYOCARDITIS (myocardium inflammation) had not resolved.<br><br>No relevant concomitant and treatment medications were reported<br><br>It was reported that patient experienced first reaction like 2nd Biontech with chills, then heart stinging and delivered to the KH due to heart muscle inflammation and it was confirmed by the doctor as side effect of Moderna (1/1000)<br><br>Company Comment:<br>This case concerns a 35-year-old male patient, with no medical history reported, who experienced the unexpected serious AESI events of Myocarditis. The events occurred approximately 2 days after the third dose of mRNA-1273 Vaccine which resulted in hospitalization. At the time of the report the outcome of the events was not resolved. The rechallenge is not applicable since no further dosing is expected. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis, the patient still has discomfort from pericarditis) in a 32-year-old | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | male patient who received mRNA-1273 (Spikevax) (batch no. 3004959) for COVID-19 immunisation.<br><br>Previously administered products included for COVID-19 immunisation: SPIKEVAX on 23-Aug-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br><br>On 27-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis, the patient still has discomfort from pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis, the patient still has discomfort from pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In October 2021, Blood test: normal (normal) Nothing abnormal.<br>In October 2021, Echocardiogram: abnormal (abnormal) Pericarditis.<br>In October 2021, Electrocardiogram: abnormal (abnormal) Hammock-like configuration v3-5.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br>No treatment information was provided. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 03-Jan-2022 and was forwarded to Moderna on 03-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), TACHYCARDIA (Racing heart (tachycardia)), FATIGUE (Fatigue/unusual tiredness), PALPITATIONS (Heart palpitations) and MYOCARDITIS (Myocarditis) in a 25-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>In 2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form.<br>On 29-Jun-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 01-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion hospitalization), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion hospitalization) and | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | PALPITATIONS (Heart palpitations) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and TACHYCARDIA (Racing heart (tachycardia)) had not resolved, FATIGUE (Fatigue/unusual tiredness) and PALPITATIONS (Heart palpitations) outcome was unknown and MYOCARDITIS (Myocarditis) had resolved with sequelae.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: not provided Not provided.<br>On an unknown date, Electrocardiogram: not provided Not provided.<br>On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) Negative COVID-19 test.<br>On an unknown date, Troponin: not sure Not sure.<br><br>Patient last menstrual period date was reported as 17-DEC-2021.<br>Patient's general practitioner (GP) advised to go hospital due to experiencing severe chest pains, rapid heartbeat, shortness of breath. Patient went to accident and emergency (A&E), they have done an electrocardiogram (ECG) and blood tests. Doctor said it may be myocarditis, which was a few weeks after first dose. Patient had second dose and sometimes Patient still get same symptoms chest pains and rapid heartbeat, shortness of breath.<br>Patient had not tested positive for COVID-19 since having the vaccine.<br>Patient was not enrolled in clinical trial.<br>Patient's report was related to possible inflammation of the heart (myocarditis or pericarditis).<br>ECG and blood test were done in A and E hospital by cardiologist<br>Treatment medication included Non-steroidal anti-inflammatory drugs (NSAIDs).<br><br>Company comment:<br>This regulatory authority case concerns a 25-year-old female patient with no relevant medical history who experienced serious unexpected events of chest pain, dyspnoea, tachycardia, fatigue, palpitations and serious expected AESI myocarditis, that occurred after the administration of mRNA-1273. Reportedly, a few weeks after the 1st dose, the patient had severe chest pains, rapid heartbeat, shortness of breath leading to A&E visit at which the patient had blood tests and ECG. The doctor said it may be myocarditis and was treated with NSAIDs. The patient experienced the same symptoms of chest pain, rapid heart beats and SOB after the second dose. The regulatory authority assessed the rechallenge as unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness as per regulatory authority.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Jan-2022: Lab tests updated. First dose information Updated. Action taken updated. | | |

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| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number [redacted] on 04-Jan-2022 and was forwarded to Moderna on 06-Jan-2022.<br>This case, reported to the [redacted]) by a pharmacist, was received via the [redacted] (Ref, [redacted]). On 03-Oct-2021, the patient received the 1st dose of this vaccine. On 31-Oct-2021, the patient received the 2nd dose of this vaccine. After the vaccination, the patient transiently experienced pyrexia higher than 38 degrees Celsius. On an unknown date, although the fever had subsided spontaneously, the patient had prolonged low-grade fever. On 02-Nov-2021, around 15:00, the patient suddenly noticed precordial pain at rest. The characteristics of the symptom was like being pushed, and the intensity of the pain was about 8 out of 10. There was no radiation or migration of the pain. At 15:30, myocarditis developed. Thereafter, the symptom did not improve, and the patient visited an emergency department of the reporting hospital. On arrival at the hospital, electrocardiogram showed ST elevation in II, III, aVF, V4, V5, and V6 while echocardiography showed no obvious wall motion abnormalities; however, blood sampling showed elevated myocardial enzymes including troponin I. Myocarditis associated with the vaccine was suspected based on the clinical course, and the patient was hospitalized for follow-up and to receive medical treatments. Viral or collagenous diseases were considered as those needed to be distinguished, and various viral antibody tests was performed, but the results were negative. On an unknown date, chest pain had improved over time and cardiac enzyme levels decreased to within normal ranges. In addition, ST elevation on electrocardiogram almost disappeared. General condition was good. On 09-Nov-2021, the symptoms resolved, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. <Imaging tests> [Cardiac MRI tests] (Date of exam: 10-Nov-2021) ・Images were obtained. ・Abnormal findings: (Myocardial edema) Finding of edema on the T2-weighted image. Patchy edema was typically found. (Myocardial injury) Delayed imaging with gadolinium on the T1-weighted image. However, the signal intensity of the myocardium was higher than that of skeletal muscle, and delayed imaging was typically seen in at least one non-ischemic area. [Cardiac ultrasound] (Date of exam: 02-Nov-2021) ・No abnormal findings were noted. ・Left ventricular ejection fraction: 64.2% [Chest X-ray] (Date of exam: 02-Nov-2021) ・Abnormal findings: enlargement of the heart [Electrocardiography] (Date of exam: 02-Nov-2021) ・Abnormal findings: ST elevation or negative T-wave <Differential diagnosis> ・Other diseases that could explain clinical symptoms and findings have been ruled out. Reporter comments continuation: In this case, the patient had no family history or medical history of heart diseases, and abnormal electrocardiogram had never been found in the medical examination to date, which was consistent with the condition that was easy to cause myocarditis after vaccination. Thus, it is strongly suspected that coronavirus vaccine was the cause of the myocarditis. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. | 17 years old male with unknown medical history who 2 days after the second dose of Spikevax expereinced precordial chest pain at rest. Patient was taken to the hospital and was found to have elevated troponin, abnormal ECG, abnormal echo, abnormal cMRI, and was diagnosed with myocarditis. Patient was discharged 7 day later when symptoms resolved. . According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ARRHYTHMIA (Diagnosed pericarditis. My home doctor said she alone in practice had at least 4 cases with the same symptomatology every day.) and PERICARDITIS (Diagnosed pericarditis. My home doctor said she alone in practice had at least 4 cases with the same | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | symptomatology every day.) in a 35-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214022) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced ARRHYTHMIA (Diagnosed pericarditis. My home doctor said she alone in practice had at least 4 cases with the same symptomatology every day.) (seriousness criterion medically significant) and PERICARDITIS (Diagnosed pericarditis. My home doctor said she alone in practice had at least 4 cases with the same symptomatology every day.) (seriousness criterion medically significant). At the time of the report, ARRHYTHMIA (Diagnosed pericarditis. My home doctor said she alone in practice had at least 4 cases with the same symptomatology every day.) and PERICARDITIS (Diagnosed pericarditis. My home doctor said she alone in practice had at least 4 cases with the same symptomatology every day.) outcome was unknown.<br><br>3x 600 mg ibuprofen.<br><br>COMPANY COMMENT:<br>This is a Regulatory case concerning 35-years-old male patient with no clinical history who experienced the unexpected AESI event of Arrhytmia and the AESI expected event of Pericarditis<br>The events occurred unknown days after 3rd dose of mRNA-1273.<br>The rechallenge was not applicable since only information about 3rd dose was disclosed<br>The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br>Event terms, seriousness and onset dates were captured as provided by the Regulatory Authority | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocardium inflammation) in a 35-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 201644) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Dec-2021, the patient experienced MYOCARDITIS (Myocardium inflammation) (seriousness criteria hospitalization and medically significant). On 13-Dec-2021, MYOCARDITIS (Myocardium inflammation) had not resolved. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Concomitant medications were not reported .<br>Treatment information was not provided.<br><br>Patient reported that no information about risk factors or pre-existing conditions No/Initial chills similar to Biontech Booster, born after 2 days breast stinging with consequence emergency room and [redacted] stay 30.01.1986 In the [redacted] possible as damage to Moderna (1/1000).<br><br>Company Comment This RA case concerns a 35 year old male with no medical history reported, who experienced Serious ( Hospitalization ) , expected , AESI event of myocaridits which occurred two days post vaccination with the 3rd dose of mRNA-1273 vaccine ( Moderna Covid 19 vaccine ) . This patient based on the narrative was vaccinated using Biontech ( Covid 19 Vaccine Pfizer ) , with no adverse events reported. There were no details of laboratory results or diagnostic procedures reported re the event Myocarditis and also the details of the hospitalization was also not reported. The re-challenge for this case is not applicable since the event occurred after the 3rd dose and no additional doses will be given and also the reported event has not yet resolved. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Pericarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 216001 and 214006) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 (COVID-19 had passed.).<br><br>On 14-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 12-Dec-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 14-Dec-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and life threatening) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and life threatening). At the time of the report, MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Pericarditis) had not resolved.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 14-Jul-2021.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Concomitant products was not provided by the reporter.<br><br>No treatment information was provided.<br>Company comment-This case concerns a 22-year-old male patient, with medical history of COVID-19, who experienced the expected serious events of MYOCARDITIS (AESI) and PERICARDITIS (AESI). The events occurred 2 days after the administration of the second dose of mRNA-1273 vaccine. At the time of the report, events had not resolved. Patient' medical history of COVID-19, remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted]) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>Patient has not had symptoms associated with COVID-19.<br><br>On 15-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 16-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness criterion hospitalization), DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization), PALPITATIONS (Heart palpitations) (seriousness criterion hospitalization) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion hospitalization). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: possible myocarditis (abnormal) Possible myocarditis.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>No concomitant medications were reported.<br><br>Patient has not had symptoms associated with COVID-19.<br><br>Patient's report related to possible inflammation of the heart (myocarditis or pericarditis) was reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | It was reported that patient symptoms led to a hospital stay for 5 hours. Patient relevant investigations or tests conducted were reported as 'Went to hospital to get tested, did ECGs and said possible myocarditis'.<br><br>Patient treatment was reported as Ibuprofen/paracetamol.<br><br>Patient underwent only ECG and no other lab investigation was performed to the patient and blood tests, such as for certain proteins (called troponin) that signal heart muscle damage were taken for the patient.<br><br>Patient has not tested positive for COVID-19 since having the vaccine. Patient is not enrolled in clinical trial.<br><br>Company Comment: This regulatory case concerns a 26-year-old, male patient with no medical history reported, who experienced the expected, serious AESI of myocarditis and the unexpected, serious events of fatigue, chest pain, pyrexia, dyspnoea, palpitations and tachycardia. The event myocarditis occurred 1 day after administration of the third dose of the Moderna mRNA-1273 vaccine. The start dates of the other events were not provided. The patient sought consult at the Accident and Emergency department. Electrocardiograms and Troponin test were done; however, the results were not provided. The doctor informed the patient that he had possible Myocarditis. He stayed in the hospital for 5 hours and was then prescribed with Ibuprofen/Paracetamol (unspecified dosage, frequency and duration). No further details were provided. The event myocarditis was resolving at the time of the report. The outcomes of the other events were unknown at the time of the report. The patient's gender remains a confounder for the event myocarditis. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Jan-2022: Follow up information received, lab data (ECG) added. Action taken updated from Unknown to not applicable. Seriousness criteria added hospitalization. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005888) for COVID-19 vaccination.<br><br>Concomitant products included TOZINAMERAN (COMIRNATY) from 10-Jan-2021 to 01-Feb-2021 for COVID-19 vaccination.<br><br>On 01-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) had resolved. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 01-Dec-2021.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Treatment information was not reported.<br><br>Company comment:<br>This case concerns a 32-year-old male patient with no medical history provided, who experienced serious expected event of Pericarditis. The exact start date of the event was not provided, however, as per structured fields of the source documents it was disclosed that time interval between vaccine administration and the start of the event was 13 days. At the time of the report, the event had resolved, however, no additional information regarding the clinical course of the event was provided. The action taken with the suspect product was reported as drug withdrawn and was kept as such, however, it could have been considered as not applicable as the patient received the third dose of the vaccine and no additional doses are planned at the moment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Having in mind that this patient received Tozinameran COVID-19 Vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ACUTE CORONARY SYNDROME (I was diagnosed with myocarditis 5 days after the 2nd vaccination and acute coronary syndrome. The doctors at [redacted]XXX said it was due to vaccination with Moderna.) and MYOCARDITIS (I was diagnosed with myocarditis 5 days after the 2nd vaccination and acute coronary syndrome. The doctors at [redacted]XXX said it was due to vaccination with Moderna.) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214012) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 02-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Dec-2021, the patient experienced ACUTE CORONARY SYNDROME (I was diagnosed with myocarditis 5 days after the 2nd vaccination and acute coronary syndrome. The doctors at [redacted]XXX said it was due to vaccination with Moderna.) (seriousness criterion hospitalization) and MYOCARDITIS (I was diagnosed with myocarditis 5 days after the 2nd vaccination and acute coronary syndrome. The doctors at [redacted]XXX said it was due to vaccination with Moderna.) (seriousness criterion hospitalization). On 11-Dec-2021, ACUTE CORONARY SYNDROME (I was diagnosed with myocarditis 5 days after the 2nd vaccination and acute coronary syndrome. The doctors at [redacted]XXX said it was due to vaccination with | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Moderna.) and MYOCARDITIS (I was diagnosed with myocarditis 5 days after the 2nd vaccination and acute coronary syndrome. The doctors at [redacted]XXX said it was due to vaccination with Moderna.) outcome was unknown.<br><br>No concomitant medications were reported.<br><br>Patient had firstly fever, then chills occured. One day later, the flu symptoms were gone but then he had severe pain in chest and left arm. With numbness of arm and left leg. Headaches and dizziness were added, diagnosis of myocarditis and acute coronary syndrome occurred. Patient was taking beta blockers as well as steroids for inflammation and novamine sulphone as pain relievers.<br><br>Company comment:<br>This case concerns a 27-year-old male patient, with no medical history, who experienced the unexpected serious event of ACUTE CORONARY SYNDROME (AESI) and the expected serious event of MYOCARDITIS (AESI). The events occurred approximately 5 days after the administration of the second dose of mRNA-1273 vaccine. Diagnosis of myocarditis and acute coronary syndrome occurred. Patient was taking beta blockers as well as steroids for inflammation and novamine sulphone as pain relievers. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 16-Dec-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Dec-2021, the patient experienced FATIGUE (Fatigue) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, FATIGUE (Fatigue), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br><br>The patient had received the first dose of Moderna vaccine on 12-Nov-2021. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | From 16-Dec-2021 to 18- Dec-2021, patient experienced symptoms of cold and cough, headache, fever (about 38°C), and muscle soreness. However, the patient did not seek medical treatment because the symptoms disappeared after December 18<br><br>On 20- Dec-2021, patient went to the Emergency Department due to chest pain and back pain and was hospitalized. After the patient received cardiac catheterization, the blood vessels were normal, but the cardiac systolic function was poor, and the patient was suspected of myocarditis.<br><br>On 22-Dec-2021 the patient had no chest tightness and pain and was discharged the hospital.<br><br>It was reported on 24-Dec- 2021, the patient said no symptoms were noticed in the past two days.<br><br>It was reported that on 27-Dec-2021, the patient said no symptoms were found, no discomfort was observed.<br><br>No treatment medications were reported.<br><br>Company comment:<br>This case concerns a 32-year-old, male patient with no relevant medical history, who experienced the unexpected serious events of Fatigue and Pyrexia; and expected serious AESI of Myocarditis. The events occurred approximately 5 days after the second dose of mRNA-1273. Events were recovering at the time of report. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 03-Jan-2022: Upon query received from business partner, Non-Significant correction was performed on 20-JAN-2022. Updated patient's age to 32-year-old from 327-year-old in company comment. | | |
| [redacted] | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 06-Dec-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. | 18-year-old male patient, with unknown medical history, who received the Astrazeneca vaccine as his 1st dose and who 16 days aftee the 2nd dose of Spikevax experienced fever, watery diarrhea, and chest pain and was found to have elevated troponin, abnormal ECG, and normal echo and was diagnosed with MYOCARDITIS. The event was resolved two days later. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported by reporter.<br>On 06-Dec-2021, patient had received the second dose of COVID-19 (Moderna) vaccine.<br>On 22-Dec-2021 visited the emergency department of our hospital. After diagnosis and treatment, patient was hospitalized for treatment. This 18-year-old young man was generally healthy before. Patient received first dose COVID-19 vaccination (AZ) on 09 and received second dose of COVID-19 vaccination (Moderna) on 06-Dec-2021. After then, patient was suffered from fever for 2 days (12/7-12/8). However, fever was noted again on 12/11, accompanied with watery diarrhea and chest pain in the following days. The chest pain aggravated followingly, so he visited our ER, where EKG revealed diffuse ST elevation. Elevation of CKMB and troponin-I were also found. Nevertheless, patient symptom had improved at ER. To rule out CAD, he was sent to cath room for CAG. The CAG revealed patent coronary artery. Under the impression of acute myocarditis, he was admitted to ICU for furthur management. On 23-Dec-2021, Under the impression of acute myocarditis, he was admitted to ICU for further management. At ICU, he remained asymptomatic and follow up cardiac enzymes were declining. Bedside echo showed preserved systolic LV function and no pericardial effusion. We had reported Moderna vaccine ADR and survey possible viral infection. Cardiac MRI had been arranged. Under stable clinical condition, he had be transfered to general ward for furthur care.<br><br>No treatment medications provided by the reporter.<br>Company Comment - This regulatory authority case concerns a 18 year old male patient with no relevant medical history, who experienced the serious (medically significant) expected event of myocarditis and was resolving at the time of the report. The event occurred approximately 16 days after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 090F21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 01-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not provided.<br><br>Treatment information was not provided. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MIOCARDITIS) in a 13-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Co-suspect product included non-company product BCG VACCINE ([redacted] BCG) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 18-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 15-Sep-2021, received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On 25-Oct-2021, the patient received dose of BCG VACCINE ([redacted] BCG) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (MIOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MIOCARDITIS) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 10-Dec-2021, Troponin I: abnormal (abnormal) 3481 pg/ml (normal up to 34)..<br>On 11-Dec-2021, Echocardiogram: normal (normal) DOPPLER-COLOR ECHOCARDIOGRAPHY: Minimum effusion only VD. Situs solitus. Normal segmental sorting. Normal systemic venous drainage. Normal size and function cardiac chambers. Non-hypertrophic left ventricle with normal systolic function 61% Systolic function study: Ejection fraction 61% by Simpson. MAPSE 18 mm. GLS:- 22% (four chambers only) Mitral valve with normal, normal functioning morphology. Diastolic function study VI: mitral valve filling pattern: E wave: 1.05 m/sec; Wave A: 0.7m/sec. TDI study: E.<br>On 11-Dec-2021, Electrocardiogram: normal (normal) Sinus rhythm. No atrial hypertrophy and PR interval within normal limits. QRS axis, amplitude and R wave progression in precordial leads normal for age. No intraventricular conduction disorders, no signs of hypertrophy. No repolarization disorders with normal corrected QT interval..<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. | 13 years old male with unknown medical history who 41 days after his 2nd dose of Spikevax received a dose of BCG, and then at an unknown time of onset developed myocarditis. Laboratory test showing elevated troponin and abmormal echo and ECG were conducted 46 days after the BCG vaccine and 87 days after the 2nd dose of Spikevax. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is unlikely based on the prolonged TTO, and the use of the BGC vaccine. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Concomitant medication was not provided.<br>Treatment information was not provided.<br><br>Company Comment: This case refers to a 13-year-old male patient with no known medical history who experienced the expected event of Myocarditis on an unspecified number of days after a dose of mRNA-1273 vaccine. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericardial inflammation) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 1: 3004955. 2: 3006273.) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 immunisation (SPIKEVAX DOS 1) on 12-Aug-2021.<br>Concomitant products included IBUPROFEN (IBUPROFEN DH) from 10-Nov-2021 to 01-Dec-2021 for an unknown indication.<br><br>On 06-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Nov-2021, the patient experienced PERICARDITIS (Pericardial inflammation) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericardial inflammation) outcome was unknown.<br><br>No treatment medication information was mentioned by reporter.<br><br>Company Comment: This case refers to a 18-year-old male patient with no known medical history who experienced the expected event of Pericarditis approximately 1 month after the second dose of mRNA-1273 vaccine. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Pain in the chest / Myocarditis/Chest pain), PERICARDITIS (Pericarditis), VENTRICULAR EXTRASYSTOLES (PVC) and HYPOAESTHESIA (symptoms were numbness in his left arm) in a 29-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 050F21A and 045C21A) for COVID-19 vaccination.<br><br>No Medical History information was reported. | 29-year-old male patient, with unknown medical history, who 4 days aftre the 2nd dose of Spikevax experienced chest pain and numbness in his arm, and was found to have elevated troponin, abnormal ECG, normal Echo and normal cMRI and was diagnosed with myopericarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 16-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 13-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 17-Sep-2021, the patient experienced MYOCARDITIS (Pain in the chest / Myocarditis/Chest pain) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), VENTRICULAR EXTRASYSTOLES (PVC) (seriousness criterion hospitalization) and HYPOAESTHESIA (symptoms were numbness in his left arm) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 17-Sep-2021 to 19-Sep-2021 due to MYOCARDITIS. The patient was treated with IBUPROFEN at an unspecified dose and frequency and METOPROLOL SUCCINATE (oral) ongoing from 17-Sep-2021 for Adverse event, at a dose of 25 milligram 1/2 tabet. At the time of the report, MYOCARDITIS (Pain in the chest / Myocarditis/Chest pain), VENTRICULAR EXTRASYSTOLES (PVC) and HYPOAESTHESIA (symptoms were numbness in his left arm) had not resolved and PERICARDITIS (Pericarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 15-Sep-2021, Troponin: high (High) Troponin elevated.<br>On 17-Sep-2021, Echocardiogram: normal (normal) Normal.<br>On 17-Sep-2021, Red blood cell sedimentation rate: 3 normal rang: 0.20.<br>On 17-Sep-2021, Troponin I: 11.10 normal rang: < or equal to 17 ng/L.<br>On 18-Sep-2021, Troponin I: 2.87 normal rang: < or equal to 17 ng/L.<br>On 24-Sep-2021, Electrocardiogram: abnormal (abnormal) Normal sinus rhythm with sinus arrhythmia ST & T wave abnormality.<br>On 24-Sep-2021, Troponin I: 15 normal rang: < or equal to 17 ng/L.<br>On 14-Oct-2021, Magnetic resonance imaging: normal (normal) Within normal limits.<br>On 14-Oct-2021, Magnetic resonance imaging heart: normal (normal) Within normal limits.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication information was provided.<br>Treatment medications included unspecified blood thinner.<br><br>The patient called to report that he had myocarditis after getting the second dose of the Moderna Covid-19 vaccine. His symptoms were pain in the chest, numbness in his left arm and pressure. He was told that he has myocarditis when the lab results came in. Patient was hospitalized from 17-Sep-2021 to 19-Sep-2021.<br>In follow up patient reported he pericarditis and PVC was noted during hospitalization. Patient did not had history of hypertension, thrombosis, cardiac arrhythmia, myocardial infraction, coronary artery disease, cancer and radiotherapy. bacterial infection was unknown. Participation in sports or strenuous activity was unknown. | the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company Comment: This spontaneous case concerns a 29 year old male , with no medical history reported , who experienced Serious , expected, AESI events of Myocarditis, pericarditis , Serious , unexpected , AESI event of Ventricular extra-systoles and Serious , unexpected event of hypoaesthesia which occurred 4 days post vaccination with the 2nd dose of mRNA-1273 vaccine ( Moderna Covid 19 vaccine ) . This patient was hospitalized due to myocarditis and was treated with Ibuprofen and Metoprolol . !2 L ecg showed Normal sinus rhythm with sinus arrhythmia ST & T wave abnormality, MRI was normal and Troponin test was elevated. The re-challenge is not applicable since the events outcome were unresolved and unknown. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Jan-2022: Significant follow up received. Events, treatment drug and laboratory data were added. | | |
| [redacted] | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 17-Dec-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication were reported.<br><br>No treatment information were reported.<br><br>Patient admitted to Hospital on 12/28/2021.<br><br>Patient's Vital signs: BP 138 / 92 mmHg HR: 130 times / min RR: 18 times / min BT: 36.6 ℃ SpO2: 99% | 38-year-old male patient, with unknown medical history, who 11 days aftre the 2nd dose of Spikevax experienced chest pain and dizziness and was found to have elevated troponin and other inflammation markers and was diagnosed with MYOCARDITIS. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | [redacted] |

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| | Patient's lab reports<br>GCS: E4V5M6<br>WBC12.48 x1000/uL<br>RBC 5.45x10^6/uL<br>Hgb 15.0 g/dL<br>PLT 73 x1000/uL<br>Sugar 404 mg/dL<br>GOT 28 IU/L<br>GPT 36 IU/L<br>Amylase 52 U/L<br>Lipase 36 U/L<br>CRP 141.83 mg/L<br>Urea N 11.8 mg/dL<br>Creatinine 0.90 mg/dL<br>Na 131.9 m mol/L<br>K 4.0 m mol/L<br>CPK 252 U/L<br>CK-MB(S) 7.0 ng/mL<br>Tropo-I 4.707 ng/mL<br>TSH 1.100 uIU/mL<br>Free T4 1.48 ng/dL<br>PT(INR) 0.94<br>PTT P 27.1 second<br>PTT C 27.2 second<br>Ca++(ionized) 32~mg/dL<br>D-Dimer□0.59 μg/mL<br><br>Patient's treatment informations<br>Sodium Chloride (Sodium Chloride 0.9% 500mL/Bag) 500 ml ST IVD 1 day<br>Piperacillin 2g+Tazobactam 0.25g (Tazocin Compound/Vial) 2 Vial Q12H IVD Medication interval: 12/29 09:00~<br>Sodium Chloride (Normal saline 0.9% 20mL/Amp) 20 ml Q12H IVD Medication interval: 12/29 09:00~<br>Sodium Chloride (Sodium Chloride 0.9% 250mL/Bag) 100 ml Q12H IVD Medication interval: 12/29 09:00~<br>Methylprednisolone sod. succinate (Solu-Medrol 40mg/Vial) 1 Vial ST IVP 1 day<br>(Aq dest 20mL/Amp) 20 ml ST IVP 1 day<br>Sodium Chloride (Sodium Chloride 0.9% 500mL/Bag) 500 ml Q12H IVD Medication interval: 12/29 09:00~<br>Moxifloxacin (Avelox 400mg/250 mL/Bot) 250 ml ST IVD 1 day<br>12/29 After evaluation, the patient was hospitalized for further examination<br><br>Company Comment - This regulatory authority case concerns a 38 year old male patient with no relevant medical history, who experienced the serious (medically significant) expected event | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | of myocarditis and was resolving at the time of the report. The event occurred approximately 11 days after the second dose of mRNA-1273 vaccine and was resolving at the time of the report. Patient complained of chest tightness and dizziness and had to be admitted to the hospital. The rechallenge was unknown. The benefit-risk relationship of the m | | |
| [redacted] | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 07-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>The Patient had received the second dose of vaccine on 10/07/2021.<br>12/03/2021 the patient visited the outpatient cardiovascular department of our hospital and complained of 10/7/2021 Moderana;<br>11/23/2021 left chest pain while changing position, worse while changing position and deep inspiration;<br>11/26/2021 intercostal Chest pain, pain during breathing so that inability to stand up;<br>12/03/2021 DOE( dyspnea on exertion)<br>The patient has a history of smoking (smoking, +)<br>[test 1101124] WBC 10.78x1000/uL。 CK-MB(S)=1.9 ng/mL; Tropo-I=0.0483 ng/mL; CPK 213 U/L; CRP (quantitative)= 22.36 mg/L;<br>Creatinine=0.99 mg/dL.<br>[examination] UCG: systolic dysfunction (LVEF 41.9% by Biplane Simpson's method and Treadmill test: negative<br>After the diagnosis, the patient's condition was stable and allowed to follow-up by the outpatient department.<br>As the adverse reaction of the COVID-19 vaccine cannot be ruled out, the physician reported the adverse reaction of the vaccine. Outpatient<br>medicine (oral): Colchicine 1 Tab BID、Strocain 1 Tab BID、Cataflam 1 Tab BID、Concor 1 Tab QD AM、[redacted] 1 Tab BID total in 14 days.<br><br>Concomitant and treatment medications were not reported.<br><br>Company Comment - This regulatory authority case concerns a 26 year old male patient with medical history of smoking, who experienced the serious (medically significant) expected event | 26-year-old male patient, with unknown medical history, who 57 days aftre the 2nd dose of Spikevax experienced chest pain while changing position and with inspiration and was found to have elevated troponin, CK, CPK, and abnormal Echo and was diagnosed with MYOCARDITIS. The patient was not hospitalied and was treated outpatient. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | of myocarditis and was resolving at the time of the report. The event occurred approximately 57 days after the second dose of mRNA-1273 vaccine and was resolving at the time of the report. Patient complained of left chest pain while changing position and during deep inspiration and dyspnea on exertion. Patient's medical history of smoking remains a confounder. The rechallenge was unknown. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 30-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Nov-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (myocarditis) was resolving.<br><br>Patient had fatigue with shortness of breath and heart stinging. In further course, stronger pricking at reduced AZ.<br><br>Concomitant products were not provided.<br><br>Treatment medication were not reported.<br><br>Company comment:<br>This regulatory authority case concerns a 24-year-old male patient with no relevant medical history who experienced serious expected AESI of myocarditis, that occurred approximately a month after the 2nd dose of the mRNA-1273 . The rechallenge was not applicable due to occurrence after the 2nd dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDIAL EFFUSION (PERICARDIAL EFFUSION) and PERICARDITIS (RECURRENT PERICARDITIS) in a 25-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for COVID-19 vaccination. | 25 years old with unknown medical history who had the 2nd dose of Spikevax and there seems to be a report of having pericarditis 50 days later. Then the patient was vaccinated with the influenza vaccine 34 days later and 10 days later experiencing another episode of pericarditis with pericardial effusion. No other information was provided. Important information is missing in the | [redacted] |

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| | Co-suspect product included non-company product INFLUENZA VACCINE INACT SAG 4V (INFLUVAC TETRA) for Vaccination.<br><br>The patient's past medical history included Pericarditis on 14-Oct-2021.<br><br>On 26-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form.<br>On 18-Nov-2021, the patient received dose of INFLUENZA VACCINE INACT SAG 4V (INFLUVAC TETRA) (Intramuscular) 1 dosage form.<br>On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) at an unspecified dose. On 28-Nov-2021, the patient experienced PERICARDIAL EFFUSION (PERICARDIAL EFFUSION) (seriousness criterion hospitalization) and PERICARDITIS (RECURRENT PERICARDITIS) (seriousness criterion hospitalization). At the time of the report, PERICARDIAL EFFUSION (PERICARDIAL EFFUSION) and PERICARDITIS (RECURRENT PERICARDITIS) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Nov-2021, C-reactive protein: 1 1.<br>On 05-Dec-2021, C-reactive protein: 140 140.<br>On 05-Dec-2021, Echocardiogram: pericardial effusion Pericardial effusion.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDIAL EFFUSION (PERICARDIAL EFFUSION) and PERICARDITIS (RECURRENT PERICARDITIS) to be possibly related.<br><br>No concomitant medication was reported. No treatment medication use was reported. Both vaccines were suspects as it was conceivable that Spikevax contributed to the incident.<br><br>Company Comment<br>This case concerns a 25-year-old female patient with a previous medical history of Pericarditis, who experienced the serious expected AESI of Pericarditis and the serious unexpected event of Pericardial effusion. The events occurred 3 month and 2 days after the second dose of mRNA-1273 vaccine. Echocardiogram supports the diagnosis of Pericardial effusion. The medical history of Pericarditis is a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting as hospitalization and retained for consistency with the RA report. | report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is conditional based on the confusing and lack of information; a causal relationship cannot be excluded due to the lack of information. | |
| [redacted] | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of DIARRHOEA (diarrhoea), ABDOMINAL PAIN (abdominal pain), STREPTOCOCCAL BACTERAEMIA (Fever relapse partially treated Strep Gp A bacteraemia), URINARY TRACT INFECTION (Urinary tract infection), MYOCARDITIS (myocarditis), PYREXIA (Fever), LEFT VENTRICULAR DYSFUNCTION (LV dysnfunction | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | - probable), STRESS CARDIOMYOPATHY (Takotsubu CMP), SEPSIS (Sepsis), COLITIS (Colitis), HYPOKALAEMIA (Hypokalaemia resolved with replacement), VOMITING (vomiting), ACUTE KIDNEY INJURY (AKI) and HEPATIC FUNCTION ABNORMAL (Worsening of liver function - infection related / contributed by Dapagliflozin) in a 39-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004736) for an unknown indication.<br><br>The patient's past medical history included Caesarean section (C section 5 years ago).<br>Family history included Coronary artery bypass graft (mother had CABGS in her 50s).<br><br>On 29-Aug-2021 at 9:42 AM, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (unknown route) 1 dosage form. On 04-Oct-2021, the patient experienced DIARRHOEA (diarrhoea) (seriousness criterion hospitalization), ABDOMINAL PAIN (abdominal pain) (seriousness criteria hospitalization and medically significant), STREPTOCOCCAL BACTERAEMIA (Fever relapse partially treated Strep Gp A bacteraemia) (seriousness criteria hospitalization and medically significant), URINARY TRACT INFECTION (Urinary tract infection) (seriousness criterion hospitalization), MYOCARDITIS (myocarditis) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness criterion hospitalization), LEFT VENTRICULAR DYSFUNCTION (LV dysnfunction - probable) (seriousness criterion hospitalization), STRESS CARDIOMYOPATHY (Takotsubu CMP) (seriousness criterion hospitalization), SEPSIS (Sepsis) (seriousness criterion hospitalization), COLITIS (Colitis) (seriousness criterion hospitalization), HYPOKALAEMIA (Hypokalaemia resolved with replacement) (seriousness criterion hospitalization), VOMITING (vomiting) (seriousness criterion hospitalization), ACUTE KIDNEY INJURY (AKI) (seriousness criterion hospitalization) and HEPATIC FUNCTION ABNORMAL (Worsening of liver function - infection related / contributed by Dapagliflozin) (seriousness criterion hospitalization). At the time of the report, DIARRHOEA (diarrhoea), ABDOMINAL PAIN (abdominal pain), STREPTOCOCCAL BACTERAEMIA (Fever relapse partially treated Strep Gp A bacteraemia), URINARY TRACT INFECTION (Urinary tract infection), MYOCARDITIS (myocarditis), PYREXIA (Fever), LEFT VENTRICULAR DYSFUNCTION (LV dysnfunction - probable), STRESS CARDIOMYOPATHY (Takotsubu CMP), SEPSIS (Sepsis), COLITIS (Colitis), VOMITING (vomiting), ACUTE KIDNEY INJURY (AKI) and HEPATIC FUNCTION ABNORMAL (Worsening of liver function - infection related / contributed by Dapagliflozin) outcome was unknown and HYPOKALAEMIA (Hypokalaemia resolved with replacement) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not provided.<br>Fever relapse partially treated Strep Gp A bacteraemia.<br>Worsening of liver function infection related contributed by Dapagliflozin. | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company Comment: This RA case concerns a 39 year old female with history of intake of Dapagliflozin , who experienced Serious ( hospitalization ) , expected , AESI event of Myocarditis and Serious , unexpected event of Acute kidney injury which occurred one month five days post vaccination with the 2nd dose of mRNA-1273 vaccine ( Moderna Covid 19 Vaccine ) . This was accompanied by other Serious ( hospitalization ) , unexpected events of vomiting , diarrhea , abdominal pain, Streptococcal bacteremia , UTI, Pyrexia , Left ventricular dysfuntion , stress cardiomyopathy , sepsis , colitis , hypokalemia and hepatic function abnormal which also occurred 1 month , five days post vaccination with the 2nd dose of mRNA-1273 vaccine . The re-challenge for this case is not applicable since the outcome of the events were reported as unknown. The history of intake of Dapaglifozin may be considered as a confounder for this case( as reported to be one factor for the worsening liver function ) . The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Mild myocardite) in a 17-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004955) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 (Easter 2020) in 2020.<br><br>On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Mild myocardite) (seriousness criterion medically significant). On 29-Nov-2021, MYOCARDITIS (Mild myocardite) had resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain), MYALGIA (Myalgia), PYREXIA (fever with chills), HEADACHE (Headache) and MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003602) for COVID-19 vaccination.<br><br>No Medical History information was reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 09-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Jul-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), MYALGIA (Myalgia) (seriousness criterion hospitalization), PYREXIA (fever with chills) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), MYALGIA (Myalgia), PYREXIA (fever with chills), HEADACHE (Headache) and MYOCARDITIS (Myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In July 2021, Angiocardiogram: not reported not reported.<br>In July 2021, Echocardiogram: not reported not reported.<br>In July 2021, Magnetic resonance imaging heart: not reported not reported.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br><br>No treatment medications were reported.<br><br>The patient has been healthy so far.<br><br>Company Comment : This regulatory case concerns a 26-year-old, so far healthy male patient with no medical history, who experienced the Serious unexpected events of Myocarditis, Chest Pain, Myalgia, Pyrexia and headache on the same day after receiving the second dose of mRNA-1273 vaccine. The patient was hospitalized and the events recovered after 10 days. Treatment details were not provided. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority's report. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 07-Jan-2022. The most recent information was received on 09-Jan-2022 and was forwarded to Moderna on 09-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ABDOMINAL PAIN UPPER (stomach pain), CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness), NECK PAIN (Neck pain), BACK PAIN (back pain), HEADACHE (headache) and MYOCARDITIS (Myocarditis) in a 25-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005889) for COVID-19 vaccination.<br><br>No Medical History information was reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 03-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced ABDOMINAL PAIN UPPER (stomach pain) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), NECK PAIN (Neck pain) (seriousness criterion medically significant), BACK PAIN (back pain) (seriousness criterion medically significant) and HEADACHE (headache) (seriousness criterion medically significant). At the time of the report, ABDOMINAL PAIN UPPER (stomach pain), CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness) and NECK PAIN (Neck pain) outcome was unknown and BACK PAIN (back pain), HEADACHE (headache) and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 06-Jan-2022, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.<br><br>Concomitant product was not provided by the reporter.<br><br>Patient had severe chest, neck and back pain with heart palpitations. It was worse when lay down. Patient had a severe headache and stomach pain also since having the booster vaccine. The patient had fatigue, myocarditis, shortness of breath, tachycardia.<br><br>Patient has not tested positive for COVID-19 since having the vaccine.<br><br>Patient was not enrolled in clinical trial.<br><br>Patient stated that the report was related to possible inflammation of the heart (myocarditis or pericarditis) and diagnosis made by a medical professional (GP). Any imaging was not carried out (chest X-ray, echocardiogram, cardiac MRI, chest computerised tomography (CT)) at that time. Condition was still ongoing. No blood tests, such as for certain proteins (called troponin) that signal heart muscle damage taken.<br><br>Treatment product was not provided. | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company comment: This RA report concerns a 25 year old female with no reported medical history , who experienced Serious ( medically significant ) , expected , AESI event of myocarditis which occurred two days post vaccination with the 3rd dose of mRNA-1273 vaccine ( Moderna Covid 19 vaccine ) . This case was accompanied by other Serious ( medically significant ) , unexpected events of chest pain , abdominal pain upper, palpitations, tachycardia , dyspnea , fatigue , neck pain , back pain and headache . The diagnosis of myocarditis was confirmed by a physician however there were no laboratory tests or other diagnostic tests that were done. The re-challenge for this case is not applicable since the events occurred after the third dose and no additional doses will be given and also outcome of events had not fully recovered. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report..<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 09-Jan-2022: Follow up received included new event of neck pain was added and product indication, action taken and dechallenge was updated. | | |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 06-Jan-2022. The most recent information was received on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of ASTHENIA (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain), HEADACHE (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain), PYREXIA (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain) and PERICARDITIS (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain) in a 26-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 017G21A) for SARS-CoV-2 immunisation.<br><br>Previously administered products included for SARS-CoV-2 vaccination: SPIKEVAX (EX COVID-19 VACCINE MODERNA) - 0 and5 ML - [redacted] on 20-Apr-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX (EX COVID-19 VACCINE MODERNA) - 0 and5 ML - [redacted]<br>Concomitant products included LEVOTHYROXINE SODIUM (EUTIROX) from 09-Dec-2021 to 22-Dec-2021 for Hypothyroidism.<br><br>On 13-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 14-Dec-2021, the patient experienced ASTHENIA (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain) (seriousness criterion medically significant), HEADACHE (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain) (seriousness criterion medically significant), PYREXIA (First two days: headache, fever>38.5, | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain) (seriousness criterion medically significant) and PERICARDITIS (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain) (seriousness criterion medically significant). At the time of the report, ASTHENIA (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain), HEADACHE (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain), PYREXIA (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain) and PERICARDITIS (First two days: headache, fever>38.5, bone pain, chills, asthenia. Day 4: dyspnoea. 5 day: chest and retrosternal pain) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Dec-2021, Ultrasound abdomen: inconclusive (Inconclusive) Inconclusive.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Company comment: This regulatory authority case concerns a 26-year-old female patient with no relevant medical history who experienced serious expected AESI pericarditis, that started occurring approximately 1 day after the second dose of the mRNA-1273 . The benefit-risk relationship of mRNA-1273 is not affected by this report.<br>No treatment information was provided by the reporter.<br><br>The vaccine registry was verified and the dose was reported as Dose 2<br><br>Verified in vaccine registry, booster dose 2<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Jan-2022: Follow-up received on 07-Jan-2022, updated medical history and updated lab data results.<br>On 13-Jan-2022: Follow up received and contains no new information. | | |
| [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of PERICARDITIS (pericarditis) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011F21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for COVID-19 vaccination: COVID-19 VACCINE NRVV AD26i (first shot).<br>Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE NRVV AD26i. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Concurrent medical conditions included Fruit allergy (tree fruits) and Hay fever.<br>Concomitant products included MOMETASONE FUROATE (FLONASE [MOMETASONE FUROATE]) from 03-Jan-2015 to an unknown date for Seasonal allergy.<br><br>On 04-Jan-2022 at 5:15 PM, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 04-Jan-2022, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). On 05-Jan-2022, the patient experienced FEELING ABNORMAL (felt meh/felt under the weather), MUSCULOSKELETAL PAIN (Pain in upper left shoulder blade area), BACK PAIN (Pain in back) and NECK PAIN (Pain in neck.). On 05-Jan-2022 at 9:00 PM, the patient experienced PERICARDITIS (pericarditis) (seriousness criterion medically significant). The patient was treated with IBUPROFEN (ADVIL [IBUPROFEN]) on 07-Jan-2022 for Pericarditis, at an unspecified dose and frequency. On 04-Jan-2022, INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) had resolved. On 19-Jan-2022, PERICARDITIS (pericarditis) had resolved with sequelae. At the time of the report, FEELING ABNORMAL (felt meh/felt under the weather), MUSCULOSKELETAL PAIN (Pain in upper left shoulder blade area), BACK PAIN (Pain in back) and NECK PAIN (Pain in neck.) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 06-Jan-2022, Blood test: results not provided Results not provided.<br>On 06-Jan-2022, Electrocardiogram: results not provided Results not provided.<br>On 06-Jan-2022, X-ray: results not provided (Inconclusive) Results not provided.<br>On 10-Jan-2022, Echocardiogram: normal (normal) normal.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered PERICARDITIS (pericarditis) to be related. No further causality assessments were provided for FEELING ABNORMAL (felt meh/felt under the weather), MUSCULOSKELETAL PAIN (Pain in upper left shoulder blade area), BACK PAIN (Pain in back), NECK PAIN (Pain in neck.) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products).<br><br>Patient received the Moderna booster shot on 04-Jan-2022 and felt under the weather on Wednesday, but by late evening, experienced the pain in upper left shoulder blade area, back and neck. shallow breathing, shortness of breath, pressure in left side of chest. He also had chest discomfort, some chest pain, especially in upper back, also rapid heart beat, irregular heart rate/palpitations and chest tightness.<br><br>Company Comment: This is a spontaneous case of Interchange of vaccine products concerning a 22-year-old, male patient with no relevant medical history reported, who experienced the expected serious AESI pericarditis. The event occurred 1 day after the booster dose of mRNA-1273 vaccine. The patient had pain in upper shoulder blade area, back and neck, shallow breathing, pressure in left side of chest and some chest discomfort. He was brought to the | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Emergency room where chest x-ray, blood work and EKG were done, results were not provided and patient was released from ER and instructed to follow up with a cardiologist. EKG was done which was normal and patient was given ibuprofen. Event pericarditis resolved after 6 days. The patient received first dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>This case was linked to [redacted]Patient Link).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Jan-2022: Follow up received was NNI<br>On 19-Jan-2022: Follow up received wherein HCP added as secondary reporter, event pericarditis stop date and outcome updated, lab data added and treatment drug start date updated. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 35-year-old patient of an unknown gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>Concomitant products included LEVOTHYROXINE SODIUM (LEVOTHYROXINE [LEVOTHYROXINE SODIUM]) for Hypothyroidism.<br><br>In December 2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Jan-2022, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) and FATIGUE (Fatigue/unusual tiredness). At the time of the report, PERICARDITIS (Pericarditis) had not resolved and CHEST PAIN (Chest pain) and FATIGUE (Fatigue/unusual tiredness) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No- Negative COVID-19 test.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>Patient not had symptoms associated with COVID-19.<br><br>Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No treatment information was provided.<br><br>This is a regulatory case concerning a 35-year-old patient of unknown gender with no reported medical history, who experienced the non-serious expected AESI event of pericarditis and other non-serious events. The events occurred on unknown day after the third dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was reported as unknown; however, could be considered as not applicable since the events occurred after the third dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 06-Jan-2022. The most recent information was received on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), SYNCOPE (Fainting) and NAUSEA (Nausea) in a 39-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 4281509240) for an unknown indication.<br><br>Patient has not had symptoms associated with COVID-19.<br><br>On 21-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 22-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization and medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization and medically significant), SYNCOPE (Fainting) (seriousness criteria hospitalization and medically significant) and NAUSEA (Nausea) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving and FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), SYNCOPE (Fainting) and NAUSEA (Nausea) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: infection Result: Infection.<br>On an unknown date, Chest X-ray: myocarditis Result: Myocarditis.<br>On an unknown date, Electrocardiogram: myocarditis Result: Myocarditis.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No- Negative COVID-19 test. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Patient not had symptoms associated with COVID-19.<br><br>Concomitant product use was not provided by the reporter.<br><br>The patient woke up with nausea and bad palpitations and chest pains and attended to the emergency department. Blood test, chest X-ray and ECG were performed. Blood test showed infection and no information regarding the results of Chest X-ray and ECG were not provided. It was stated that the symptoms led to hospital stay, however, as per case description, the patient stayed in hospital one morning. The patient was diagnosed with myocarditis. Treatment medications included painkillers.<br><br>Company comment: This case concerns a 39-year-old female patient with no medical history provided, who experienced serious unexpected events of Fatigue, Chest pain, Dyspnoea, Palpitations, Tachycardia and Syncope. In addition, the patient experienced serious expected event of special interest Myocarditis which occurred the day after the patient had received the mRNA-1273 vaccine (as third dose, booster). According to the case narrative the patient woke up with nausea, bad palpitations and chest pains and attended to the emergency department. Blood test, chest X-ray and ECG were performed. Blood test showed infection (as stated), and no information regarding the results of Chest X-ray and ECG were not provided. The patient was diagnosed with myocarditis and stayed in hospital for one morning. Treatment medications included painkillers. At the time of this report, the event of Myocarditis was resolving, while the outcome of the remaining events was unknown. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Jan-2022: Significant follow-up received on 07-Jan-2022 which contains newevents details (nausea), serious criteria (hospitalization) and laboratory diagnosis was added. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain) and PERICARDITIS (Pericarditis) in a 22-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005686) for an unknown indication.<br><br>Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 12-Mar-2021 to 10-Jun-2021 for Immunization, DROSPIRENONE, ETHINYLESTRADIOL (YASMIN) for Polycystic ovaries.<br><br>On 14-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 16-Dec-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria disability and medically significant). On an unknown date, | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | the patient experienced CHEST PAIN (Chest pain) (seriousness criteria disability and medically significant). At the time of the report, CHEST PAIN (Chest pain) outcome was unknown and PERICARDITIS (Pericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: results not reported Results not reported.<br>On an unknown date, Echocardiogram: pericarditis pericarditis.<br>On an unknown date, Electrocardiogram: results not reported Results not reported.<br>On an unknown date, Magnetic resonance imaging: results not reported Results not reported.<br>On an unknown date, Troponin: normal (normal) normal.<br><br>48 hours after vaccine patient experienced bad chest pain, went to A and E and had bloods done. Ultimately an echocardiogram showed evidence of pericarditis.<br>No treatment information was provided.<br>Patient has not had symptoms associated with COVID-19 and not had a COVID-19 test.<br>Patient did not test positive for COVID-19 since having the vaccine.<br>Diagnosis of pericarditis by cardiologist, the patient had Cardiac MRI, Echo-cardiogram. ECG, blood tests, troponin was normal and the event did not lead to hospital stay.<br><br>Company comment:<br>This regulatory authority case concerns a 22-year-old female patient with no reported medical history and previous administration of COVID-19 Vaccine AstraZeneca, who experienced serious unexpected events of chest pain and expected AESI of pericarditis, that occurred approximately 2 days after the 3rd dose of the mRNA-1273 . Reportedly, 48 hours following vaccination, the patient experienced bad chest pain and went to A&E and had blood work done. Ultimately, an echocardiogram showed pericarditis. The rechallenge was not applicable due to occurrence after the 3rd dose. The regulatory authority assessed the rechallenge as unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness as per regulatory authority.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Jan-2022: Follow up received contains additional laboratory data and update action taken. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted]) on 07-Jan-2022. The most recent information was received on 09-Jan-2022 and was forwarded to Moderna on 09-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (breathlessness), SINUS TACHYCARDIA (sinus tachycardia), FATIGUE (Fatigue), CHEST PAIN (Chest Pain) and MYOCARDITIS (Myocarditis) in a 39-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>Concomitant products included PREGABALIN for Hemicrania. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | In 2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. In 2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced DYSPNOEA (breathlessness) (seriousness criterion medically significant), SINUS TACHYCARDIA (sinus tachycardia) (seriousness criterion medically significant), FATIGUE (Fatigue) (seriousness criterion medically significant) and CHEST PAIN (Chest Pain) (seriousness criterion medically significant). At the time of the report, DYSPNOEA (breathlessness), SINUS TACHYCARDIA (sinus tachycardia), FATIGUE (Fatigue) and CHEST PAIN (Chest Pain) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Dec-2021, Electrocardiogram: sinus tachycardia sinus tachycardia.<br>On an unknown date, Fibrin D dimer: negative (Negative) Negative.<br>On an unknown date, Heart rate: 100 100 bpm.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No medical history was reported.<br>The patient developed central chest pain and exertional breathlessness. Investigated in 1' care - 12 lead electrocardiogram (ECG) showed sinus tachycardia 100 beats per minutes (bpm), negative D-Dimer. Fatigue..<br>This report was related to possible myocarditis or pericarditis.<br>The patient was not admitted to hospital and not seen by a cardiologist.<br>The patient was treated with NSAIDS.<br>ECG was carried out, "20 Dec 2021 - sinus tachycardia".<br>Tests like troponin measurement, Chest X-ray, Echocardiogram, Chest Computed Tomography, MRI, Cardiac Biopsy, Coronary angiography were not performed.<br>There was no presence of pericardial rub, or changes in heart sounds.<br>The patient also had sinus tachycardia 100 BPM.<br><br>Company comment: This regulatory authority case concerns 39-years-old, female patient with no reported medical history, who experienced the expected serious AESI event of Myocarditis and unexpected serious event of Dyspnea, Sinus Tachycardia, Chest pain, Fatigue and Tachycardia (seriousness criterion medically significant). The events occurred on unknown date after the third dose mRNA- 1273 vaccination and the outcome was reported as unknown. Patient had a central chest pain, fatigue and exertional dyspnea. Patient went to primary care, 12 lead ECG showed sinus tachycardia 100 bpm and negative D-Dimer test. The case was assessed as serious as per Regulatory Authority's report due to important medical event. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |

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| | Most recent FOLLOW-UP information incorporated above includes:<br>On 09-Jan-2022: Significant Follow up received. Events Dyspnoea and Tachycardia were deleted as per the new source document. Lab tests were added. Suspect drug indication, action taken and de-challenge were updated. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 07-Jan-2022. The most recent information was received on 09-Jan-2022 and was forwarded to Moderna on 09-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), IRREGULAR BREATHING (irregular breathing), DIZZINESS (dizziness), SYNCOPE (Fainting) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005287) for an unknown indication.<br><br>The patient's past medical history included Suspected COVID-19 from 10-Jul-2021 to 18-Jul-2021.<br><br>On 20-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 30-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant), IRREGULAR BREATHING (irregular breathing) (seriousness criterion medically significant), DIZZINESS (dizziness) (seriousness criterion medically significant) and SYNCOPE (Fainting) (seriousness criterion medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and SYNCOPE (Fainting) outcome was unknown, IRREGULAR BREATHING (irregular breathing) and DIZZINESS (dizziness) was resolving and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: yes - positive covid-19 test (Positive) Yes - Positive COVID-19 test.<br>No concomitant product was provided.<br><br>The patient had some heart palpitations, chest pains, dizziness, irregular breathing and heart beating. At the moment the patient still had some minor chest stings. This report related to possible inflammation of the heart (myocarditis or pericarditis). The last date of administration of Covid 19 vaccine Moderna was on 20 Dec 2021. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Were any blood tests, such as for certain proteins (called troponin) that signal heart muscle damage taken?: "No"<br><br>Patient had not tested positive for COVID-19 since having the vaccine.<br><br>Patient was not enrolled in clinical trial.<br><br>No treatment information was provided.<br><br>Company comment: This regulatory authority case concerns a 37-year-old, male patient with no relevant medical history, who experienced the unexpected serious events of Dizziness, Irregular breathing, Fatigue, Chest pain, Dyspnoea, Palpitations, Syncope and Tachycardia, and expected serious AESI event of Myocarditis. The event Myocarditis occurred 10 days after the third dose of mRNA 1273 vaccine. The events Dizziness, Irregular breathing, Fatigue, Chest pain, Dyspnoea, Palpitations, Tachycardia and Syncope occurred on an unknown date after the third mRNA- 1273 vaccine. The diagnosis of myocarditis was not made by a professional and no tests were done to confirm the diagnosis. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. The seriousness criteria of the events were assessed as per regulatory authority report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 09-Jan-2022: Follow up received included action taken of suspect and clinical course of narrative was updated. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 09-Jan-2022 and was forwarded to Moderna on 09-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest Pain) and PERICARDITIS (Pericarditis) in a 22-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 83Ji229E) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 05-Jan-2022, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced PERICARDITIS (Pericarditis). On an unknown date, the patient experienced CHEST PAIN (Chest Pain). On 07-Jan-2022, PERICARDITIS (Pericarditis) had not resolved. At the time of the report, CHEST PAIN (Chest Pain) outcome was unknown.<br><br>The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | The concomitant medication was not reported.<br>Patient had suffered sharp positional chest pain starting in the evening after vaccine, no shortness of breath or leg swelling.<br>Patient had not tested positive for COVID-19 since having the vaccine.<br>Patient was not enrolled in clinical trial.<br>The report was not related to possible blood clots or low platelet counts. The report was related to possible myocarditis or pericarditis. Patient took treatment of NSAID. ECG, Chest X-ray, Cardiac MRI, Cardiac Biopsy, Coronary angiography were not performed.<br>Presence of pericardial rub, or changes in heart sounds was unknown. Patient was asymptomatic.<br>Company comment: This regulatory case concerns a 22-year-old male patient, with no medical history reported, who experienced the non-serious expected event of PERICARDITIS. The event occurred on the same day of the third dose of mRNA-1273. The event CHEST PAIN is also reported. The rechallenge is reported unknown, but it could be considered as not applicable since no information about further dosing has been disclosed. The benefit-risk relationship of the mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted]) on 09-Jan-2022. The most recent information was received on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (Short of breath), PYREXIA (Feverish), MYOCARDITIS (Myocarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations) and SYNCOPE (Fainting) in a 21-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000022A) for COVID-19 vaccination.<br><br>Concomitant products included TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 17-Aug-2021 to 17-Aug-2021 and TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 17-Jun-2021 to 17-Jun-2021 for COVID-19 vaccination.<br><br>On 21-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced DYSPNOEA (Short of breath) (seriousness criteria hospitalization, disability and medically significant), PYREXIA (Feverish) (seriousness criteria hospitalization, disability and medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization, disability and medically significant), CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization, disability and medically significant) and SYNCOPE (Fainting) (seriousness criteria hospitalization, disability and medically significant). At the time of the report, DYSPNOEA (Short of breath) and | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | PYREXIA (Feverish) was resolving, MYOCARDITIS (Myocarditis) had resolved with sequelae and FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations) and SYNCOPE (Fainting) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Dec-2021, SARS-CoV-2 test: negative (Negative) no - Negative COVID-19 test.<br>On an unknown date, Blood test: result not reported Result not Reported.<br>On an unknown date, Echocardiogram: normal (normal) normal.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) myocarditis/pericarditis.<br><br>Day of booster became very feverish for 3 days with very sore jabbed arm, essentially unable to leave bed, even with paracetomol & ibuprofen. Fainted whilst feeling nautious the evening of the jab. On 23rd/24th of December 2021 noticed weird sensation in heart/sternum area of feeling very week/fluttery with achey pains in vicinity and feeling very short of breath. This worsened steadily until he went to A&E on advice from [redacted] to have ECG, blood pressure, X-ray, blood tests, stethoscope - all came back fine and doctor suggested that cause could be immune related inflammation of cartilage in sternum resulting in pressure in chest area.<br><br>Company Comment: This regulatory case concerns a 21-year-old male patient, with no reported medical history, with an Interchange of vaccine products two doses was with TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2),4 months before current vaccination, who experienced the unexpected serious events of Dyspnoea, Pyrexia, Fatigue, Chest pain and Palpitations, expected serious AESI event of Myocarditis and expected serious event of Syncope. The events started on the following day, and on the next 3 days after the administration of the third dose of mRNA-1273 vaccine. Patient went to A&E on 27/12/21 as previously recorded. Discharged with diagnosis of inflamed sternum cartilage and told to take ibuprofen/paracetomol to manage discomfort. Spoke to GP, on monday 10/12/21 as chest pain continued. Advised to get blood test & ECG on 12/1/21. Blood test taken, ECG done - cardiologist diagnosed him with myocarditis/pericarditis and said he could spend the night in hospital, but he chose to be discharged that day. Had echocardiogram which came back all good looking for fluid buildup. Discharged with 2x colchichine daily for 2-3 months & 3x900g aspirin daily for at least 1 week. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority´s report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Jan-2022: Except SARS-CoV-2 test rest all laboratory data added. Concomitant drugs added. Suspect drug action taken and indication updated. Pyrexia and Dyspnoea removed as an event. Additional relevant information added in inarrative. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis), CARDIAC FLUTTER (Heart fluttering), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), DYSPNOEA | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | (Shortness of breath) and PALPITATIONS (Heart palpitations) in a 19-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3006325) for an unknown indication.<br><br>Concomitant products included TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 29-Jun-2021 to an unknown date for an unknown indication.<br><br>On 08-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 08-Jan-2022, the patient experienced CARDIAC FLUTTER (Heart fluttering) (seriousness criterion medically significant). On an unknown date, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), PYREXIA (Fever) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant) and PALPITATIONS (Heart palpitations) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (myocarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), DYSPNOEA (Shortness of breath) and PALPITATIONS (Heart palpitations) outcome was unknown and CARDIAC FLUTTER (Heart fluttering) was resolving.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>No treatment medication was provided.<br><br>The patient felt two instances of heart fluttering and momentary faintness about 6 hours after booster dose administrated.<br>The patient was not enrolled in clinical trial<br>There was possible inflammation of the heart (myocarditis or pericarditis).<br>Company comment: This is a regulatory authority case concerning a 19-years-old female patient, with no medical history reported in the case and previously vaccinated with COVID-19 MRNA VACCINE BIONTECH, who experienced the serious expected AESI of Myocarditis, the serious unexpected AESI of Cardiac flutter and the serious unexpected events of Fatigue, Chest pain, Pyrexia, Dyspnoea and Palpitations. The event Cardiac flutter occurred approximately one day after the administration of the third dose of mRNA-1273 vaccine and the rest of the events occurred on an unknown date. The events were assessed with the seriousness criteria of Medically Significant by the reporter and, at the time of the report, the outcome for the event Cardiac flutter was Recovering/Resolving and for the events Myocarditis, Fatigue, Chest pain, Pyrexia, Dyspnoea and Palpitations Unknown. No further information on clinical course, diagnostic tests performed, or treatment details were disclosed. The rechallenge | | |

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| | was reported as Unknown. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Increasingly intense chest pains going from a level 3 to 8 in a few days. Call for an ambulance in emergency for fear of stroke Hospitalization and treatment of 3 months for a perica) in a 36-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3004494 and 3004494) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 24-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day.<br>On 22-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 25-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Increasingly intense chest pains going from a level 3 to 8 in a few days. Call for an ambulance in emergency for fear of stroke Hospitalization and treatment of 3 months for a perica) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Increasingly intense chest pains going from a level 3 to 8 in a few days. Call for an ambulance in emergency for fear of stroke Hospitalization and treatment of 3 months for a perica) had not resolved.<br><br>No concomitant medication was provided by reporter.<br>No treatment drug was provided by reporter.<br>The patient was vaccinated on 24-Sep-2021 (1st dose) and 22-Oct-2021 (2nd dose) with Spikevax and experienced, after 4 days of latency from the end of the vaccination cycle (on 25-Oct-2021), a pericarditis, the diagnosis of which was made as a result of hospitalization. The patient would have received a 3-month therapy for the adverse event described and manifested with chest tenderness Chest pain more and more intense going from level 3 to 8 in some days. Received call for an emergency ambulance by AVC Hospitalization crainte and treatment of 3 months for a pericarditis.<br><br>Company comment: This is a regulatory case concerning a 36 year-old, male patient with no reported medical history, who experienced the serious (due to medically important condition and hospitalization) expected, AESI of Pericarditis. The event occurred approximately 3 days after the second dose of mRNA-1273 vaccine. The outcome of the event was reported as not recovered. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| [redacted] | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 32-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Jul-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form once a day. On 17-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criterion hospitalization). In July 2021, MYOCARDITIS (Perimyocarditis) had resolved.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered MYOCARDITIS (Perimyocarditis) to be possibly related.<br><br>Concomitant medications were not reported.<br><br>Company comment: This is a regulatory case concerning a 32 year-old, male patient with no reported medical history, who experienced the serious (due to hospitalization) expected, AESI of Myocarditis. The event occurred approximately 3 days after the second dose of mRNA-1273 vaccine. Treatment with Anti-inflammatory therapy, beta blocker and colchicine was prescribed and the outcome of the event was reported as recovered. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Perimyocarditis is likely to be post-vaccination.<br>Treatment information includes analgesics, anti-inflammatory therapy, beta blocker, brufen and colchicine. patient further titrate beta-blocker therapy and begin decalage of NSAID therapy. Colchicine will be continued for 3 months and beta blocker was used in order to reduce adrenergic stimulus, in preventing arrhythmias during fibrosis and the treatment leads to complete regression of symptoms.<br><br>Diagnostic tests includes electrocardiogram showed concave elevation in dLi, DLi, aVF, V4-V5-V6 and underleveling in V1 with descending PR tract as well as a course of myocaridocytonecrosis enzymes with troponin nadir at 239 ng/1. MRI confirms clinical suspicion of myocarditis, documenting minimal sub epicardial/mediomural necrosis/myocardial fibrosis in the mediomural and mediomural interolateral wall compatible with mild myocarditis in the absence of changes or significant reduction in left ventricular function (FE 57%) and slight increase in inflammatory parameters also. On 19 July 2021 patient performed cardio MRI which shows normal size and heart rate and FE 63% without pericardial effusion and Eco cardio TT also shows no valve defects or pericardial effusion with FE 57%. | 32-year-old male patient, with unknown medical history, who 3 days aftre the 2nd dose of Spikevax expereinced febrile state and epigastric pain, irradiating to the jubuli, shoulders and in interscapular region and was found to have elevated troponin, abnormal ECG, abnormal echo, and aabnormal cMRI and was diagnosed with MYOPERICARDITIS. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and cMRI results; a causal relationship cannot be excluded | [redacted] |

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| | Patient also had febrile state and epigastric pain, irradiating to the jubuli, shoulders and in interscapular region after vaccination. Patient not had any major cardiological or internistic background but transferred to Intense Care for myopericarditis.<br><br>During the treatment indices of phlogosis and myocardiocytonecrosis enzymes normalize and arrhythmias and telemetric monitoring is not documented. Patient back to home on 21 July 2021 with stable condition after giving asymptomaticity and circulation compensation. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of PULMONARY EMBOLISM (Pulmonary Embolism), VACCINATION COMPLICATION (covid-19 vaccine causing adverse effect in therapeutic use) and MYOCARDITIS (myocarditis) in a 39-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 049F21A) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 04-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 04-Dec-2021, the patient experienced PULMONARY EMBOLISM (Pulmonary Embolism) (seriousness criterion medically significant), VACCINATION COMPLICATION (covid-19 vaccine causing adverse effect in therapeutic use) (seriousness criterion medically significant) and MYOCARDITIS (myocarditis) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (Pulmonary Embolism), VACCINATION COMPLICATION (covid-19 vaccine causing adverse effect in therapeutic use) and MYOCARDITIS (myocarditis) outcome was unknown.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant drug information provided.<br>No treatment drug information provided.<br>Patient experienced body redness, facial redness, nausea, feeling vomiting, dizziness, headache, feeling body hot, it look likes fainting. Lab data includes EKG 12 Lead NSR HR72 bmp Trop I Neg D-dimer Normal tested on an unknown date. Patient received treatment on 04-DEC-2021.<br><br>This is a regulatory authority case concerning a 39-year-old, female patient with no relevant medical history, who experienced the unexpected serious events of Pulmonary embolism, Vaccination complication and expected serious event of myocarditis. The events occurred approximately on the same day after the third dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was unknown since no information about the first dose was disclosed. The events outcome were reported as unknown. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 36-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214016) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: Moderna Vaccine (Dose 1: Moderna Vaccine, 02/08/2021, Left Arm, Intramuscular Injection and Lot No: 214011.) on 02-Aug-2021.<br>Past adverse reactions to the above products included No adverse event with Moderna Vaccine.<br><br>On 30-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>No treatment information was provided<br>Company comment: This is a regulatory case concerning a 36-year-old, male patient with no medical history reported, who experienced the serious expected, according CCDS, AESI of Myocarditis. The event occurred approximately 3 days after the second dose of mRNA-1273 vaccine. The rechallenge was reported as unknown. The case was assessed as serious as per Regulatory Authority's report due to hospitalization. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. . | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 36-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003181) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 19-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had resolved. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported.<br>No treatment information reported.<br><br>Company comment: This case concerns a 36-year-old male patient, with no medical history reported in this case, who experienced the serious expected event of Pericarditis (AESI). The event occurred on an unknown date after the administration of the second dose of the mRNA-1273 Vaccine. The event was assessed with the seriousness criteria of Medically Significant by the reporter, and, at the time of the report the outcome of the event was reported as Recovered/Resolved. No further information on clinical course, diagnostic test (if performed) or treatment details were disclosed. The rechallenge was reported as Unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via Zuellig Pharma (Reference number: [redacted] on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (chest tightness), DYSPNOEA (difficulty in breathing), CHEST PAIN (left chest pain to the left jaw and left arm), PAIN IN JAW (left chest pain to the left jaw and left arm), PAIN IN EXTREMITY (left chest pain to the left jaw and left arm) and MYOCARDITIS (Probable myocarditis) in a 26-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3005841) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 03-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 09-Dec-2021, the patient experienced CHEST DISCOMFORT (chest tightness) (seriousness criterion medically significant), DYSPNOEA (difficulty in breathing) (seriousness criterion medically significant), CHEST PAIN (left chest pain to the left jaw and left arm) (seriousness criterion medically significant), PAIN IN JAW (left chest pain to the left jaw and left arm) (seriousness criterion medically significant), PAIN IN EXTREMITY (left chest pain to the left jaw and left arm) (seriousness criterion medically significant) and MYOCARDITIS (Probable myocarditis) (seriousness criterion medically significant). At the time of the report, CHEST DISCOMFORT (chest tightness), DYSPNOEA (difficulty in breathing), CHEST PAIN (left chest pain to the left jaw and left arm), PAIN IN JAW (left chest pain to the left jaw and left arm), PAIN IN EXTREMITY (left chest pain to the left jaw and left arm) and MYOCARDITIS (Probable myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 09-Dec-2021, Troponin T: 151.4 (Inconclusive) 151.4.<br>On 10-Dec-2021, Troponin T: 139.5 (Inconclusive) 139.5. | 26-year-old female patient, with unknown medical history, who 6 days after the 3rd dose of Spikevax experienced chest pain, chest discomfort, dypsnoea, and was found to have elevated troponin and was diagnosed with MYOCARDITIS. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication provided.<br>Date of treatment :2021-12-09<br>Each time the pain was approximately 30 minutes since 08:00 am of 09/12/21 after receiving the third dose of Moderna vaccine on 03/12/2021.<br>Serial number was provided as STV000649.<br><br>Company comment:<br>This regulatory case concerns a 26-year-old, female patient with no reported medical history, who experienced the unexpected, serious (Medically significant) events of dyspnoea, pain in jaw, pain in extremity, chest pain and expected, according CCDS, serious (Medically significant) AESI of Myocarditis, among others. The events occurred 6 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient COVID-19 vaccination schedule. It was reported that troponin T was increased 6 days after vaccination. Regulatory authority reported the diagnosis as probable myocarditis. It was not reported if the previous two doses of her COVID-19 vaccination schedule were mRNA-1273 vaccines as well. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis), OLIGOMENORRHOEA (menstrual cycles), COVID-19 (SARS-CoV-2 infection), LYMPHADENOPATHY (Swollen lymph nodes) and MENSTRUATION DELAYED (Late period) in a 27-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000014A) for an unknown indication.<br><br>Co-suspect product included non-company product TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 14-Jul-2021, the patient received second dose of TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) (unknown route) 1 dosage form.<br>On 05-Dec-2021, received first dose of TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) (unknown route) dosage was changed to 1 dosage form.<br>On 07-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 07-Nov-2021, the patient experienced COVID-19 (SARS-CoV-2 infection). On an unknown date, the patient experienced MYOCARDITIS (Myocarditis), OLIGOMENORRHOEA (menstrual cycles), LYMPHADENOPATHY (Swollen lymph nodes) and MENSTRUATION DELAYED (Late period). At the time of the report, MYOCARDITIS (Myocarditis) and OLIGOMENORRHOEA (menstrual cycles) had not | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | resolved, COVID-19 (SARS-CoV-2 infection) and MENSTRUATION DELAYED (Late period) had resolved and LYMPHADENOPATHY (Swollen lymph nodes) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Nov-2021, SARS-CoV-2 test: yes - positive covid-19 test (Positive) Positive.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>After the 1st and 2nd vaccines, patient had delayed periods. Both menstrual cycles were delayed which caused both cycles to be roughly 40-50 days instead of 21-28 days.<br><br>Both vaccines and the booster vaccine caused swollen lymph nodes in patient's arm, armpit and neck.<br><br>Patient was not enrolled in clinical trial<br><br>No concomitant medication details were provided by reporter.<br><br>No treatment medication details were provided by reporter.<br>Company comment: This is a regulatory case concerning a 27-year-old, female patient with no medical history reported, with an interchange of vaccine products (two doses was with COVID-19 MRNA VACCINE BIONTECH, approximately 1 month before current vaccination) who experienced the non-serious expected , according to CCDS, AESI of Myocarditis and the non – serious unexpected , according CCDS, AESI of COVID-19. The event COVID-19 (7-NOV-2021) occurred before third dose of mRNA-1273 vaccine (7-JAN-2022) and after COVID-19 MRNA Vaccine BNT162B2 (14-JUL-2021), and at the time of the report, the outcome of the event COVID-19 was recovered/ resolved. No onset date was provided for Myocarditis reported. The event COVID-19 could be in association with event Myocarditis. The rechallenge was reported as unknown. The case was assessed as non-serious as per Regulatory Authority's report. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (Difficulty breathing), PERICARDITIS (Pericarditis), the first episode of DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), the second episode of DYSPNOEA (Shortness of breath) and TACHYCARDIA (Racing heart (tachycardia)) in a 40-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000014A) for an unknown indication. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | The patient's past medical history included Knee operation.<br><br>On 20-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced the first episode of DYSPNOEA (Shortness of breath) (seriousness criterion medically significant). On an unknown date, the patient experienced DYSPNOEA (Difficulty breathing) (seriousness criterion medically significant), PERICARDITIS (Pericarditis) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), the second episode of DYSPNOEA (Shortness of breath) (seriousness criterion medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant). At the time of the report, DYSPNOEA (Difficulty breathing) and PERICARDITIS (Pericarditis) was resolving and FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), the last episode of DYSPNOEA (Shortness of breath) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) Negative.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>patient felt unwell and had shortness of breath and a tight chest. On 27-Dec-2021 the patient rang[redacted] and was advised to attend A and E. The wait time was too long so he returned home and started to feel better after a few days. He went to A and E and they took blood tests, ECG and a chest X-ray. All came back fine but the symptoms all suggested pericarditis he was advised to rest and take ibuprofen. The patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. The diagnosis and any specific details of the diagnosis were given by doctor at A and E. Patient was on treatment medication "Ibuprofen". CC: This case concerns a 40-year-old male patient, with no relevant medical history reported in this case, who experience the serious unexpected events of Dyspnoea (reported as Difficulty breathing), Pericarditis (AESI), the first episode of Dyspnoea (Reported as Shortness of breath), Fatigue, Chest Pain and the second episode of Dyspnoea (Reported as Shortness of breath) and Tachycardia. The events Dyspnoea (reported as Difficulty breathing), Pericarditis (AESI), Fatigue, Chest Pain and the second episode of Dyspnoea (Reported as Shortness of breath) and Tachycardia occurred in an unknown date and the outcome at the time of the report was Recovering/Resolving for Dyspnoea (reported as Difficulty breathing) and Pericarditis and was Unknown for the events Fatigue, Chest Pain and the second episode of Dyspnoea (Reported as Shortness of breath) and Tachycardia. The event first episode of Dyspnoea (Reported as Shortness of breath) occurred approximately 4 days after the administration of the 3rd dose of the mRNA-1273 vaccine and the outcome at the time of the | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | report was Not Recovered/Not Resolved. The rechallenge could be considered not applicable since the events occurred after the 3rd dose and no additional dosing will be given. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ANGINA PECTORIS (heart pain), MYOCARDITIS (Myocarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) in a 28-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005688) for an unknown indication.<br><br>The patient's past medical history included Heart rate.<br>Concurrent medical conditions included Low blood pressure.<br>Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 18-Jun-2021 to an unknown date for COVID-19 vaccination.<br><br>On 16-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 03-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). On an unknown date, the patient experienced ANGINA PECTORIS (heart pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization, disability, medically significant and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability, medically significant and life threatening), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization, disability, medically significant and life threatening) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, ANGINA PECTORIS (heart pain), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>Patient had no history of heart conditions. He was a very fit and healthy person prior and now he had debilitating heart pain and palpitations and shortness of breath. It had been two weeks since onset of symptoms and it was getting progressively worse. The symptoms lead to a | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | hospital stay for 2 days. It was related to possible inflammation of the heart (myocarditis or pericarditis).<br>Treatment for the events included ibuprofen.<br>Laboratory data included chest X-ray and ECG<br><br>Company Comment: This regulatory case concerns a 28-year-old male patient with past medical history of Heart rate and Concurrent medical conditions of Low blood pressure, with an Interchange of vaccine products two doses of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) 3 months and 25 days before the current vaccination, who experienced the unexpected serious events of Angina pectoris, Fatigue, Chest pain, Dyspnoea, Palpitations and Tachycardia and expected serious AESI event of Myocarditis. The events Angina pectoris, Fatigue, Chest pain, Dyspnoea, Palpitations and Tachycardia occurred on an unknown date and the event Myocarditis occurred 18 days after the third dose of mRNA-1273 vaccine. Patients medical history and Interchange of vaccine products remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority´s report due to important medical condition, hospitalization, disability and life threatening.<br><br>.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 12-Jan-2022: Follow up information received on 12-Jan-2022, included Action taken was updated | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (headache), COUGH (cough), MYOCARDITIS (Perimyocarditis), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations) and TACHYCARDIA (Tachycardia) in a 38-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>Concurrent medical conditions included Suspected COVID-19 since 09-Jan-2022.<br>Concomitant products included TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for an unknown indication.<br><br>On 22-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced HEADACHE (headache) (seriousness criterion hospitalization), COUGH (cough) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), CHEST PAIN (Chest Pain) (seriousness criterion hospitalization), PYREXIA | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | (Fever) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), PALPITATIONS (Palpitations) (seriousness criterion hospitalization) and TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization). At the time of the report, HEADACHE (headache) and COUGH (cough) had resolved, MYOCARDITIS (Perimyocarditis) had not resolved and FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations) and TACHYCARDIA (Tachycardia) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 10-Jan-2022, SARS-CoV-2 test: no (Negative) Negative COVID-19 test.<br>On an unknown date, Electrocardiogram: result not reported Result not reported.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>The patient looked unwell and distressed, he was hot to touch and having temperature of 39.6. He had no DIB, no SOB, chest clear no sounds added, had red, painful throat with cough. His liver function test was negative. He had been taken COVID- 19 mRNA (nucleoside modified) Vaccine Moderna 0.1 mg / 0.5 mL dose dispersion for injection multidose vials booster on 22-Dec-2021. He had left side chest pain going to the throat and left arm, was 7/10 and worsening on lying position, which was better on sitting position. He also had tachycardia 124, ECG ST elevation in V2, V3, V4, possible pericarditis or myocarditis post COVID-19 booster complication. The patient had headache, dizziness no LOC, fast negative pearla, no rash. He was treated with painkillers (Ibuprofen 400mg and Paracetamol 1g) then conveyed to hospital for investigation and treatment. Patient had not tested positive for COVID-19 since having the vaccine and was not enrolled in clinical trial.<br>Company comment: This regulatory case concerns a 38-year-old male patient, with no relevant medical history, who experienced the serious unexpected events of HEADACHE, COUGH, FATIGUE, CHEST PAIN, PYREXIA, DYSPNOEA, PALPITATIONS and TACHYCARDIA, and the serious expected AESI of MYOCARDITIS. The event MYOCARDITIS occurred eighteen days after the third dose of mRNA-1273 vaccine. The events HEADACHE, COUGH, FATIGUE, CHEST PAIN, PYREXIA, DYSPNOEA, PALPITATIONS and TACHYCARDIA occurred after an unknown time interval after the third dose of the mRNA-1273 vaccine. The rechallenge is reported unknown, but it could be considered as not applicable since no information about further dosing has been disclosed. On an unknown date an electrocardiogram was performed with no result reported. A SARS-CoV-2 test with negative result, was performed on the following day that the event MYOCARDITIS started.The concomitant COVID-19 MRNA VACCINE remains a confounder.The benefit-risk relationship of the mRNA-1273 is not affected by this report. | | |

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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 12-Jan-2022 and was forwarded to Moderna on 12-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (heart muscle inflammation) in a 38-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Spinal muscular atrophy.<br><br>On 26-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (heart muscle inflammation) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (heart muscle inflammation) had not resolved.<br><br>mRNA-1273 (Spikevax) (Unknown) dosing remained unchanged.<br><br>No concomitant medications were provided by the reporter.<br>No treatment information was provided by the reporter.<br><br>Company comment: This is a regulatory case concerning a 38-year-old male patient with medical history of spinal muscular atrophy, who experienced the unexpected serious AESI of Myocarditis approximately four days after the third dose of mRNA-1273 vaccine. The patient was hospitalized and did not recover from the event at the time of report. Patient's medical history remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 12-Jan-2022. The most recent information was received on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of HEART RATE INCREASED (heart rate), CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), HYPERTENSION (Blood pressure high) and MYOCARDITIS (Myocarditis) in a 32-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 06-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 10-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced HEART RATE INCREASED (heart rate) (seriousness criteria | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization and medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization and medically significant) and HYPERTENSION (Blood pressure high) (seriousness criteria hospitalization and medically significant). At the time of the report, HEART RATE INCREASED (heart rate) had not resolved, CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and HYPERTENSION (Blood pressure high) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>The patient felt as though he was not getting any blood to his heart. Felt like he was about to have a heart attack. Had to go to A&E. Got examined and heart rate fell back down. 24 hours later and still do not feel 100 percent.<br>Patient has not tested positive for COVID-19 since having the vaccine.<br>Patient has not had symptoms associated with COVID-19. Not had a COVID-19 test.<br><br>This report was relate to possible inflammation of the heart (myocarditis or pericarditis).<br>The patient stayed in the hospital for few hours.<br>The patient had ECG, result not provided.<br><br>No concomitant medication was reported.<br>No treatment information was reported.<br><br>Company comment: This case refers to a 32-year-old male patient with no known medical history who experienced the serious unexpected events of Heart rate increased, Chest pain, Palpitations, Tachycardia and the expected event of Myocarditis. Myocarditis occurred approximately 4 days after the third dose of mRNA-1273 vaccine while the events of Heart rate increased, Chest pain, Palpitations and Tachycardia occurred on unknown date after the vaccine. The patient experienced high blood pressure and elevated heart rate hence he went to the emergency department, stayed for a few hours and his heart rate fell back to normal. Myocarditis was not diagnosed by a medical professional, ECG was done but no results were provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 13-Jan-2022: Follow up appended includes events and action taken updated | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 12-Jan-2022. The most recent information was received on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) in a 27-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 21-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant) and CHEST PAIN (Chest pain) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.<br><br>Concomitant product use was not provided by the reporter.<br><br>The patient was very fit young male received booster Tue 21st Dec.<br><br>Patient experienced mild chest pain Fri 24th Dec, ongoing since then.<br><br>Patient has not tested positive for COVID-19 since having the vaccine.<br><br>Patient was not enrolled in clinical trial.<br><br>Company Comment: This case refers to a 27-year-old male patient with no known medical history who experienced the serious, expected AESI event of Myocarditis and serious unexpected event of Chest pain. The events occurred 3 days after the third dose of mRNA-1273 vaccine. Patient had mild chest pain and is still ongoing. Myocarditis was not diagnosed by a medical professional, no imaging was done. At the time of report, events had not resolved. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 13-Jan-2022: Follow up received included seriousness criteria, suspect drug indication, action taken, event onset date, outcome and narrative was updated. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022.<br>This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PARAESTHESIA (Tingling in cheek), HYPOAESTHESIA | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | (Numb sensation in the forearm), CHEST DISCOMFORT (Constant pressure across the chest) and MYOCARDITIS (Cardiac muscle inflammation) in a 29-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 in December 2020.<br><br>On 19-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Oct-2021, the patient experienced PARAESTHESIA (Tingling in cheek) (seriousness criterion hospitalization), HYPOAESTHESIA (Numb sensation in the forearm) (seriousness criterion hospitalization), CHEST DISCOMFORT (Constant pressure across the chest) (seriousness criterion hospitalization) and MYOCARDITIS (Cardiac muscle inflammation) (seriousness criterion hospitalization). On 05-Oct-2021, PARAESTHESIA (Tingling in cheek), HYPOAESTHESIA (Numb sensation in the forearm), CHEST DISCOMFORT (Constant pressure across the chest) and MYOCARDITIS (Cardiac muscle inflammation) had resolved.<br><br>Concomitant medications were not reported.<br>Treatment information was not provided.<br>Company comment: This is a regulatory case concerning a 29-year-old, male patient with a history of COVID-19, who experienced the serious expected, according CCDS, AESI of Myocarditis and the serious unexpected, according CCDS, events of Paraethesia, Hypoaesthesia and Chest discomfort. The event occurred approximately 74 days after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable since the events happened after the second dose and no information on additional dosing is available. The medical history of COVID-19 remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority's report due to hospitalization. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and TROPONIN INCREASED (Troponin increased) in an 18-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 06-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. | 18-year-old male patient, with unknown medical history, who 3 days after the 3rd dose of Spikevax experienced chest pain, purexia, fatigue, palpitations, dypsnoea, tachycardia, and was found to have elevated troponin, abnormal ECG, normal echo and was diagnosed with MYOCARDITIS. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On an unknown date, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). On an unknown date, the patient experienced FATIGUE (Fatigue) (seriousness criteria hospitalization, disability, medically significant and life threatening), CHEST PAIN (Chest Pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), PYREXIA (Fever) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization, disability, medically significant and life threatening), PALPITATIONS (Palpitations) (seriousness criteria hospitalization, disability, medically significant and life threatening), TACHYCARDIA (Tachycardia) (seriousness criteria hospitalization, disability, medically significant and life threatening) and TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and TROPONIN INCREASED (Troponin increased) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 09-Jan-2022, Troponin: high (High) n elevation to 8000 (peak) ng/L.<br>On an unknown date, Blood test: not provided not provided.<br>On an unknown date, Chest X-ray: normal (normal) Normal.<br>On an unknown date, Echocardiogram: normal (normal) Normal Lv function.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Lateral ST segment elevation.<br>On an unknown date, Investigation: presence of pericardial rub presence of pericardial rub, or changes in heart sounds and ectopy, no heart failure or arrhythmia Ectopy, no heart failure or arrhythmia.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On an unknown date, Troponin: all over 5,000 including at discharge (serial) (Inconclusive) All over 5,000 including at discharge (serial).<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>The patient had relevant investigations or tests conducted included Echo / bloods. He was admitted to hospital and was hospitalized, for 4 days. He was seen by cardiologist and was diagnosed with Myocarditis.The treatment provided included Steroids / NSAIDS / colchicine. On 09-Jan-2022, cardiac troponin was measured, and was raised. The peak value of Troponin was 8,000 ng/L.His ECG was carried out and result were Lateral ST segment elevation. Cardiac MRI was not carried out, awaited as outpatient. The patient was not asymptomatic. Reporter stated, any recurrent myocarditis in a young man with this degreee of troponin rise was concerning even if the recorded LV function today was normal. | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company comment: This is a regulatory authority case concerning an 18-years-old male patient, with no medical history reported in the case, who experienced the serious expected AESI of Myocarditis and the serious unexpected events of Fatigue, Chest pain, Pyrexia, Dyspnoea, Palpitations, Tachycardia and Troponin increased. The event Myocarditis occurred approximately four days after the administration of the third dose of the mRNA-1273 vaccine while the rest of the events were reported to occur on an unknown date. The events were assessed with the seriousness criteria of Life threatening, Hospitalization, Disability and Medically Significant by the reporter and, at the time of the report, the outcome for the event Myocarditis was Not Recovered/Not Resolved and Unknown for the rest of the events. It was informed that the patient was hospitalized and had an electrocardiogram (Lateral ST segment elevation), an echocardiogram (normal function) and troponin levels measured (peak elevation to 8000ng/L) as part of the diagnostic tests performed. Reported treatment included Steroids, Non-steroidal anti-inflammatory drugs and Colchicine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 16-Jan-2022: Follow-up received with significant information: Lab data (Troponin , Blood test ,Troponin, Investigation, Investigation) added and result updated. Suspect product Dose 2 details added and action taken updated. Event (Troponin increased) added. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 14-Jan-2022 and was forwarded to Moderna on 14-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), STRESS CARDIOMYOPATHY (Broken heart syndrome), DYSPNOEA (Dyspnoea), ARRHYTHMIA (Arrhythmia), PAIN (Radiating pain), EXERCISE TOLERANCE DECREASED (Exercise tolerance decreased), MYOCARDITIS (Myocarditis) and HEART RATE IRREGULAR (Heart rate irregular) in a 30-year-old female patient who received mRNA-1273 (Spikevax) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 15-Apr-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Jun-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), STRESS CARDIOMYOPATHY (Broken heart syndrome) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), ARRHYTHMIA (Arrhythmia) (seriousness criterion hospitalization), PAIN (Radiating pain) (seriousness criterion hospitalization), EXERCISE TOLERANCE DECREASED (Exercise tolerance decreased) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization) and HEART RATE IRREGULAR (Heart rate irregular) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), STRESS CARDIOMYOPATHY (Broken heart syndrome), DYSPNOEA (Dyspnoea), ARRHYTHMIA (Arrhythmia), PAIN (Radiating pain), EXERCISE TOLERANCE DECREASED (Exercise tolerance decreased), MYOCARDITIS (Myocarditis) and HEART RATE IRREGULAR (Heart rate irregular) had not resolved. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | No concomitant medication was reported<br>No treatment medication was reported<br><br>Company Comment: This case concerns a 30-year-old female patient, with no relevant medical history reported in this case, who experienced the serious unexpected adverse events of Arrhythmia (AESI), Chest Pain, Stress Cardiomyopathy, Dyspnoea, Pain, Exercise Tolerance Decreased and Heart Rate Irregular and the serious expected AESI Adverse Event of Myocarditis. The events occurred approximately 1 month and 20 days after the administration of the 2nd dose of the mRNA-1273 vaccine and the outcome at the time of the report was Not Recovered/Not Resolved. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. The events Arrhythmia and Myocarditis were reported as serious by the RA. The seriousness Criteria was: Hospitalized. Seriousness was automatically upgraded per IME list for the events; in accordance with the RA criteria, this severity was manually downgraded to mirror with SD. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) and MYOCARDITIS (Myopericarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004730) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 immunisation: SPIKEVAX on 23-Jul-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br><br>On 23-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved and MYOCARDITIS (Myopericarditis) had resolved.<br><br>No concomitant medication was given.<br>No treatment medication was given. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This case was received via [redacted] (Reference number: [redacted]) on 14-Jan-2022 and was forwarded to Moderna on 14-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of SYNCOPE (Fainting), MYOCARDITIS (Myocarditis), LETHARGY (lethargic), ARTHRALGIA (joint pain), FATIGUE (Fatigue/unusual tiredness) and CHEST PAIN (Chest pain) in a 35-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000014A) for an unknown indication.<br><br>Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) for COVID-19 vaccination, INFLUENZA VACCINE (INFLUENZA VIRUS) for Flu vaccination.<br><br>On 22-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced SYNCOPE (Fainting) (seriousness criterion medically significant), LETHARGY (lethargic) (seriousness criterion medically significant), ARTHRALGIA (joint pain) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant) and CHEST PAIN (Chest pain) (seriousness criterion medically significant). On 03-Jan-2022, MYOCARDITIS (Myocarditis) had resolved. At the time of the report, SYNCOPE (Fainting), FATIGUE (Fatigue/unusual tiredness) and CHEST PAIN (Chest pain) outcome was unknown and LETHARGY (lethargic) and ARTHRALGIA (joint pain) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>No treatment information was provided.<br><br>The patient had joint pain and tightness of chest following day, for about following 10 days had tightness and ache at back of chest where heart was. Not had anything like this before. Could felt additional pain on swallowing. Felt very tired and lethargic.<br>Patient was not currently breastfeeding.<br>Patient had not tested positive for COVID-19 since having the vaccine and was not enrolled in clinical trial.<br>There was possible inflammation of the heart (myocarditis or pericarditis).<br><br>Company Comment: This is a regulatory case concerning a 35-year-old female patient with no relevant medical history, who experienced the serious expected AESI event of myocarditis; | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | serious expected event of syncope, and serious per reported severity unexpected events of lethargy, arthralgia, fatigue and chest pain. The event of myocarditis occurred on the next day after the third dose of mRNA-1273 vaccine administration and the remaining events occurred on unknown dates. The events were assessed as related to the product administration. The rechallenge was reported as unknown; however, could be considered as not applicable since the events occurred after the third dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 16-Jan-2022. The most recent information was received on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MALAISE (unwell), PERICARDITIS (Pericarditis), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia), HYPERTENSION (Blood Pressure High), PAIN IN EXTREMITY (Pain in extremity), PAIN IN JAW (Pain in jaw), PYREXIA (Pyrexia) and DYSPNOEA (Dyspnoea) in a 39-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>The patient's past medical history included Non-smoker.<br>Concurrent medical conditions included Latex allergy and Suspected COVID-19 since 12-Nov-2021.<br>Concomitant products included PARACETAMOL from 12-Nov-2021 to an unknown date for COVID-19, LEVONORGESTREL (MIRENA) from 03-Apr-2016 to an unknown date for Embedded IUD, TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 11-Jan-2021 to an unknown date and TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 29-Mar-2021 to an unknown date for Vaccination.<br><br>On 07-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 12-Nov-2021, the patient experienced FATIGUE (Fatigue) (seriousness criteria disability and medically significant) and PYREXIA (Pyrexia) (seriousness criteria disability and medically significant). On 07-Jan-2022, the patient experienced CHEST PAIN (Chest Pain) (seriousness criteria disability and medically significant). On 10-Jan-2022, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria disability and medically significant). On an unknown date, the patient experienced MALAISE (unwell) (seriousness criteria disability and medically significant), PALPITATIONS (Palpitations) (seriousness criteria disability and medically significant), TACHYCARDIA (Tachycardia) (seriousness criteria disability and medically significant), HYPERTENSION (Blood Pressure High) (seriousness criteria disability and medically significant), PAIN IN EXTREMITY (Pain in extremity) (seriousness criteria disability and medically significant), PAIN IN JAW (Pain in jaw) (seriousness criteria disability and medically significant) and DYSPNOEA (Dyspnoea) (seriousness criteria disability and medically significant). On 16-Nov-2021, PYREXIA (Pyrexia) outcome was unknown. At the time of the report, MALAISE (unwell), PERICARDITIS (Pericarditis), CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | HYPERTENSION (Blood Pressure High), PAIN IN EXTREMITY (Pain in extremity) and PAIN IN JAW (Pain in jaw) was resolving and FATIGUE (Fatigue), TACHYCARDIA (Tachycardia) and DYSPNOEA (Dyspnoea) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 11-Nov-2021, SARS-CoV-2 test: yes - positive covid-19 test (Positive) Yes - Positive COVID-19 test.<br>On 11-Jan-2022, Blood test: a/a, gp told me slightly elevated. (High) a/a, GP told me slightly elevated..<br>On 11-Jan-2022, Electrocardiogram: result not provided (Inconclusive) Result not provided.<br>On 11-Jan-2022, Myocardial necrosis marker: result not provided (Inconclusive) Result not provided a/a.<br>On 11-Jan-2022, Troponin: result not provided (Inconclusive) a.a Result not provided.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Nil medical history Fit and well. The patient had agreed all symptoms plus COVID trajectory (positive COVID on 11-Nov-21, very unwell for 6 weeks) points to worsened pericarditis due to effects of Moderna booster. Prescribed Naproxen 2 weeks. Awaited for an outcome. She was very unwell. Bedbound. Nil previous reaction to Pfizer vaccines x2. Patient visited Emergency department on 07-Jan-2022 with raised BP and palpitations. She was at rest for 2 days during work (Physio). ECG and full bloods examination were negative. Junior Dr plus second opinion from his ED consultant said probable mild pericarditis. The treatment recommended was NSAIDS and rest. GP tell consultation was done on 13-Jan-2022 : NSAID advice. The troponin was measured on 11-Jan-2022. The cardiac troponin was normal. ECG was carried out on 11-Jan-2022. The signs of a systemic disease that might be responsible were 8 weeks post COVID. Since the patient had received the vaccine, she had not tested positive for covid-19.<br><br>Emergency department on 07/01/22 with raised BP and palpitations at rest for 2 days during work (Physio). ECG and full bloods and examination done.<br>Junior Dr. plus second opinion from his ED consultant said probable mild pericarditis, treatment recommended NSAIDS and rest.<br>GP Tel consultation 13/1/22 re: NSAID advice. Agreed all symptoms plus COVID trajectory (positive COVID 11/11/21, very unwell for 6 weeks) points to worsened Pericarditis due to effects of Moderna booster. Prescribed Naproxen 2 weeks. Await a outcome. Very unwell off work. Bedbound. Nil previous reaction to Pfizer vaccines x2. Patient has not tested positive for COVID-19 since having the vaccine<br>Patient is not enrolled in clinical trial.<br>Does your report relate to possible blood clots or low platelet counts. If yes, we will ask you additional questions at the end of this report: Yes<br>Does your report relate to possible myocarditis or pericarditis. If yes, | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Jan-2022: Follow-up added contains significant information - Blood pressure high event added, and action taken updated.<br>On 21-Jan-2022: Follow-up received on 21-jan-2022: Lab data added, concomitant drug information updated, new events added, event date and outcome updated. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 14-Jan-2022. The most recent information was received on 16-Jan-2022 and was forwarded to Moderna on 16-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of TACHYCARDIA (Racing heart (tachycardia)), PALPITATIONS (Heart palpitations), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness), TREMOR (Tremor), SHOCK (Shock) and PERICARDITIS (Pericarditis) in a 32-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3006325) for COVID-19 immunisation.<br><br>Concurrent medical conditions included Non-smoker and Abstains from alcohol.<br><br>On 05-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 06-Jan-2022, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On 10-Jan-2022, the patient experienced TREMOR (Tremor) (seriousness criterion medically significant) and SHOCK (Shock) (seriousness criterion medically significant). On an unknown date, the patient experienced TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant) and FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant). At the time of the report, TACHYCARDIA (Racing heart (tachycardia)), PALPITATIONS (Heart palpitations), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness), TREMOR (Tremor) and SHOCK (Shock) outcome was unknown and PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: results not reported Results not reported.<br>On an unknown date, Electrocardiogram: results not reported Results not reported.<br>On an unknown date, SARS-CoV-2 test: no (Negative) Negative.<br>On an unknown date, Scan: results not reported Results not reported.<br>On an unknown date, Troponin: normal (normal) Normal. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | No concomitant medications were provided. The patient had not had symptoms associated with COVID-19. About 24 hours vaccination symptoms occurred. He phoned [redacted] straight away for advice, then they said I needed to go into accident and emergency. I was told it was highly likely it was caused by the vaccination and that he had pericarditis. he was given advice of no arduous activity and over the counter ibuprofen until it go. However, four days later his body went into shock and he started shaking uncontrollably and felt like he was having a heart attack. He had been given colchicine that he was taking for 3 months now, so that was still ongoing and he was now off work for two weeks when he was meant to be deploying abroad. On the day of his symptoms, he could not do anything, so he was sat on his sofa and thought it was indigestion because he was perfectly fine all week. He had previously had no underlying health issues especially around my heart area, he was fit and healthy and had been [redacted] for 13 years. He had not previously been diagnosed with Covid-19 and every start of the working week and end, they had to take a lateral flow test for work policy and he tested negative the week of this jab. He had not tested positive for COVID-19 since having the vaccine and was not enrolled in clinical trial. His report was related to possible inflammation of the heart (myocarditis or pericarditis). He mentioned that the diagnosis was made by a medical professional, cardiologist. He was treated with Ibuprofen and colchicine. He had done ECG and scan, results were unknown. Patient had the troponin test and troponin level was normal.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 16-Jan-2022: Added current condition of Non-smoker and Abstains from alcohol, event onset date was updated for Pericarditis, new event of Shaking and Shock added to the case, added new lab tests, updated drug start date and action taken.<br><br>Company comment:<br>This RA case concerns a 32 year old male, with no relevant medical history reported, who experienced Serious ( Medically significant ) , expected, AESI event of pericarditis which occurred one day after vaccination with the 3rd dose of mRNA-1273 vaccine. Five days post vaccination with the 3rd dose , he experienced Serious ( medically significant ) , unexpected events of tremor , shock while on an unknown date after vaccination with the 3rd dose , he experienced Serious Unexpected events of tachycardia , palpitation , chest pain , dyspnea and fatigue. This patient was treated initially conservatively with bedrest and ibuprofen after the first A and E visit however after 4 days the symptoms worsened thinking it was a heart attacck , he went back to A and E where he was given colchicine to complete for 3 months. His troponin I was reported as normal , 12 L ecg , scan and blood test results were not reported. The re-challenge for this case is not applicable since the events occurred after the 3rd dose and no additional doses will be given and also the outcome of the event is not resolved. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 16-Jan-2022 and was forwarded to Moderna on 16-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Sharp stabbing pain in left chest on breathing in worse when lying down shortness of breath), FATIGUE (Fatigue/unusual tiredness), DYSPNOEA (Shortness of breath), TACHYCARDIA (Racing heart (tachycardia)) and PERICARDITIS (Pericarditis) in a 35-year- | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 07-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 11-Jan-2022, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Sharp stabbing pain in left chest on breathing in worse when lying down shortness of breath) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Sharp stabbing pain in left chest on breathing in worse when lying down shortness of breath) and PERICARDITIS (Pericarditis) was resolving and FATIGUE (Fatigue/unusual tiredness), DYSPNOEA (Shortness of breath) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: results not reported Results not reported..<br>On an unknown date, Chest X-ray: results not reported. Results not reported..<br>On an unknown date, Electrocardiogram: results not reported. Results not reported..<br>On an unknown date, SARS-CoV-2 test: no- negative covid-19 test (Negative) No- Negative COVID-19 test.<br><br>Concomitant medications were not reported.<br><br>Patient had no symptoms associated with COVID-19. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial.<br><br>Patient experienced sharp, stabbing pain in left chest on breathing in. It was worse when lying down. He also experienced shortness of breath, fatigue, pericarditis and tachycardia. The diagnosis was made by a medical professional (Cardiologist).<br><br>Treatment medication included Ibuprofen.<br><br>Company Comment: This regulatory case concerns a 35-year-old, male patient with no medical history reported, who experienced the expected, serious AESI of pericarditis and the unexpected, serious events of chest pain, fatigue, dyspnoea and tachycardia. The event pericarditis occurred 4 days after administration of the third dose of the Moderna mRNA-1273 | | |

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| | vaccine. The start dates of the other events were not provided. Electrocardiogram, Chest X-ray and blood tests were done, however, the results were not provided. He was prescribed with ibuprofen (unspecified dosage, frequency and duration). The events pericarditis and chest pain were resolving at the time of the report. The outcomes of the other events were unknown at the time of the report. The patient's gender remains a confounder for the event pericarditis. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Jan-2022: Additional follow-up information received added laboratory data, suspect drug action taken was updated and event of chest pain was deleted. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 16-Jan-2022 and was forwarded to Moderna on 16-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (myocarditis), TACHYARRHYTHMIA (Tachyarrhythmia), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and MALAISE (Unwell) in a 33-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 21-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form.<br>On 14-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form.<br>On 10-Jan-2022, received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 10-Jan-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced TACHYARRHYTHMIA (Tachyarrhythmia) (seriousness criteria hospitalization, medically significant and life threatening). On an unknown date, the patient experienced MYOCARDITIS (myocarditis) (seriousness criteria hospitalization, medically significant and life threatening), FATIGUE (Fatigue) (seriousness criteria hospitalization, medically significant and life threatening), CHEST PAIN (Chest Pain) (seriousness criteria hospitalization, medically significant and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization, medically significant and life threatening), PALPITATIONS (Palpitations) (seriousness criteria hospitalization, medically significant and life threatening), TACHYCARDIA (Tachycardia) (seriousness criteria hospitalization, medically significant and life threatening) and MALAISE (Unwell) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (myocarditis) and TACHYARRHYTHMIA (Tachyarrhythmia) had not resolved and FATIGUE (Fatigue), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and MALAISE (Unwell) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 13-Jan-2022, Chest X-ray: results not reported Results not reported.<br>On 13-Jan-2022, Troponin: 4.0 ng/l Troponin 4.0 ng/l.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>After vaccination patient felt unwell and developed tachyarrhythmia. As this did not resolve patient consulted on 13 January 2022 and was admitted to hospital with suspected myocarditis.<br><br>Does report relate to possible myocarditis or pericarditis: Yes | | [redacted] |

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| | Patient was admitted to hospital did not received any results yet, Still in hospital. Patient seen by a cardiologist was unknown. patient was not yet formally diagnosed.<br><br>The laboratory examination was done that includes troponin that was measured on 13 January 2022 and the result was found to be normal. the peak of troponin value was found 4.0 ng/l, the troponin reference range was 0 - 9 ng/l.<br><br>Company comment: This is a regulatory authority case concerning a 33-years-old female patient, with no medical history reported in the case, who experienced the serious expected AESI of Myocarditis, the serious unexpected AESI of Tachyarrhythmia and the serious unexpected events of Fatigue, Chest pain, Dyspnoea, Palpitations, Tachycardia and Malaise. The event Myocarditis occurred on an unknown date after the administration of the third dose of the mRNA-1273 vaccine, the event Tachyarrhythmia occurred approximately one day after the administration of the third dose of the mRNA-1273 vaccine, while the rest of the events were reported to occur on an unknown date. The events were assessed with the seriousness criteria of Life threatening, Hospitalization and Medically significant by the reporter and, at the time of the report, the outcome for the events Myocarditis and Tachyarrhythmia was Not Recovered/Not Resolved and Unknown for the rest of the events. It was informed that the patient was hospitalized and had a Chest X-ray performed (results not available) and Troponin levels within normal ranges. No further information on other diagnostic tests performed or treatment details was disclosed. The rechallenge was reported as Unknown. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Jan-2022: Follow up received Lab data, lab test date, product information and events updated. | | |
| [redacted] | This spontaneous prospective pregnancy case was reported by a consumer and describes the occurrence of PERICARDITIS (diagnosed with pericarditis from the booster shot) in a 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 066M21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Mitral valve prolapse (Patient has experienced heart palpitations in the past from Mitral Valve Prolapse (MVP).) and COVID-19 (COVID infection caused chest tightness.Recovered from COVID-19 after 10 days) on 01-Dec-2021.<br>Concurrent medical conditions included Allergy (allergies), Barrett's esophagus and Asthma (severe asthma).<br>Concomitant products included EPINEPHRINE BITARTRATE (ASTHMAHALER) for Asthma, PANTOPRAZOLE for Barrett's esophagus, ASPIRIN [ACETYLSALICYLIC ACID] for Pre-eclampsia, MINERALS NOS, VITAMINS NOS (PRENATAL VITAMINS [MINERALS NOS;VITAMINS NOS]) and FLUOXETINE for an unknown indication.<br><br>On 16-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. The patient's last menstrual period was on an unknown date and the estimated date of delivery was 13-May-2022. On 16-Jan-2022, the patient experienced PALPITATIONS (heart started racing (booster)/heart rate was 151 BPM (walking)/resting heart rate is 105 BPM), CHEST DISCOMFORT (little bit of chest tightness), DYSPNOEA (trouble breathing), COUGH (coughing), INSOMNIA (hard to sleep at night), HEADACHE (headache) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy). On an unknown date, the patient experienced PERICARDITIS (diagnosed with | 35 years old female pregnant (gestation period not reported) with medical history of mitral valve prolapse, Barrett's esophagus, asthma, and COVID-19 infection a month before, who the same day after the 3rd dose of Spikevax developed palpitations, chest discomfort, cough and dyspnea and emergency room doctors diagnosed her with pericarditis. No further details regarding diagnostic tests or treatment performed were disclosed. According to the WHO causality assessment this report is conditional based on the lack of information; a causal relationship cannot be excluded due to the lack of information. | [redacted] |

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| | pericarditis from the booster shot) (seriousness criterion medically significant). The patient was treated with PARACETAMOL (TYLENOL [PARACETAMOL]) for Headache, at an unspecified dose and frequency. On 16-Jan-2022, MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) had resolved. At the time of the report, PERICARDITIS (diagnosed with pericarditis from the booster shot), PALPITATIONS (heart started racing (booster)/heart rate was 151 BPM (walking)/resting heart rate is 105 BPM), CHEST DISCOMFORT (little bit of chest tightness), DYSPNOEA (trouble breathing), COUGH (coughing), INSOMNIA (hard to sleep at night) and HEADACHE (headache) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 01-Dec-2021, SARS-CoV-2 test: positive (Positive) Patient was diagnosed with COVID-19 infection.<br>In 2022, Heart rate: 151 bpm Walking heart rate was 151 BPM and 105 bpm resting heart rate was 105 BPM.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Patient reported that couple of hours after receiving the booster dose, heart started racing. She also reported a little bit of chest tightness with a deep breath, trouble breathing, coughing and headache. Patient also reported it was hard to sleep at night.<br><br>She was diagnosed with COVID-19 infection on 01Dec2021. She reported the COVID infection caused chest tightness. Patient was not hospitalized, was not given antibody treatment for COVID-19 infection.<br>She reported she has experienced heart palpitations in the past from Mitral Valve Prolapse.<br><br>Caller stated she is pregnant, she is having a baby boy.<br><br>Treatment medication was reported for headache (Tynelol) and for rest of events it was not reported.<br><br>Company comment: This is a case of maternal exposure during pregnancy for this 35-year-old female patient with medical history of Mitral valve prolapse and COVID-19 diagnosed on 01-Dec-2021; who experienced serious (medically significant), expected, AESI event of pericarditis. It was reported that after the third dose of mRNA-1273 vaccine she developed palpitations, chest discomfort, cough and dyspnea and emergency room doctors diagnosed her with pericarditis. No further details regarding diagnostic tests or treatment performed were disclosed. The patient's last menstrual period was on an unknown date and the estimated date of delivery is 13-May-2022. Patient will continue to be contacted for further monitoring of AEs during the pregnancy. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |

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| | This case was linked to [redacted](Patient Link).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 31-Jan-2022: Significant follow-up document was received on 31-JAN-2022-Case seriousness was upgraded. New event(Pericarditis) was added.. Historical condition(COVID-19), Lab data were added in patient tab. Barret's esophagus was changed to current condition. | | |
| [redacted] | This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (acute myopericarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>LITERATURE REFERENCE:<br>Sciaccaluga C, Ascenzi FD,Cameli M, Gallotta M, Menci D, Antonelli G,et al. Acute myopericarditis after mRNA COVID-19 vaccine. Eur Heart J. 2021;23:G167<br><br>No Medical History information was reported.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (acute myopericarditis) (seriousness criteria hospitalization and medically significant) and PYREXIA (fever). The patient was hospitalized for 9 days due to MYOCARDITIS. At the time of the report, MYOCARDITIS (acute myopericarditis) and PYREXIA (fever) outcome was unknown. Related<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Magnetic resonance imaging heart: myopericarditis myopericarditis.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (acute myopericarditis) and PYREXIA (fever) to be related.<br><br>No concomitant and treatment medication was reported by the reporter.<br>Their course is generally benign, with symptoms onset after 24-72 h from the dose. Patient experienced fever on the same day of the vaccine and symptoms consistent with myopericarditis three days after the dose.<br>summarizes the main non-invasive findings that suggested and confirmed the diagnosis of acute myopericarditis.<br><br>Company comment: This is a literature case concerning a 20 year-old, male patient with no reported medical history, who experienced the serious (due to medically important condition and hospitalization) expected, AESI of Myocarditis. The event occurred approximately 3 days after the second dose of mRNA-1273 vaccine. The patient was hospitalized for 9 days. The | Literature articule for a 20-year old and 21-years old. Both the patients were administered the vaccine on the same day. They both experienced fever on the same day of the vaccine and symptoms consistent with myopericarditis three days after the 2nd dose, which was confirmed by cardiac magnetic resonance. The disease course was benign in both patients, and only one patient presented rare ventricular arrhythmias on the admission day. They were both discharged on the 9th day of the in-hospital stay. **Conclusions**: Myopericarditis is usually considered an uncommon adverse reaction after various vaccinations, reported also after the mRNA COVID-19 vaccine. Several explanations have been proposed, including an abnormal activation of the immune system leading to a pro-inflammatory cascade responsible for myocarditis development. The temporal aspect of these case reports is rather peculiar and it is useful to underscore that both vaccines belonged to the same batch of vaccines. However, despite these cases, vaccination against COVID-19 far outweighs the risk linked to COVID-19 infection and remains the best option to overcome this disease. | [redacted] |

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| | rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>This case was linked to [redacted](Patient Link).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Jan-2022: Follow up received by safety 21-Jan-2021 included an Email with [redacted] received from [redacted] team and does not contain any new information. | | |
| [redacted] | This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (myopericarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>LITERATURE REFERENCE:<br>Sciaccaluga C, Ascenzi FD,Cameli M,Gallotta M,Menci D,Antonelli G, et al.. Acute myopericarditis after mRNA COVID-19 vaccine. Eur Heart J. 2021;23:G167<br><br>No Medical History information was reported.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (myopericarditis) (seriousness criteria hospitalization and medically significant). an unknown date, the patient experienced PYREXIA (Fever). The patient was hospitalized for 9 days due to MYOCARDITIS. At the time of the report, MYOCARDITIS (myopericarditis) and PYREXIA (Fever) outcome was unknown. Related<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Magnetic resonance imaging heart: abnormal (abnormal) summarizes the main non-invasive findings that suggested and confirmed the diagnosis of acute myopericarditis.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (myopericarditis) and PYREXIA (Fever) to be related.<br><br>No concomitant and treatment medication was reported by the reporter.<br>Their course is generally benign, with symptoms onset after 24-72 h from the dose. Patient experienced fever on the same day of the vaccine and symptoms consistent with myopericarditis three days after the dose.<br>summarizes the main non-invasive findings that suggested and confirmed the diagnosis of acute myopericarditis | Literature articule for a 20-year old and 21-years old. Both the patients were administered the vaccine on the same day. They both experienced fever on the same day of the vaccine and symptoms consistent with myopericarditis three days after the 2nd dose, which was confirmed by cardiac magnetic resonance. The disease course was benign in both patients, and only one patient presented rare ventricular arrhythmias on the admission day. They were both discharged on the 9th day of the in-hospital stay. **Conclusions**: Myopericarditis is usually considered an uncommon adverse reaction after various vaccinations, reported also after the mRNA COVID-19 vaccine. Several explanations have been proposed, including an abnormal activation of the immune system leading to a pro-inflammatory cascade responsible for myocarditis development. The temporal aspect of these case reports is rather peculiar and it is useful to underscore that both vaccines belonged to the same batch of vaccines. However, despite these cases, vaccination against COVID-19 far outweighs the risk linked to COVID-19 infection and remains the best option to overcome this disease. | [redacted] |

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| | Company comment: This is a literature case concerning a 21 year-old, male patient with no reported medical history, who experienced the serious (due to medically important condition and hospitalization) expected, AESI of Myocarditis. The event occurred approximately 3 days after the second dose of mRNA-1273 vaccine. The patient was hospitalized for 9 days. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>This case was linked to [redacted] (Patient Link).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Jan-2022: Follow up received by safety 21-Jan-2022 included an Email with [redacted] received from [redacted] team and contains no newInformation. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of FIBRIN D DIMER INCREASED (Fibrin D dimer increased), MUSCULOSKELETAL PAIN (Arthromyalgia), HEADACHE (Headache), PYREXIA (Fever), DYSPNOEA EXERTIONAL (Dyspnoea exertional), DIZZINESS (Dizziness) and PERICARDITIS (Pericarditis) in a 32-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214029) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Migraine (IN TTO WITH BOTULINUM TOXIN). Concomitant products included TOZINAMERAN (COMIRNATY) from 09-Jan-2021 to 30-Jan-2021 for COVID-19 vaccination, BOTULINUM TOXIN TYPE A (BOTOX) for Migraine.<br><br>On 02-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 03-Dec-2021, the patient experienced HEADACHE (Headache) (seriousness criteria hospitalization and medically significant). On 15-Dec-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). On 21-Dec-2021, the patient experienced FIBRIN D DIMER INCREASED (Fibrin D dimer increased) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced MUSCULOSKELETAL PAIN (Arthromyalgia) (seriousness criteria hospitalization and medically significant), PYREXIA (Fever) (seriousness criteria hospitalization and medically significant), DYSPNOEA EXERTIONAL (Dyspnoea exertional) (seriousness criteria hospitalization and medically significant) and DIZZINESS (Dizziness) (seriousness criteria hospitalization and medically significant). At the time of the report, FIBRIN D DIMER INCREASED (Fibrin D dimer increased) outcome was unknown, MUSCULOSKELETAL PAIN (Arthromyalgia), HEADACHE (Headache), PYREXIA (Fever), DYSPNOEA EXERTIONAL (Dyspnoea exertional) and DIZZINESS (Dizziness) had resolved and PERICARDITIS (Pericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On 21-Dec-2021, Blood test: abnormal (abnormal) HIGH DIMER D (880 NG/ML). NORMAL REST. NEGATIVE CMV, VEB AND MYCOPLASMA SEROLOGIES.<br>On 21-Dec-2021, Computerised tomogram thorax: result not provided (Inconclusive) No TEP data.<br>On 21-Dec-2021, Culture throat: crp negative CRP NEGATIVE CORONAVIRUS, INFLUENZA A and B, RESPIRATORY SYNCYTIAL VIRUS.<br>On 22-Dec-2021, Echocardiogram: result not provided (abnormal) Dysfunction of VI. Do not pericardial effusion.<br>On 23-Dec-2021, Magnetic resonance imaging heart: possible pericarditis Possible pericarditis.<br>On 23-Dec-2021, Ventilation/perfusion scan: no tep data No TEP data.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No treatment medication were reported<br><br>Company Comment: This RA case concerns a 32 year old female vaccinated initially for two doses using Tozinameran, treated with Botulinum type a for migraine , who experienced Serious ( Medically significant, Hospitalization ) , expected AESI event of Pericarditis which occurred 13 days post vaccination with the 3rd dose of mRNA-1273 vaccine ( Mdoerna Covid 19 vaccine. One day post vaccination with the 3rd dose of mRNA-1273 vaccine , she experienced Serious ( Medically significant , hospitalization ) , unexpected event of headache. Twenty days post vaccination with the 3rd dose , she experienced Serious ( Hospitalizaiton , Medically Significant ) , unexpected event of Fibrin D Dimer increased while on an unknown date post vaccination with the 3rd dose , she experienced Serious , unexpected events of musculoskeletal pain, pyrexia , dyspnea exertional and dizziness. This patient underwent different blood test and diagnostics blood test significant was the increased in the D -dimer, serologic test for RSV , coronavirus , INFLUENZA A and B, CMV, VEB and MYCOPLASMA were negative. including CRP , Throat swab no results , Echocardiogram no pericardial effusion noted and LV dysfunction while the MRI revealed possible pericarditis .Lung perfusion Scan and Ct scan of the thorax was done but results were not reported. No treatment details were reported. The re-challenge for this case is not applicable since the events occurred after the 3rd dose and no additional doses will be given. The history of vaccination with Tozinameran and treatment with botulinum type a may be considered as confounders for this case. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. | | |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 18-Jan-2022. The most recent information was received on 31-Jan-2022 and was forwarded to Moderna on 31-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Acute myocarditis) and CHEST PAIN (Chest pain) in a 39-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216035) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. | 39-year-old male patient, with medical history of dyslipidemia and hypertension and previous primary series vaccination with Cominarty, who 5 days after the 3rd dose of Spikevax expereinced chest pain and was found to have elevated troponin, CRP, abnormal echo, abnormal ECG, and abnormal cMRI and was diagnosed with | [redacted] |

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| | Previously administered products included for Product used for unknown indication: Comirnaty on 14-Jun-2021.<br>Past adverse reactions to the above products included No adverse drug reaction with Comirnaty.<br>Concurrent medical conditions included Dyslipidaemia and Primary hypertension (Stage 1).<br><br>On 24-Dec-2021 at 11:30 AM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced BODY TEMPERATURE INCREASED (Body temperature increased). On 25-Dec-2021, the patient experienced HEADACHE (Headache). On 26-Dec-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization). On 30-Dec-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion hospitalization). On 26-Dec-2021, BODY TEMPERATURE INCREASED (Body temperature increased) had resolved. At the time of the report, MYOCARDITIS (Acute myocarditis) was resolving, HEADACHE (Headache) outcome was unknown and CHEST PAIN (Chest pain) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 27-Dec-2021, Angiocardiogram: no stenoses in coronary arteries (normal) coronary angiogram - no stenoses in coronary arteries..<br>On 27-Dec-2021, C-reactive protein (Unknown-5): 40.83 (High) 40.83 milligram per litre.<br>On 27-Dec-2021, Troponin I (Unknown-15.6): 3242.8 (High) 3242.8 nanogram per litre, 6093.4 (High) 6093.4 nanogram per litre and 17915.7 (High) 17915.7 nanogram per litre.<br>On 28-Dec-2021, Echocardiogram: ejection fraction decreased (abnormal) ejection fraction decreased (51percent) , diffuse left ventricle hypokinesia with slightly decreased left ventricle ejection fraction, decreased left ventricle myocardial longitudinal deformation. Pericardium normal..<br>On 28-Dec-2021, Electrocardiogram: abnormal (abnormal) ECG - sinus rhythm 80 BPM, slight ST segment elevations on leads I, aVL and V6 with slightly negative T waves. In comparison with previous ECGs, ST segment elevations are decreasing..<br>On 30-Dec-2021, Magnetic resonance imaging heart: myocardial oedema (abnormal) cardiac MRI with contrast medium - no signs of myocardial perfusion abnormalities. During late contrasting (10-15th minute) pathologic patchy contrast medium accumulation seen in myocardium middle and subepicardial compartment in whole left ventricle, but more pronounced in anterior wall and ventricular septum. In this region, T2 mapping values of myocardium are increased before contrast medium administration. The changes seen correspond with myocardial oedema, which most likely is due to acute myocarditis..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication information was provided. | MYOCARDITIS. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | |

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| | No treatment medication was provided.<br><br>Company comment:<br>This is a regulatory case concerning a 39-year-old male patient with medical history of primary hypertension, and dyslipidaemia, who experienced serious expected event of special interest myocarditis, serious unexpected event of chest pain and non serious expected events of body temperature increased and headache. The event of body temperature increased occurred during the same day after administration of the mRNA-1273 vaccine (as third dose), the event of headache occurred the day after vaccination, while the event of chest pain occurred two days after vaccination and the event of myocarditis three days after vaccination. The patient had increased C-reactive protein and Troponin I levels, and the echocardiogram showed decreased ejection fraction, diffuse left ventricle hypokinesia with slightly decreased left ventricle ejection fraction and decreased left ventricle myocardial longitudinal deformation. An ECG showed light ST segment elevations with slightly negative T waves, and MRI showed myocardial oedema, which most likely was due to acute myocarditis. At the time of this report, the events of chest pain and body temperature increased had resolved, the event of myocarditis was resolving, and the outcome of the event of headache was unknown. The rechallenge is not applicable, since the events occurred after the third vaccination. Having in mind that this patient received Comirnaty vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 31-Jan-2022: Significant follow up up information received on 31-Jan-2022. Reporter information, historical vaccine comirnaty dates, Acute myocarditis event onset date and stop date of Body temperature increased were updated. | | |
| MOD-2022-454552 | This case was initially received via Takeda Pharmaceuticals (Reference number: 2022TJP008191) on 17-Jan-2022. The most recent information was received on 01-Feb-2022 and was forwarded to Moderna on 08-Feb-2022.<br><br>This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, v21132899). On 01-Feb-2022, follow-up information was received from a physician. It was assumed that the patient had been on medication with benzbromarone for gout treatment. On an unknown date, the patient received the 1st dose of this vaccine. On 13-Nov-2021, the patient received the 2nd dose of this vaccine. On 15-Nov-2021, around 09:00, the patient complained of pyrexia and physical deconditioning and contacted the workplace for being absent from work. The specific value of pyrexia was unknown. On 16-Nov-2021, at 9:30, the patient could not be contacted. At 14:00, the patient could not be contacted. The patient died suddenly on the same day. On 17-Nov-2021, at 13:30, the patient could not be contacted. Around 16:50, the patient was found dead at home. On 18-Nov-2021, postmortem CT showed no abnormal findings. The cause of death was unknown, and the administrative autopsy was performed. **Coronary artery examination showed findings of up to 75% of stenosis in all three major branches.** The cause of death was diagnosed as myocarditis based on the findings of focal inflammatory cell infiltration mainly with macrophages and interstitial edema in the myocardial interstitial tissue, acidophilic and | 39 years old male with medical history of gout and sleep apnea who 4 days after after the 2nd dose of Spikevax was found dead at home. Autopsy results showed 75% stenosis in all three major branches of coronary arteries; myocarditis was also diagnosed based on the findings of focal inflammatory cell infiltration mainly with macrophages and interstitial edema in the myocardial interstitial tissue, acidophilic and wavy degeneration of the myocardium, and pericoronary inflammation in the histopathological examination. Information provided for this report is heavily confounded by the autopsy findings which indicates a concurrent medical history of CAD and aterosclerosis as well as the ocurrence of an acute MI. According to the WHO causality assessment this report is unlikely. | JP-TAKEDA-2022TJP008191 |

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| | wavy degeneration of the myocardium, and pericoronary inflammation in the histopathological examination. The cause of death was identical to the adverse event, and there was a relationship. In the differential diagnosis, other diseases which could explain clinical manifestation and findings were denied. The outcome of myocarditis was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The patient had been taking oral benzbromarone, which was initiated on unknown date, for more than several months, and it is unlikely that there is a causal relationship between the drug and acute myocarditis. Therefore, the occurrence of adverse events is not related to benzbromarone. Since gout and sleep apnoea syndrome was unlikely to be causally related to the occurrence of myocarditis, the adverse event is not associated with the pathological factors of gout and sleep apnoea syndrome. Follow-up received on 01-FEB-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Narrative, Reporter Comments Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), FATIGUE (Fatigue/unusual tiredness), DYSPNOEA (short breath), SYNCOPE (Fainting), HEADACHE (Headache) and MYOCARDITIS (Myocarditis) in a 36-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No medical history reported<br>.<br>Concomitant products included TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 28-May-2021 to an unknown date and TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 21-Jul-2021 to an unknown date for an unknown indication.<br><br>On 22-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 16-Jan-2022, the patient experienced HEADACHE (Headache) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), DYSPNOEA (short breath) (seriousness criterion medically significant) and SYNCOPE (Fainting) (seriousness criterion medically significant). On 17-Jan-2022, HEADACHE (Headache) had resolved. At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), FATIGUE (Fatigue/unusual tiredness) and SYNCOPE (Fainting) outcome was unknown and DYSPNOEA (short breath) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On 16-Jan-2022, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>No treatment information was provided.<br>Patient not had symptoms associated with COVID-19<br><br>Patient had chest pain in the heart position every a few seconds which was less severe when lying down but more frequent otherwise, for example when standing or walking. Also had short breath when the pain was strong. Patient was not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial.<br><br>Patient stated that the report was related to possible inflammation of the heart (myocarditis or pericarditis). Patient went to A and E but was told to just get some rest.<br>The symptoms did not lead to a hospital stay. The diagnosis was made by a medical professional. No imaging and any blood tests were carried out.<br><br>Company comment:This case concerns a 36-year-old, male patient with no medical history reported, previously vaccinated with TOZINAMERAN, who experienced the unexpected events of headache, chest pain, dyspnoea (two events), palpitations, fatigue and syncope and expected event of myocarditis, which were considered as medically significant. The event of headache occurred 25 days after the third dose of mRNA-1273 while the rest of the events occurred on unknown date. As reported, the patient had chest pain in the heart position every a few seconds which was less severe when lying down but more frequent otherwise, for example when standing or walking. Also patient had short breath when the pain was strong. Patient stated that the report was related to possible inflammation of the heart (myocarditis or pericarditis). Patient went to A and E but was told to just get some rest. The symptoms did not lead to a hospital stay. The diagnosis was made by a medical professional. and no imaging and any blood tests were carried out, as reported. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Jan-2022: Action taken of suspect was updated to not applicable. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003610) for COVID-19 vaccination.<br><br>Dose 1: Moderna Vaccine, 25/05/2021, Left Arm, Intramuscular Injection, Lot #: 3002542.<br>Previously administered products included for Product used for unknown indication: Moderna Vaccine (Dose 1: Moderna Vaccine, 25/05/2021, Left Arm, Intramuscular Injection and Lot #: 3002542) on 25-May-2021.<br>Past adverse reactions to the above products included No adverse reaction with Moderna Vaccine. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On 06-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No Concomitant medications were reported.<br>No Treatment information was reported.<br><br>Company comment: This case concerns a 33-year-old male patient, with no reported medical history, who experienced the serious, expected event of myocarditis. The event occurred 18 days after the second dose of mRNA 1273 COVID-19 vaccine. No further information has been provided. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 19-Jan-2022 and was forwarded to Moderna on 19-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of INFLAMMATION (inflammation), CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and SWELLING (Swelling) in a 22-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000014A) for an unknown indication.<br><br>Concomitant products included ETHINYLESTRADIOL, LEVONORGESTREL (MICROGYNON [ETHINYLESTRADIOL;LEVONORGESTREL]) for Birth control pill, TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 28-Jun-2021 to an unknown date for an unknown indication.<br><br>On 05-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 06-Jan-2022, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced INFLAMMATION (inflammation) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant) and SWELLING (Swelling) (seriousness criterion medically significant). At the time of the report, INFLAMMATION (inflammation), CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) had not resolved and DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and SWELLING (Swelling) outcome was unknown. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.<br><br>No medical history was reported.<br>Patient has not had symptoms associated with COVID-19. Patient took over-the-counter ibuprofen to try and mitigate inflammation and swelling and had little impact and patient had a doctor's appointment on 20/01/22 for further investigation.<br>Patient was neither pregnant nor breastfeeding.<br>Diagnosis was done by a GP (general physician).<br>Patient did not underwent any imaging procedure.<br>Re-challenge was reported as unknown.<br><br>Company Comment: This regulatory case concerning a 22-year-old, female patient with no relevant medical history reported, with an Interchange of vaccine products two doses of TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) 4 months and 12 days before the current vaccination, who experienced the unexpected serious events of Inflammation, Chest pain, Dyspnoea, Palpitations, Tachycardia and Swelling and expected serious AESI event of Myocarditis. The events Inflammation, Dyspnoea, Palpitations, Tachycardia and Swelling occurred on an unknown day and the events Chest pain and Myocarditis occurred 1 day after the third dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority´s report due to important medical condition.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Jan-2022: Follow-up received on 20-Jan-2021: Action taken of the suspect product was updated. New Event Swelling was added. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (fatigue) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1101221-CDC) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 02-Dec-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Dec-2021, the patient experienced FATIGUE (fatigue) and MYOCARDITIS (Myocarditis). At the time of the report, FATIGUE (fatigue) and MYOCARDITIS (Myocarditis) was resolving. Not Provided<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. | Lack of information in the case, particularly diagnostic exam results. | |

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| | On 02-DEC-2021 Patient had dizziness after vaccination.<br>On 14-DEC-2021 Symptoms persist, with chest tightness and pain, arrhythmia, and dyspnea<br>On 17-DEC-2021 Due to the worsening symptoms, the case went to doctor for a blood panel, electrocardiogram and cardiac ultrasound examination.<br>The results were that the CKMB index was too high, the heart was in hypertrophy and there was a lot of psychological pressure, the diagnosis was myocarditis.<br>2021/12/17 Continue to follow-up in the clinic's outpatient service<br>On 04-JAN-2022 Patient was transferred to [redacted] Cardiology Outpatient Clinic due to discomfort.<br>Concomitant medication of the patient was not reported.<br>No treatment information was provided by the reporter.<br><br>Company comment:<br>This is a regulatory authority case concerning a 19-year-old, male patient with no reported medical history, who experienced the expected, non-serious, AESI event of myocarditis and expected, non-serious event of fatigue. The event myocarditis exact occurrence unknown but stated that the event occurred after the second dose of mRNA-1273 vaccine administration while the event fatigue occurrence unknown with respect to the second dose of mRNA-1273 vaccine administration. The events were described as patient experienced dizziness after vaccination. Patient developed chest tightness and pain, arrhythmia and dyspnea and due to worsening of the symptoms patient sought consult and diagnostics were done such as blood panel, electrocardiogram and cardiac ultrasound with the following results CKMB index was high with cardiac hypertrophy. The patient was diagnose with myocarditis. The outcome of the events myocarditis and fatigue were resolving from the time of last observation. No reported treatment information. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 26-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G21A) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Asthma.<br><br>On 07-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 11-Dec-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No concomitant medications was reported.<br><br>No treatment drug details was reported.<br><br>Company comment: This is a regulatory authority case concerning a 26-year-old male patient with no relevant medical history, who experienced expected event of pericarditis (seriousness criterion medically significant). The event occurred 4 days after the administration of second dose of mRNA-1273 vaccine. No information about the first dose was disclosed. Clinical course and treatment details were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 19-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214022) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 03-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. In 2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No Concomitant medication was reported.<br>No treatment medications were reported.<br><br>Company comment: This is a regulatory authority case concerning a 19-year-old female patient with no medical history reported, who experienced expected event of pericarditis (seriousness criterion medically significant). On 03-Sep-2021 the patient received second dose of mRNA-1273 vaccine; the event occurred in 2021, on an unspecified day. No information about the first dose was disclosed. Clinical course and treatment details were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A_1110124-CDC) for an unknown indication.<br><br>No Medical History information was reported. | 28-year-old male patient, with unknown medical history, who 3 days after the 2nd dose of Spikevax experienced intermitent chest pain was found to have elevated troponin, CK/MB, abnormal ECG and was diagnosed with MYOCARDITIS. According to the WHO causality assessment this | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 03-Jan-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) .5 milliliter. On 06-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: abnormal (abnormal) EKG showed STEMI".<br>On an unknown date, Myocardial necrosis marker: increased (High) cardiac enzymes increased (CK/MB 276/28.9, ratio 10.47%, Tnl 2.325)".<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be related.<br><br>Concomitant product use was not provided by the reporter.<br><br>The patient received the first dose of Moderna vaccine at Hospital on 02-Nov-2021, and the second dose of Moderna vaccine on 03-Jan-2022. On 06-Jan-2022, the patient developed intermittent chest pain in the morning and visited the Outpatient Department of Cardiology Hospital for treatment. Because EKG showed STEMI (ST-elevation myocardial infarction), the patient was transferred to the Emergency Department for a blood sampling test, and cardiac enzymes increased (CK/MB (creatine kinase myocardial band) 276/28.9, ratio 10.47%, Tnl 2.325). The patient was diagnosed with myocarditis, and then transferred to the intensive care room for observation and treatment after receiving cardiac catheterization. After cardiac catheterization, the patient was transferred to the intensive care unit for observation and treatment. On 07-Jan-2022, the patient was transferred to a general ward after the condition improved. Current treatment information included: Hospital informed VAERS (which caused the patient to be hospitalized or prolonged the patient's hospitalization duration). Subsequent follow-up: Hospital has uploaded the test data and admission disease summary, and the recovery of the patient will be tracked by the public health side.<br><br>Company Comment : This case concerns a 28-year-old male patient, with no medical history reported, who experienced the expected serious AESI event of Myocarditis. The events occurred approximately 4 days after receiving the second dose of mRNA-1273 Vaccine which resulted in hospitalization. Patient sought consult due to intermittent chest pain. EKG done showed STEMI, hence referral to ED. Blood tests done revealed increased cardiac enzymes thus patient was diagnosed with Myocarditis. Cardiac catheterization was done with subsequent ICU admission. The patient was transferred to a general ward after the condition improved. At the time of the report the outcome of the event was not resolved. The rechallenge is not applicable since no further dosing is expected. The reporter assessed the events as related to the product. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004954) for COVID-19 vaccination.<br><br>The patient's past medical history included Pericarditis in 2012.<br>Previously administered products included for COVID-19 immunisation: SPIKEVAX on 16-Aug-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br><br>On 14-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In 2021, Blood test: result unknown (Inconclusive) Result unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br><br>No treatment medications were reported.<br><br>Company comment: This is a regulatory authority case concerning a 37-year-old male patient with medical history of pericarditis in 2012, who experienced expected event of pericarditis (seriousness criteria hospitalization). On 14-Sep-2021 the patient received second dose of mRNA-1273 vaccine; the event occurred on an unknown date. Clinical course and treatment details were not provided. Patient's medical history remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Adiposis.<br>Concurrent medical conditions included Arterial hypertension. | 31 year old male with medical history of hypertension who 6 days after the 3rd dose of Spikevax was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is unassessable based on the | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 14-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not reported.<br>Treatment information was not reported.<br><br>Company Comment: This RA case concerns a 31 year old male with no relevant medical history reported who experienced, Serious ( Hospitalization ) , expected , AESI event of myocarditis. This event occurred 7 days post vaccination with the 3rd dose of mRNA-1273 vaccine ( Moderna Covid 19 Vaccine ) . This patient was reported to have been hospitalized but there were no details reported. Also there were no reports of any laboratories, diagnostic procedures done or any treatment details given. The re-challenge for this case is not applicable since the event occurred after the 3rd dose and no additional doses will be given and also the outcome of the event was not resolved. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. | lack of information. A causal relationship cannot be excluded due to the lack of other information. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 32-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 12-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Jul-2021, the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). On 23-Oct-2021, PERICARDITIS (Acute pericarditis) had resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br><br>No treatment medications were reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company comment: This is a regulatory authority case concerning a 32-year-old male patient with no medical history reported, who experienced expected event of pericarditis (seriousness criterion medically significant). The event occurred 5 days after the administration of second dose of mRNA-1273 vaccine. No information about the first dose was disclosed. Clinical course and treatment details were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 27-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 05-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>The concomitant medications were not reported. The treatment information was reported as aspirin, colchicine,bisoprolol, enalapril.<br><br>The patient received third dose of vaccine on 05-JAN-2022. Patient developed chest tightness on 08-JAN morning .<br>The patient was admitted to the hospital for acute coronary syndrome or myocarditis.<br><br>The lab data's was reported as elevated troponin -I,CXR Showed no cardiomegaly nor pulmonary edema, EKG showed normal sinus rhythm. On 08-JAN cardiac 2D Echo showed 69%-normal wall motion, cardiac 2D echo showed EF36% ,LV global hypokinesia, Troponin I showed 2.14- > 4.94->6.89-> 5.66-> 2.47.Patient also had acute heart failure, EF was reported as 36%, related to acute peri myocarditis and sinus rhythm. On 11-JAN patient was transferred to general ward and hospitalized for observation with symptoms of mild chest tightness and chest pain.<br>Post first and second dose patient developed mild soreness on hands. Patient has no history of chronic disease.<br><br>This is a regulatory authority case concerning a 27-year-old, male patient with no relevant medical history, who experienced the expected serious event of myocarditis. The events occurred approximately 3 days after the third dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was unknown since no information about the first dose was disclosed. The event | 27 year sold male with unknown medical history who 3 days after the 3rd dose of Spikevax develooed chest tighness and was found to have elevated troponin, CXR Showed no cardiomegaly nor pulmonary edema, EKG showed normal sinus rhythm, Echo showed 69%-normal wall motion, cardiac 2D echo showed EF36% ,LV global hypokinesia. Patient also had acute heart failure. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | was reported as resolving. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022.<br>This regulatory authority case was reported by a non-health professional and describes the occurrence of PERICARDITIS (Periocarditis, to be confirmed myocarditis with MRI) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concomitant products included DICLOFENAC SODIUM for an unknown indication.<br><br>On 20-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 20-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Periocarditis, to be confirmed myocarditis with MRI) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Periocarditis, to be confirmed myocarditis with MRI) had not resolved.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 20-May-2021.<br><br>No treatment information was provided.<br><br>Company comment: This regulatory authority case concerns a 30-year-old male patient, with no medical history reported in this case, who experienced the serious expected AESI of Pericarditis. The event occurred approximately two months after the administration of the second dose of the mRNA-1273 vaccine. The event was assessed by the reporter with the seriousness criteria of Hospitalization, and, at the time of the report, the patient had not recovered from the event. No further information on clinical course, diagnostic tests (if performed) or treatment details were disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] ) on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis), FATIGUE (Fatigue), CHEST PAIN (Chest Pain) and DYSPNOEA (Dyspnoea) in a 30-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: SARS-COV-2 VACCINE and SARS-COV-2 VACCINE.<br>Past adverse reactions to the above products included No adverse event with SARS-COV-2 VACCINE and SARS-COV-2 VACCINE. | 30-year-old female patient, with unknown medical history, who the next day after the 3rd dose of Spikevax experienced FATIGUE, CHEST PAIN, DYSPNOEA and was diagnosed with PERICARDITIS. Laboratory results showed elevated troponin, normal CXR, SARS-CoV-2 test negative. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is conditional based on the lack of information; a | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 22-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 23-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue) (seriousness criterion medically significant), CHEST PAIN (Chest Pain) (seriousness criterion medically significant) and DYSPNOEA (Dyspnoea) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving and FATIGUE (Fatigue), CHEST PAIN (Chest Pain) and DYSPNOEA (Dyspnoea) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Dec-2021, Chest X-ray: normal (normal) Normal.<br>On 23-Dec-2021, Electrocardiogram: not provided Not provided.<br>On 23-Dec-2021, Troponin: less than 2 Less than 2.<br>On 18-Jan-2022, Troponin: less than 2 Less than 2.<br>On an unknown date, SARS-CoV-2 test: negative covid-19 test (Negative) No - Negative COVID-19 test.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication use information was not provided by reporter.<br>Patient had not had symptoms associated with COVID-19.<br>Patient was not tested positive for COVID-19 since having the vaccine.<br>Reporter was not sure, if the patient was enrolled in clinical trial.<br>Patient was hospitalized twice, each less than 24 hrs.<br>Patient was diagnosed with likely resolving pericarditis.<br>Patient was treated with NSAIDS.<br>On 23-Dec-2021 and 18-Jan-2022, cardiac troponin level was unknown.<br>Peak troponin value was less than 2.<br>There was no change in patient's troponin serial values.<br>On 23-Dec-2021, patient's ECG showed possible early pericarditis changes.<br><br>Company comment: This regulatory case concerns a 30-year-old female patient, with no relevant medical history, who experienced the serious expected events of FATIGUE, CHEST PAIN, DYSPNOEA and the serious expected AESI of PERICARDITIS. The event PERICARDITIS occurred on the following day of the third dose of mRNA-1273 vaccine. The events FATIGUE, CHEST PAIN and DYSPNOEA occurred after an unknown time interval after the third dose of the mRNA-1273 vaccine. The rechallenge is reported unknown but it could be considered as not applicable since no information about the further dosing has been disclosed. Patient's electrocardiogram showed possible early pericarditis changes, but no change | causal relationship cannot be excluded due to the lack of information. | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | in troponin serial values. The benefit-risk relationship of the mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 21-Jan-2022: Added lab data, historical drugs, updated event seriousness, indication and action taken for the suspect drug. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 20-Jan-2022. The most recent information was received on 27-Jan-2022 and was forwarded to Moderna on 27-Jan-2022.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Chest Pain), CHEST DISCOMFORT (Chest tightness) and NAUSEA (Nausea) in a 34-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000029A) for COVID-19 vaccination.<br><br>The patient's past medical history included Nonsmoker.<br>Previously administered products included for Vaccination: COVID-19 MRNA VACCINE BIONTECH on 26-May-2021; for COVID-19 vaccination: COVID-19 MRNA VACCINE BIONTECH.<br>Past adverse reactions to the above products included No adverse event with COVID-19 MRNA VACCINE BIONTECH and COVID-19 MRNA VACCINE BIONTECH.<br><br>On 09-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 16-Jan-2021, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion medically significant) and CHEST DISCOMFORT (Chest tightness) (seriousness criterion medically significant). On 16-Jan-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced NAUSEA (Nausea) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving and CHEST PAIN (Chest Pain), CHEST DISCOMFORT (Chest tightness) and NAUSEA (Nausea) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 16-Jan-2022, Basophil count: 0.03 x10/l 0.03 x10/L.<br>On 16-Jan-2022, Eosinophil count: 0.05 x10/l 0.05 x10/L.<br>On 16-Jan-2022, Haematocrit: 0.418 l/l 0.418 L/L.<br>On 16-Jan-2022, Haemoglobin: 148 g/l 148 g/L.<br>On 16-Jan-2022, Immature granulocyte count: 0.02 x10/l 0.02 x10/L.<br>On 16-Jan-2022, Lymphocyte count: 0.79 x10/l (Low) 0.79 x10/L.<br>On 16-Jan-2022, Mean cell haemoglobin: 32.7 pg hi 32.7 pg HI.<br>On 16-Jan-2022, Mean cell haemoglobin concentration: 354 g/l hi 354 g/L HI.<br>On 16-Jan-2022, Mean cell volume: 92.3 fl 92.3 fL.<br>On 16-Jan-2022, Mean platelet volume: 9.9 fl 9.9 fL.<br>On 16-Jan-2022, Monocyte count: 0.37 x10/l 0.37 x10/L. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On 16-Jan-2022, Neutrophil count: 3.89 x10/l 3.89 x10/L.<br>On 16-Jan-2022, Platelet count: 124 x10/l (Low) 124 x10/L.<br>On 16-Jan-2022, Red blood cell count: 4.53 x10/l 4.53 x10/L.<br>On 16-Jan-2022, Red cell distribution width: 12.3 % 12.3 %.<br>On 16-Jan-2022, White blood cell count: 5.13 x10/l 5.13 x10/L.<br>On an unknown date, Blood test: results not reported Results not reported.<br>On an unknown date, Chest X-ray: non-concerning non-concerning.<br>On an unknown date, Electrocardiogram: no changes no changes.<br>On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>Laboratory data included on 16-Jan-2022, nucleated red blood cell count was 0.00 x10/L and NRBC count per 100 WBC was 0.0/100WBC.<br><br>The diagnosis from the hospital was possible pericarditis, chest pain worse on lying flat but no ECG changes, was being reviewed by echocardiogram in 3-4 weeks.<br><br>Patient has not tested positive for COVID-19 since having the vaccine.<br><br>The report relates to possible inflammation of the heart like myocarditis or pericarditis.<br><br>Relevant investigations included ECG, blood tests and chest x-ray.<br><br>The patient was admitted to hospital and was less than 24hour stay on ambulatory unit.<br><br>Diagnosis information included cardiology advice sought and advised to treat as pericarditis with echocardiogram advised in 3-4 weeks.<br><br>Treatment for the event included colchicine and Nonsteroidal anti-inflammatory drugs (NSAIDs).<br><br>Company comment: This is a regulatory authority case concerning a 34-year-old, male patient, non-smoke, with no other medical history reported, who experienced the unexpected, serious event of chest pain and chest discomfort and the expected, serious, AESI event of pericarditis. The event pericarditis occurred 7 days after the third dose of mRNA-1273 vaccine administration. The patient described chest pain worse on lying flat. Patient sought consult and was diagnosed as possible pericarditis. Diagnostics were done as follows, ECG: no electrocardiogram changes and chest x-ray: non-concerning. Patient was treated as a case of | | |

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| | pericarditis, given colchicine and nonsteroidal anti-inflammatory drugs and advised to have a repeat ECG in 3-4 weeks. At the time of report, pericarditis was resolving. Patient received Covid-19 vaccine BioNTech 7 months prior to the dose of mRNA-1273 Vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 27-Jan-2022: Follow-up received contains updated medical history, lab data and new events added. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of TACHYCARDIA (Tachycardia) and MYOCARDITIS (myocardium inflammation) in a 23-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 16-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jun-2021, the patient experienced TACHYCARDIA (Tachycardia). On an unknown date, the patient experienced MYOCARDITIS (myocardium inflammation). On 20-Aug-2021, TACHYCARDIA (Tachycardia) was resolving. At the time of the report, MYOCARDITIS (myocardium inflammation) outcome was unknown.<br><br>No concomitant medications were reported.<br><br>No treatment medications were reported.<br><br>Company comment:<br>This is a regulatory authority case concerning a 23-year-old, male patient with no reported medical history, who experienced the unexpected, non-serious event of tachycardia and expected, non-serious, AESI event of myocarditis. The event tachycardia occurred 25 days before the second dose of mRNA-1273 vaccine administration while the event myocarditis occurrence unknown with respect to the second dose of mRNA-1273 vaccine administration. No reported treatment information. The outcome of the event tachycardia was resolving while the event myocarditis the outcome was unknown from the time of last observation. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (HEART MUSCLE INFLAMMATION) in a 28-year-old male patient who | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | received mRNA-1273 (Spikevax) (batch nos. 3004670 and 3002920) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 immunisation (Spikevax Dos 1) on 27-Jun-2021.<br><br>On 10-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (HEART MUSCLE INFLAMMATION) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (HEART MUSCLE INFLAMMATION) was resolving.<br><br>No concomitant medications were reported.<br>No treatment medications were reported.<br><br>Company Comment - This regulatory authority case concerns a 28 year old male patient with no relevant medical history, who experienced the serious expected AESI event of myocarditis. The event occurred approximately 2 months after the second dose of mRNA-1273 vaccine, and was resolving at the time of the report. The rechallenge was not applicable as there are no plans for future dosing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 21-Jan-2022. The most recent information was received on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATION ABNORMAL (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis), CHEST PAIN (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis), HEADACHE (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis), PYREXIA (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) and MYOCARDITIS (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) in a 14-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000004A) for COVID-19 vaccination. | 14-year-old male patient with unknown medical history, who the night after the second dose of Spikevax experienced fever and headache and 2 days later developed oppressive chest pain and respiration abnormal. Patient went to the ED were laboratory showed elevated Troponin and PCR, ECG with widespread concave elevation in the absence of secularity, echocardiogram normal, and cMRI performed 7 days later was normal . Patient was admitted to UTIC and treated with colchicine and ibuprofen. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded. | [redacted] |

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| | Previously administered products included for SARS-CoV-2 immunisation: SPIKEVAX on 30-Nov-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br>Concurrent medical conditions included Food allergy (walnuts).<br><br>On 28-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 28-Dec-2021, the patient experienced RESPIRATION ABNORMAL (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) (seriousness criterion hospitalization), CHEST PAIN (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) (seriousness criterion hospitalization), HEADACHE (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) (seriousness criterion hospitalization), PYREXIA (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) (seriousness criterion hospitalization) and MYOCARDITIS (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) (seriousness criterion hospitalization). At the time of the report, RESPIRATION ABNORMAL (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis), CHEST PAIN (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis), HEADACHE (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis), PYREXIA (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) and MYOCARDITIS (in the night of 28/12 fever at 37.5 c and headache. from the night of 31/12 appearance of respirophasic chest pain. access to ps with subsequent recovery in utic with diagnosis of myopericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 31-Dec-2021, C-reactive protein: negative (Negative) Negative.<br>On 31-Dec-2021, Echocardiogram: negative (Negative) Negative.<br>On 31-Dec-2021, Electrocardiogram: negative (Negative) Negative.<br>On 31-Dec-2021, Troponin: negative (Negative) Negative.<br>On 07-Jan-2022, Magnetic resonance imaging heart: negative (Negative) Negative.<br>On 10-Jan-2022, Blood test: negative (Negative) Negative.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. | | |

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| | For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>On 30-Dec, patient complained of oppressive breath-phasic chest pain, so patient accessed in PS. Laboratory tests of myocardiocytonecrosis were done (Troponin 14300 ng/l, PCR 2.3 mg/dl).<br>At the ECG widespread concave elevation in the absence of secularity. At the echocardiogram focus not significant morpho functional changes. Patient was admitted to UTIC.<br>Patient took Colchicine 0.5 OD and Brufen 600 mg TID therapy.<br>Company comment: Company comment: This is a regulatory case concerning a 14-year-old male patient with no relevant medical history, who experienced the serious expected event Myocarditis (AESI) approximately 2 days after the second dose of mRNA-1273. Patient had fever and headache the night after vaccination and 2 days later developed oppressive chest pain and respiration abnormal so patient accessed for medical attention. Laboratory showed Troponin 14300 ng/l and PCR 2.3 mg/dl, ECG with widespread concave elevation in the absence of secularity and echocardiogram focus not significant morpho functional changes. Patient was admitted to UTIC and treated with colchicine and ibuprofen. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 10-Feb-2022: Follow up document received on 10 Feb 2022 contains lab test results and sender's comment was updated. | | |
| [redacted] | This regulatory authority case was reported by a consumer and describes the occurrence of DIZZINESS (light headedness), SEIZURE (seizure), MYOCARDITIS (Myocarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), SYNCOPE (Fainting), HEADACHE (Headache), BACK PAIN (Back pain), DEPRESSED LEVEL OF CONSCIOUSNESS (Depressed level of consciousness) and VISUAL IMPAIRMENT (Visual impairment) in a 40-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 0000014) for an unknown indication.<br><br>No medical history of collapse seizure or family history, and no medication being taken. Patient was not pregnant, patient was not currently breastfeeding.<br>The patient's past medical history included Suspected COVID-19 from 28-Jul-2021 to 11-Aug-2021.<br>Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for an unknown indication.<br><br>On 19-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 06-Jan-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced | Not a case of myocarditis. All results were within normal levels. Patient discharged | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | DIZZINESS (light headedness) (seriousness criteria hospitalization and medically significant), SEIZURE (seizure) (seriousness criteria hospitalization and medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization and medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization and medically significant), SYNCOPE (Fainting) (seriousness criteria hospitalization and medically significant), HEADACHE (Headache) (seriousness criteria hospitalization and medically significant), BACK PAIN (Back pain) (seriousness criteria hospitalization and medically significant), DEPRESSED LEVEL OF CONSCIOUSNESS (Depressed level of consciousness) (seriousness criteria hospitalization and medically significant) and VISUAL IMPAIRMENT (Visual impairment) (seriousness criteria hospitalization and medically significant). At the time of the report, DIZZINESS (light headedness) and FATIGUE (Fatigue/unusual tiredness) was resolving, SEIZURE (seizure), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), SYNCOPE (Fainting), BACK PAIN (Back pain), DEPRESSED LEVEL OF CONSCIOUSNESS (Depressed level of consciousness) and VISUAL IMPAIRMENT (Visual impairment) outcome was unknown, MYOCARDITIS (Myocarditis) had resolved with sequelae and HEADACHE (Headache) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On **01-Aug-2021, SARS-CoV-2 test: yes - positive covid-19 test (Positive) Yes - Positive COVID-19 test.**<br>On an unknown date, Blood test: clear (normal) clear.<br>On an unknown date, Chest X-ray: clear (normal) clear.<br>On an unknown date, Computerised tomogram: clear (normal) clear.<br>On an unknown date, Electrocardiogram: clear (normal) clear.<br>On an unknown date, Investigation: since return from holiday had further tests- clear (normal) Since return from holiday had further tests- clear.<br>Patient collapsed on holiday. Right before that the patient had strange visual reactions, it lasted for 2 minutes approximately. Patient was not fully conscious for 8-10 minutes, and it could be a seizure, even if patient had no medical or family history of seizures. The patient was taken to hospital where CT scan, bloods, chest X -ray, and ECG were performed, all was clear. Since return from holiday patient had further tests (not specified), it was also clear. Patient also experienced pain in centre of chest with exertion, even if just walking, pain in centre of back when laying down, light headedness which has since got better, fatigue in the first week after collapse, now it has improved. Headaches in the first week, now resolved. Myocarditis was only mentioned in the final questionnaire, but not in patient's narrative. Patient was hospitalized for 5 hours. The diagnosis made by a medical professional was Unknown.<br><br>Company comment: This is a regulatory case concerning a 40-year-old female patient with no relevant medical history, who experienced the serious unexpected serious events Dizziness, | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Seizure, Myocarditis, Fatigue, Chest pain, Dyspnea, Palpitations, Tachycardia, Syncope, Headache, Back pain, Depressed level of consciousness, Visual impairment and expected serious event of Myocarditis. The event Myocarditis occurred 18 days after the third dose of mRNA-1273 COVID 19 Vaccine. On an unknown date the events Dizziness, Seizure, Fatigue, Chest pain, Dyspnea, Palpitations, Tachycardia, Syncope, Headache, Back pain, Depressed level of consciousness, Visual impairment occurred after receiving third dose of mRNA-1273. Patient was taken to the hospital, where CT scan, bloods, chest x Ray, ECG were performed, all was clear and was discharged after 5 hours. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 01-Feb-2022: Significant follow-up contains additional events and updated medical information. | | |
| [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 36-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 09-Jun-2021 at 6:00 PM, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form.<br>On 08-Jul-2021 at 10:15 AM, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form.<br>On 23-Dec-2021 at 6:00 PM, received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and ILLNESS (very ill). At the time of the report, MYOCARDITIS (Myocarditis) and ILLNESS (very ill) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 05-Jan-2022, Blood test: normal (normal) Search for food allergies/ Result none.<br>On 10-Jan-2022, Blood test: normal (normal) Search for diseases / Result none.<br><br>No relevant concomitant and treatment medications were reported<br>Patient was never suffered from allergies or skin disorders.<br>It was reported that patient's body cannot handle the vaccine<br><br>Company comment:<br>This case concerns a 36-year-old female patient with no medical history reported, who experienced serious expected AESI of myocarditis, that occurred after the 2nd dose of the mRNA-1273 however, the exact time to onset was not provided. No further details were provided other than that the patient was hospitalized due to the event. The rechallenge was not | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | applicable due to occurrence after the 2nd dose and nature of the event. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Local evaluator comment:<br>This spontaneous report from [redacted] reported by a consumer, concerns a 36-year-old, female patient, with no medical history reported, who experienced, according to [redacted] SmPC, the expected serious adverse event of special interest (AESI) of myocarditis and non-serious unexpected event of illness. The event occurred unspecified time after the 2nd dose of the mRNA-1273. Reportedly, the patient was very ill after the 2nd dose and was hospitalized due to myocarditis. No further details were provided. The rechallenge was not applicable due to nature of the event and occurrence after the 2nd dose. The company assessed the event as related to the vaccine. According to the latest version of the RMP, Myocarditis was included in the SmPC Sections 4.3 Contraindications, 4.4 Special Warnings and Precautions for Use and 4.8 Undesirable effects. Routine risk minimisation activities recommend specific clinical measures to address the risk by health-care professionals being alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition. (SmPC Section 4.4). Additional risk minimization measures includes Direct Healthcare Professional Communication was disseminated on 19 July 2021 to inform HCPs regarding the risk of myocarditis / pericarditis following vaccination with Spikevax. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>This case was linked to [redacted] (Patient Link).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 21-Jan-2022: Translation received on 25-JAN-2022, which contains significant information. Patient demographics, dosage details, narrative updated | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 24-Jan-2022. The most recent information was received on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever) and DYSPNOEA (Shortness of breath) in a 26-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 0000501A) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS and SARS-COV-2 VIRUS.<br>Past adverse reactions to the above products included No adverse event with SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 12-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), PYREXIA (Fever) (seriousness criterion medically significant) and DYSPNOEA (Shortness of breath) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved and FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever) and DYSPNOEA (Shortness of breath) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: not provided (Inconclusive) Not provided.<br>On an unknown date, Electrocardiogram: not provided (Inconclusive) Not provided.<br>On an unknown date, Ultrasound chest: not provided (Inconclusive) Not provided.<br>No concomitant medications were provided by the reporter.<br>Patient not had symptoms associated with COVID-19. Patient not had a COVID-19 test.<br>Patient was not tested positive for COVID-19 since having the vaccine.<br>Patient was not enrolled in clinical trial.<br>The report was related to possible inflammation of the heart (myocarditis or pericarditis). The symptoms did not led to the hospital stay.<br>The diagnosis was made by a medical professional (Cardiologist, GP).<br>Ibuprofen was prescribed as treatment medication.<br>ECG, blood test, chest ultrasound were performed.<br>It was unknown whether any blood tests, such as for certain proteins (called troponin) that signal heart muscle damage were performed.<br><br>Company comment: This is a regulatory case concerning a 26 year-old, male patient with no reported medical history, who experienced the serious ( (medically significant according to Authority report) expected, AESI of pericarditis and the serious unexpected events of fatigue, chest pain, pyrexia and dyspnoea. The events occurred on an unknown date after the third dose of mRNA 1273 COVID-19 Vaccine. The patient reported the diagnosis was performed by a cardiologist and ibuprofen was prescribed as treatment, no laboratory tests nor imaging were provided. The outcome of the event pericarditis was reported as not recovered. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 25-Jan-2022: Follow-up received on 25-Jan-2022- Historical Vaccine (SARS COV2 Virus) added , Lab data (Electrocardiogram, Blood test, Ultrasound chest ) added , Suspect product indication added , action taken updated | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004730) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: COVID-19 VACCINE JANSSEN on 28-Jun-2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE JANSSEN.<br><br>On 24-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Nov-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On 29-Nov-2021, PERICARDITIS (Pericarditis) had resolved.<br><br>No concomitant medications were reported.<br><br>No treatment medications were reported.<br><br>Company Comment: This is a regulatory case concerning a 19-year-old male patient with no relevant medical history, who experienced the serious expected AESI event of pericarditis. The event occurred 2 days after the second dose of mRNA-1273 vaccine administration and was recovered 5 days later. No treatment medications were reported. The event was assessed as related to the product administration per temporal association. The rechallenge was not applicable since the events occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 25-Jan-2022: Translated document received on 26-Jan-2022 contains, non significant information | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | No concomitant and treatment medications reported.<br><br>Company Comment: This is a regulatory case concerning a 28-year-old male patient with no reported medical history, who experienced the serious expected AESI event of myocarditis. The event occurred on unknown day after the second dose of mRNA-1273 vaccine administration. The outcome was unknown at the time of this report and no treatment medications were reported. The event was assessed as related to the product administration. The rechallenge was not applicable since the event occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Stomach burning sensation of.<br><br>On 14-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Nov-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) was resolving.<br><br>No concomitant medications were provided.<br>Treatment for the events were not provided.<br>Last date of administration 14-NOV-2021.<br><br>This case concerns a 37-year-old male patient with no relevant medical history, who experienced the unexpected serious event of Chest Pain, and expected serious adverse event of special interest, Myocarditis, all events caused hospitalization of the patient as reported by the regulatory authority. The events occurred in 3 days after receiving the second dose of mRNA-1273 Vaccine No clinical or treatment details were given. It was reported that the outcome of the events was resolving. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>LITERATURE REFERENCE:<br>Echeverry T, Norris M, Weber V. Myocarditis after COVID-19 vaccination. Circulation. 2021;144(1):A14205 | 31-year-old male with no past medical history who presented with burning chest pain for two days after receiving his second mRNA COVID-19 vaccine. The pain was associated with orthopnea and paroxysmal nocturnal dyspnea. Initial EKG showed no acute ischemic changes. Blood work revealed elevated troponin of 1.7 and negative CRP and ESR. Transthoracic echocardiogram | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | No Medical History information was reported.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was treated with METOPROLOL for Myocarditis, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, C-reactive protein: negative (Negative) negative CRP.<br>On an unknown date, Echocardiogram: 55% revealed an ejection fraction of 55% with no wall motion abnormalities..<br>On an unknown date, Electrocardiogram: normal (normal) Initial EKG showed no acute ischemic changes..<br>On an unknown date, Magnetic resonance imaging heart: abnormal (abnormal) showed an area of myocardial hyper-enhancement in the apical anterior segment suggesting the diagnosis of myocarditis.<br>On an unknown date, Red blood cell sedimentation rate: negative (Negative) Negative.<br>On an unknown date, Troponin: 1.7 (High) Blood work revealed elevated troponin of 1.7.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be related.<br><br>No concomitant medications were reported.<br><br>Patient presented with burning chest pain for two days after receiving his second mRNA COVID-19 vaccine. The pain was associated with orthopnea and paroxysmal nocturnal dyspnea<br><br>Patient was discharged with Metoprolol and was instructed to refrain from strenuous exercise. Patient was seen outpatient, and endorses to still experience intermittent burning substernal chest pain.<br><br>Author concluded that they present this case as a recognition of the relationship between myocarditis and mRNA COVID-19 vaccines will allow these patients presenting with chest pain to receive higher value care while hopefully sparing them from receiving unnecessary invasive cardiac procedures.<br><br>Company comment: This is a literature case concerning a 31-year-old male patient with no medical history reported, who experienced the expected serious AESI of Myocarditis. The patient was presented with burning chest pain for two days after the second dose of mRNA-1273 vaccine. The patient was hospitalized, and the diagnosis was established by cardiac magnetic resonance imaging. The treatment included Metoprolol and the patient was discharged | revealed an ejection fraction of 55% with no wall motion abnormalities. The following day patient had CMR that showed an area of myocardial hyper-enhancement in the apical anterior segment suggesting the diagnosis of myocarditis. Patient was discharged with Metoprolol and was instructed to refrain from strenuous exercise. Patient was seen outpatient, and endorses to still experience intermittent burning substernal chest pain. According to the WHO causality assessment this case is considered possible | |

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| | with intermittent burning substernal chest pain; the outcome was reported as unknown. Rechallenge was not applicable since the event occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Jan-2022: Follow-up received by safety on 31-Jan-2022 included an Email with [redacted] received from [redacted] team, updated laboratory data and duration of event. | | |
| [redacted] | This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (mRNA vaccine induced myocarditis) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>LITERATURE REFERENCE:<br>Singh A, Hiltner. Myocarditis due to mRNA COVID-19 vaccine administration. Chest. 2021;161(1 ):A57<br><br>The patient's past medical history included COVID-19 (Patient had been diagnosed with confirmed COVID-19 infection seven months prior to presentation.).<br>Concurrent medical conditions included Asthma.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (mRNA vaccine induced myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (mRNA vaccine induced myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Investigation: abnormal (abnormal) Elevated cardiac and infammatory markers, but further workup was negative for signifcant coronary artery disease.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MYOCARDITIS (mRNA vaccine induced myocarditis) to be related.<br><br>The disease course was mild. Treatment was conservative and he experienced resolution of most of the reported symptoms. Follow up was reassuring.<br><br>The diagnosis was made based on the constellation of clinical fndings, exclusion of other causes of myocarditis and the temporal relationship to C-19 vaccine administration. Notably, the case occurred in patient with confrmed previous COVID-19 infection.<br><br>Company comment: This is a literature case concerning a 30-year-old male patient with medical history of COVID-19 infection seven months prior to presentation and asthma, who | Literature report for a 30 years old male with medical history of asthma and COVID019 infection 7 months prior of his 2nd dose of Spikevax. Patient had elevated cardiac and inflammatory markers but further workup was negative. This report is heavily confounded by the previous history of COVID-19 infection. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | experienced the expected serious AESI of Myocarditis 24 hours after the second dose of mRNA-1273 vaccine. The outcome was reported as recovering. Medical history remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>This case was linked to [redacted] (Patient Link).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 31-Jan-2022: Follow up received by safety on 31-Jan-2022 has Email received from [redacted] team and does not contain any new information. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYALGIA (Muscle Pain), MYOCARDITIS (After the booster prick bothered the heart. 4 days later went to urgency after exercise. Determination is heart muscle inflammation.) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 29-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216038) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 immunisation: Comirnaty on 30-Jun-2021 and Comirnaty on 03-Aug-2021.<br>Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.<br><br>On 23-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced MYALGIA (Muscle Pain) (seriousness criterion hospitalization) and MYOCARDITIS (After the booster prick bothered the heart. 4 days later went to urgency after exercise. Determination is heart muscle inflammation.) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). At the time of the report, MYALGIA (Muscle Pain), MYOCARDITIS (After the booster prick bothered the heart. 4 days later went to urgency after exercise. Determination is heart muscle inflammation.) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had not resolved.<br><br>Concomitant medication was not reported.<br>Treatment medication was received. But did not know if they help. No Improvement Examinations - All investigations for the Heart. No exercise for at least a month. 2 weeks of quiet rest. After the booster prick suffer from the heart. 4 days later urgent after load after exercise. Determination was heart muscle inflammation.<br>This regulatory case concerns a 29-year-old female patient with history of Covid-19 Vaccination with Comirnaty vaccine,who experienced the serious unexpected events of Myalgia and COVID-19 immunisation (Revaccination with different COVID-19 vaccine)was reported and serious expected event of Myocarditis.The events occurred on the same day after | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | the third dose of mRNA-1273 (Spikevax).The benefit-risk relationship of mRNA-1273 (Spikevax). is not affected by this report.<br>Limited information regarding these events has been provided at this time.reports of diagnostic tests,confirmation by the heath care provider and hospital records not reported,the diagnosis of Myocarditis was not confirmed per sd | | |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022. The most recent information was received on 25-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This case was initially received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022. The most recent information was received on 25-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 26-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214020) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 24-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 milliliter. On 27-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Acute pericarditis) to be related.<br><br>Concomitant medications were not provided by the reporter.<br>Treatment information was not provided.<br><br>This is a regulatory case concerning a 26-year-old female patient with no medical history reported, who experienced the serious expected AESI event of Pericarditis.The event occurred 3 dayS after administration of the second dose of mRNA-1273 (Spikevax).The benefit-risk relationship of mRNA-1273 (Spikevax) is not affected by this report.<br>Limited information regarding this event has been provided at this time.reports of diagnostic tests,confirmation by the heath care provider not reported<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 25-Jan-2022: Translation document received on 28-Jan-2022. Event verbatim and reporter's causality updated. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022. | 37 year old, male patient, with no reported relevant medical history, who 2 days after the 2nd dose of Spikevax was diagnosed with myocarditis. Laboratory test included high Sensitivity Troponin | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 03-Jan-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 05-Jan-2022, Electrocardiogram: abnormal (abnormal) 05/01/2022 EKG with RS and supralevel in the upper inferolateral face..<br>On 06-Jan-2022, Troponin I: high (High) 06/01/2022 High Sensitivity Troponin I Cardiac Markers 12273.5 pg/mL 0.0 - 34.2 07/01/2022 Cardiac Markers: High Sensitivity Troponin I 14196.3 pg/mL 0.0 - 34.2.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 03-Jan-2022.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant product was provided by the reporter.<br>No treatment medication was provided.<br><br>Company comment. This regulatory authority case concerns a 37– year – old, male patient, with no reported relevant medical history, who experienced the expected serious AESI event of myocarditis. The event occurred 2 days after the administration of one dose of mRNA-1273 vaccine, considered as second dose of COVID-19 vaccine schedule. No information about previous vaccination schedule was provided. At the time of the report the outcome of the event was not recovered. The case was assessed as serious as per Regulatory Authority´s report due to hospitalization; however, no details on hospitalization dates or treatment were provided in the source document. Laboratory test included high Sensitivity Troponin I, which was elevated, and the electrocardiogram is reported with RS and supralevel in the upper inferolateral face. The benefit-risk relationship of mRNA-1273 is not affected by this report. | I, which was elevated, and the electrocardiogram is reported with RS and supralevel in the upper inferolateral face. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue), CHILLS (Chills) and MYOCARDITIS (heart muscle inflammation (confirmed by cardiologists)) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. | 31 year old male with no reported medical history, who 2 days after the 3rd dose of Spikevax experienced fatigue and chills and was diagnosed with Myocarditis. The event myocarditis was confirmed by cardiologist after several ECG, blood tests and MRI ( results not reported) . | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | No Medical History information was reported.<br><br>On 02-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Dec-2021, the patient experienced FATIGUE (Fatigue), CHILLS (Chills) and MYOCARDITIS (heart muscle inflammation (confirmed by cardiologists)). At the time of the report, FATIGUE (Fatigue) and MYOCARDITIS (heart muscle inflammation (confirmed by cardiologists)) had not resolved and CHILLS (Chills) had resolved.<br>No concomitant medications were reported<br>No treatment information was provided<br><br>From 04.12.2021, severe Chills initially. I'm usually very cold resistant, but now I had to sleep with a t-shirt, sweater, jacket and two blankets, but I still thought I'd freeze to death. In addition, a strong feeling of weakness. From 06.12.2021, difficulties in managing small stairs, even small physical exertion were hardly possible. Instant shortness of breath and sweating, as well as stinging and pressure in the heart region. I am a [redacted] in active duty, usually do not cause any problems with such activities as I am physically fit. First presentation to general practitioner + cardiologist on 06.12.2021. Here already suspected heart muscle inflammation after Vaccination. Complete protection since then. Heart muscle inflammation was confirmed by cardiologists after several ECG (also 24 hours), blood tests and MRI. High probability that this is due to [redacted] with Moderna. Sick leave has been sent until further notice. Drug treatment with nebivovol, [redacted] and [redacted] is necessary. date of birth: [redacted] 1990<br><br>Company Comment: This RA case concerns a 31 year old male with no reported medical history , who experienced Non-serious, expected, AESI even of Myocarditis and other non-serious , expected events of fatigue and chills which occurred 3 days post vaccination with the 3rd dose of mRNA-1273 vaccine ( Moderna Covid 19 Vaccine ). The event myocarditis was confirmed by cardiologist after several ECG (also 24 hours), blood tests and MRI ( results not reported) . Treatment includes Nebivovol, Ramipril [redacted] and [redacted] ( Mg and K ) . The re-challenge for this case is not applicable since the events occurred after the 3rd dose and no additional doses will be given . The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. | According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of INFLUENZA LIKE ILLNESS (heart muscle inflammation, Fever, flu-like symptoms, body aches, headache, fatigue) and MYOCARDITIS (heart muscle inflammation, Fever, flu-like symptoms, body aches, headache, fatigue) in a 35-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214017) for COVID-19 vaccination.<br><br>No Medical History information was reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 13-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Dec-2021, the patient experienced INFLUENZA LIKE ILLNESS (heart muscle inflammation, Fever, flu-like symptoms, body aches, headache, fatigue) and MYOCARDITIS (heart muscle inflammation, Fever, flu-like symptoms, body aches, headache, fatigue). At the time of the report, INFLUENZA LIKE ILLNESS (heart muscle inflammation, Fever, flu-like symptoms, body aches, headache, fatigue) and MYOCARDITIS (heart muscle inflammation, Fever, flu-like symptoms, body aches, headache, fatigue) had not resolved.<br><br>Concomitant medications were not provided.<br>Treatment information was not provided.<br><br>Company Comment: This RA case concerns a 35 year old male with no reported medical history , who experienced Non-serious , expected, AESI event of myocarditis and non-serious , unexpected event of infuenza like illness which occurred one day post vaccination with the 3rd dose of mRNA-1273 vaccine ( Moderna Covid 19 Vaccine ) . Details like blood tests, diagnostic procedures to support the event myocarditis were not reported and also treatment information was not provided. The re-challenge for this case is not applicable since the events occurred after the 3rd dose and no additional doses will be given and also the events outcome was reported as unresolved. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocardium inflammation) in a 39-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced MYOCARDITIS (myocardium inflammation) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (myocardium inflammation) had not resolved.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br><br>Company comment. This regulatory authority case concerns a 39– year – old, female patient, with no reported relevant medical history, who experienced the expected serious AESI event of myocarditis. The event occurred 9 days after the administration of one dose of mRNA-1273 vaccine, considered as third dose of COVID-19 vaccine schedule. No information about previous vaccination schedule was provided. The case was assessed as serious as per Regulatory Authority´s report due to hospitalization; however, no details on laboratory data, | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | and/or clinical course were provided in the source document. The patient experienced palpitations and chest pressure and she presented to the emergency room, where she was in observation for three days. At the time of the report the outcome of the event was not recovered. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000030A) for COVID-19 vaccination.<br><br>No medical history information was provided.<br>Concomitant products included PREDNISONE (DELTACORTENE) for Autoimmune uveitis.<br><br>On 04-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter.<br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Jan-2022, Laboratory test: inconclusive (Inconclusive) Inconclusive.<br>On 10-Jan-2022, Laboratory test: inconclusive (Inconclusive) Inconclusive.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Treatment information was not provided.<br><br>Company comment: This regulatory authority case concerns a 26-year-old female patient, user of prednisone for autoimmune uveitis, who experienced the non-serious expected AESI of MYOCARDITIS. The event occurred 4 days after receiving a third dose of mRNA-1273. No information about previous vaccination schedule was provided. Reported lab data included 2 unspecified lab tests that were reported as inconclusive. Patient's history of an autoimmune condition remains as a confounder since it can be considered a risk factor for developing myocarditis. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was captured as provided by the Regulatory Authority.<br><br>Myopericarditis chronologically onset in relation to the third vaccine dose with mRNA vaccine | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via [redacted] (Reference number: [redacted]) on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) and CHEST PAIN (Chest pain) in a 33-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No medical history was provided by the reporter. | 33-year-old male patient, with no medical history reported, who the same day after the 3rd dose with Spikevax experience chest pain and was diagnosed with pericarditis. EKG was abnormal compatible with pericarditis. Patient was given antibiotics 8 days later for an unknwon indication. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Concomitant products included AMOXICILLIN SODIUM, CLAVULANATE POTASSIUM (CO-AMOXICLAV [AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM]) from 26-Dec-2021 to 02-Jan-2022 for an unknown indication.<br><br>On 18-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) had not resolved and CHEST PAIN (Chest pain) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: abnormal (abnormal) ECG changes and symptoms likely due to pericarditis (seen by hospital medical team)..<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter considered PERICARDITIS (Acute pericarditis) to be possibly related. No further causality assessment was provided for CHEST PAIN (Chest pain).<br><br>The patient had pericarditis possibly secondary to Moderna booster vaccination which he had just before developing chest pain, been thoroughly investigated and electrocardiogram (ECG) changes and symptoms likely due to pericarditis (seen by hospital medical team).<br><br>Treatment information was not provided.<br><br>Company comment:<br>This case concerns a 33-year-old male patient, with no medical history reported, who experienced the serious (medically significant) expected AESI of pericarditis and serious unexpected event of chest pain after the third dose of mRNA-1273. Pericarditis occurred the same day of vaccination and was not recovered at the time of report. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information. | |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 21-Jan-2022 and was forwarded to Moderna on 26-Jan-2022.<br>This case was received via Takeda Pharmaceuticals (Reference number: [redacted]) on 21-Jan-2022 and was forwarded to Moderna on 26-Jan-2022.<br>This case, initially reported to the [redacted] ([redacted]) by a (physician), was received via the [redacted] (Ref, [redacted]. At the age of 18, the patient underwent craniotomy to remove brain tumour in the left lateral temporal lobe, and oral administration of carbamazepine was completed more than five years ago. On 09-Jan-2022, at 13:00, the patient received the 3rd dose of this vaccine. On 10-Jan-2022, at 11:00, pyrexia developed. The patient took acetaminophen and loxoprofen sodium hydrate. On 11-Jan-2022, around 15:00, pyrexia resolved. On 12-Jan-2022, around 16:00, the patient had pulsatile | 29 years old male with previous medical history of brain tumor, who 3 days after the 3rd dose of Spikevax developed chest pain, headache, chest tightness and was found to have elevated CRP, abnormal EKG and Echo. Patient was diagnosed with Pericarditis. Patient was discharged 3 days later. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | headache in the left side of the head persisting for one minute. Around 20:00, intermittent chest pain and feeling of tightness developed. On 13-Jan-2022, at 08:00, the patient visited a medical institution. The patient had acute chest pain or chest tightness. CK, CK-MB, and D-dimer did not increase. CRP was elevated to 1.46 mg/dL. Echocardiography showed high signal intensity in the anterior wall, abnormal pericardial effusion, and inflammation of the pericardium. Electrocardiogram showed increases of 0.5 minutes in II, III, and aVF. Consultation was made with an internal medicine physician, and the patient was hospitalized. The patient was diagnosed with suspected epicarditis. Oral administration of naproxen 600 mg and colchicine 0.5 mg was started. Other disorders that can explain clinical symptoms/findings were ruled out by differential diagnosis. On 14-Jan-2022, chest X-ray was performed, and there was no abnormality. On 16-Jan-2022, in the morning, the symptoms disappeared. The symptoms were resolving, and the patient was discharged from the hospital. The outcome of pyrexia was reported as resolved. The outcome of suspected epicarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information. | |
| [redacted] | This literature-non-study case was reported in a literature article and describes the occurrence of ENDOCARDITIS (non-infectious endocarditis and myocarditis) and MYOCARDITIS (non-infectious endocarditis and myocarditis) in a 20-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>LITERATURE REFERENCE:<br>Aikawa T, Ogino J, Kita Y, Funayama N, Oyama-Manabe N. Non-infectious endocarditis and myocarditis after COVID-19 mRNA vaccination. Eur Heart J Case Rep. 2022;6(1):1-2<br><br>No Medical History information was reported.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced ENDOCARDITIS (non-infectious endocarditis and myocarditis) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (non-infectious endocarditis and myocarditis) (seriousness criteria hospitalization and medically significant) and PYREXIA (Fever). The patient was hospitalized for 3 days due to ENDOCARDITIS and MYOCARDITIS. At the time of the report, ENDOCARDITIS (non-infectious endocarditis and myocarditis), MYOCARDITIS (non-infectious endocarditis and myocarditis) and PYREXIA (Fever) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Angiocardiogram: abnormal (abnormal) subepicardial delayed enhancement in the left ventricular anterior wall.<br>On an unknown date, Biopsy heart: abnormal (abnormal) distinct endocardial thickening consisting of erythrocytes and myeloperoxidase-positive neutrophils.<br>On an unknown date, Blood creatinine (50-210): 376 u/l (High) 376 U/L. | 20-year-old previously healthy man presented to the hospital with<br>chest pain 2 days after his 2nd dose of Spikevax. He had a fever of 37.5, and COVID-19 test returned negative. Electrocardiography showed ST-segment elevation, Echocardiography showed mid-anterior wall motion abnormality in the left ventricle. Elevated troponin T; creatinine kinase and C-reactive protein. Coronary computed tomography (CT) angiography demonstrated no coronary abnormalities. CT showed subepicardial delayed enhancement in the left<br>ventricular anterior wall, cardiovascular magnetic resonance imaging indicated acute myocarditis. Right ventricular endomyocardial biopsy revealed a distinct endocardial thickening consisting of erythrocytes and myeloperoxidase-positive neutrophils. A focal infiltration of mononuclear cells was also found in the endocardium, which were identified as natural killer (NK) cells with dense granules of about 250 nm diameter in the cytoplasm by electron microscopy. Autoantibodies associated<br>with connective tissue diseases were negative. His symptoms<br>improved overnight without any treatment and he was discharged<br>3 days after admission. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On an unknown date, Body temperature: 37.5 degree celcious 37.5 Degree celcious.<br>On an unknown date, C-reactive protein: 2.40 mg/dl (High) 2.40 mg/dL normal value lessthan 0.30.<br>On an unknown date, Echocardiogram: abnormal (abnormal) mid-anterior wall motion abnormality in the left ventricle.<br>On an unknown date, Electrocardiogram: elevation ST-segment elevation in leads I, aVL, and V2–6.<br>On an unknown date, Magnetic resonance imaging: abnormal (abnormal) indicating acute myocarditis.<br>On an unknown date, Microscopy: abnormal (abnormal) natural killer(NK) cells with dense granules of about 250 nm diameter.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.<br>On an unknown date, Troponin T: 509 ng/l (High) 509 ng/L normal value was less than or equal 14.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered ENDOCARDITIS (non-infectious endocarditis and myocarditis), MYOCARDITIS (non-infectious endocarditis and myocarditis) and PYREXIA (Fever) to be related.<br><br>No concomitant and treatment medications were reported by the reporter.<br><br>Patient symptoms include Chest pain.<br><br>Company comment: This is a literature case concerning a 20-year-old male patient with no reported medical history, who experienced the serious expected AESI event of myocarditis, serious unexpected event of endocarditis and non-serious expected event of pyrexia. The events occurred within 2 days after the second dose of the mRNA-1273 vaccine. The patient was hospitalized for 3 days. The treatment details were not provided, the events recovered at the time of this report. The rechallenge was not applicable, as the events were reported after the second dose and no information on additional dosing available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Additional information has been requested.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 27-Jan-2022: Follow up received by safety on 27-Jan-2022 has Email with [redacted] received from [redacted] team and contains significant information in Literature information, Reporter information, outcome of the event, seriousness criteria(hospitalized) and lab test results | | |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted]) on 25-Jan-2022 and was forwarded to Moderna on 27-Jan-2022.<br>This case, initially reported to the [redacted] ([redacted]) by a (physician), was received via the [redacted] (Ref, [redacted] Myocarditis was assessed as serious by the MAH. On an unknown date, New coronavirus vaccine (product name unknown) the patient received the 1st dose of vaccine. On an unknown date, New coronavirus vaccine (product name unknown) the patient received the 2nd dose of vaccine. On an unknown date, | 34 year old, male patient, with no reported relevant medical history, who 4 days after the 3rd dose of Spikevax experienced chest pain which persisted for one hour, and he presented to the emergency department where no electrocardiographic changes were reported, and echocardiography showed no functional decline or cardiac effusion. Laboratory | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | body temperature before the vaccination: 36.3 degrees Celsius. On 21-Jan-2022, at 15:46, the patient received the 3rd dose of this vaccine. On 25-Jan-2022, at 05:00, chest pain developed without any trigger and persisted for one hour. Around 06:00, the patient visited the emergency outpatient department in the reporting hospital. There were no electrocardiographic changes, and echocardiography showed no obvious functional decline or cardiac effusion. Blood collection showed CRP: 1.51, high-sensitivity troponin I: 2,207, CL: 161, and CK-MB: 9. The symptoms were ongoing and unchanged. The outcome of myocarditis was reported as ongoing and unchanged. Follow-up investigation will be made. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship.<br><br>Company comment-<br>This regulatory authority case concerns a 34– year – old, male patient, with no reported relevant medical history, who experienced the expected serious AESI event of myocarditis (important medical event). The event occurred after the administration of one dose of mRNA-1273 vaccine, considered as third dose of COVID-19 vaccine schedule. No information about previous vaccination schedule was provided. Four days after vaccination, the patient developed chest pain which persisted for one hour. He presented to the emergency department where no electrocardiographic changes were reported, and echocardiography showed no functional decline or cardiac effusion. Laboratory test were performed, with elevated blood creatine phosphokinase MB (9 U/L) and high-sensitivity troponin I (2207 ng/mL). No treatment was provided in the source document. At the time of the report the outcome of the event was not recovered. The benefit-risk relationship of mRNA-1273 is not affected by this report. | test were performed, with elevated blood creatine phosphokinase MB (9 U/L) and high-sensitivity troponin I (2207 ng/mL). According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 27-Jan-2022 and was forwarded to Moderna on 27-Jan-2022.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (MYOCARDITE) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214031 and 3005834) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 10-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 08-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 10-Oct-2021, the patient experienced MYOCARDITIS (MYOCARDITE) (seriousness criterion life threatening). At the time of the report, MYOCARDITIS (MYOCARDITE) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Treatment details not provided.<br>Concomitant drug details not provided. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Company comment. This regulatory authority case concerns a 18-year-old, male patient with no reported relevant medical history, who experienced the expected serious AESI event of myocarditis. The event occurred 2 days after the second dose of mRNA-1273 (correct interval between the doses). At the time of the report the outcome of the event was recovering. The case was assessed as serious as per Regulatory Authority´s report due to life threatening criteria. There are no details in the source document about the clinical course, tests or treatment received for medical reviewing. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 27-Jan-2022 and was forwarded to Moderna on 27-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CORONARY ARTERY DISSECTION (Myocarditis and coronary dissection) and MYOCARDITIS (Myocarditis and coronary dissection) in a 21-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 030G21A) for COVID-19 vaccination.<br><br>Previously administered products included for SARS-CoV-2 vaccination: SPIKEVAX on 10-May-2021; for COVID-19 immunisation: SPIKEVAX on 14-Jun-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX and SPIKEVAX.<br><br>On 29-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 dosage form. On 02-Jan-2022, the patient experienced CORONARY ARTERY DISSECTION (Myocarditis and coronary dissection) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis and coronary dissection) (seriousness criterion hospitalization). At the time of the report, CORONARY ARTERY DISSECTION (Myocarditis and coronary dissection) and MYOCARDITIS (Myocarditis and coronary dissection) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported .<br>Treatment information was not provided.<br><br>Company comment include<br>This is a regulatory case concerning a 21-year-old female patient with no medical history reported,who experienced the serious unexpected event of Coronary artery dissection and serious expected AESI event of Myocarditis The events occurred 5 days after administration of third dose of mRNA-1273 (Spikevax).The benefit-risk relationship of mRNA-1273 (Spikevax). is not affected by this report<br>Limited information regarding these events has been provided at this time.reports of diagnostic tests,confirmation by the heath care provider and hospital records not reported | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 27-Jan-2022 and was forwarded to Moderna on 27-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Heart muscle inflammation Start: 13.12.21 no end yet) in a 20-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005690) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 02-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Dec-2021, the patient experienced MYOCARDITIS (Heart muscle inflammation Start: 13.12.21 no end yet) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Heart muscle inflammation Start: 13.12.21 no end yet) had not resolved.<br><br>No Information about risk factors or pre-existing conditions was provided. Flu-like symptoms already occurred 2 hours after vaccination, they lasted about 2.5 days.1.5 weeks after vaccination, patient felt a pressure in the chest and heart chest. After two days she went to the doctor, and got a briefing at the [redacted] immediately after the ECG. A cardiologist detected heart muscle inflammation. It was the first dose with Moderna ,before two vaccinations were with Astrazeneca.<br>Concomitant product usage were not provided.<br>Treatment details were not provided.<br><br>Company comment: This case concerns a 20-year-old female patient, with no reported medical history, who experienced the serious, expected event of myocarditis after the third dose of mRNA 1273 COVID-19 vaccine which led to hospitalization. The patient initially had flu-like symptoms 2 hours after the vaccination which lasted about 2.5 days. Around 1.5 weeks after the vaccination, patient felt chest pressure and consulted a doctor and had an EC G done. Cardiologist detected heart muscle inflammation. The patient received two doses of ASTRAZENCA vaccine prior to the mRNA 1273 vaccine. At the time of report, event had not resolved. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Up to 39.8 degrees), MALAISE (Malaise), CHILLS (Chills) and MYOCARDITIS (29.05.2021 with RTW in [redacted] with suspected heart attack. Diagnosis: myocaditis) in a 40-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3001944) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: Spikevax COVID-19 mRNA Vaccine on 13-Apr-2021. | 40-year-old male patient with no medical history reported, who 3 days after the 2nd dose of Spikevax experienced chest pain with cold sweat, which persisted for 24 hours. The patient visited the emergency department where diagnostic tests included an ECG (result not provided) and troponin levels (reported as 350). Diagnosis was myocarditis, for which he remained hospitalized. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the | [redacted] |

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| | Past adverse reactions to the above products included No adverse event with Spikevax COVID-19 mRNA Vaccine.<br><br>On 25-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-May-2021, the patient experienced PYREXIA (Up to 39.8 degrees) (seriousness criterion hospitalization), MALAISE (Malaise) (seriousness criterion hospitalization) and CHILLS (Chills) (seriousness criterion hospitalization). On 28-May-2021, the patient experienced MYOCARDITIS (29.05.2021 with RTW in [redacted] with suspected heart attack. Diagnosis: myocaditis) (seriousness criterion hospitalization). On 26-May-2021, CHILLS (Chills) had resolved. On 27-May-2021, MALAISE (Malaise) had resolved. On 30-May-2021, MYOCARDITIS (29.05.2021 with RTW in [redacted] with suspected heart attack. Diagnosis: myocaditis) was resolving. On 26-Jun-2021, PYREXIA (Up to 39.8 degrees) had resolved.<br>No concomitant and treatment medications were reported.<br><br>On 25 May 2021 at 12:00 patient received vaccine and at 22:00 started vaccination response, chills and fever until 39.8 as well as headache.<br>On 26 May 2021 all day malaise with headache, slept all day.<br>On 27 May 2021 better well-being, but with headache until noon.<br>On 28 May 2021 in the morning, chest pain begins with cold welding with low loads (stairs and bending), symptomatic free in the afternoon.<br>On 29 May 2021 back chest pain with cold sweat, called emergency, then hospitalization with especially HI.<br><br>Patient underwent ECG, Sono unobtrusive, then blood sampling (troponin 350).<br><br>Company comment:<br>This case concerns a 40-year-old male patient with no medical history reported, who experienced the unexpected, serious (hospitalization) event of myocarditis. The event occurred approximately 1 month and a half after the first dose of mRNA-1273 and 3 days after the second dose of mRNA-1273. After the second dose of the vaccine, the patient experienced pyrexia, chills and malaise. Three days after the vaccine, the patient experienced chest pain with cold sweat, which persisted for 24 hours. The patient visited the emergency department where diagnostic tests included an ECG (result not provided) and troponin levels (reported as 350). Diagnosis was myocarditis, for which he remained hospitalized. The benefit-risk relationship of mRNA-1273 is not affected by this report. | events, as well as the elevated troponin; a causal relationship cannot be excluded | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ARRHYTHMIA (heart rhythm disturbance just before infact or soagar cardiac arrest), PFEIFFER SYNDROME (Whistler glandular fever heart muscle inflammation intensive, [redacted] and MYOCARDITIS (Pfeifferic glandular fever heart muscle inflammation intensive, [redacted] in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. | 18-year-old male patient with no medical history reported, who 98 days after the 2nd dose of Spikevax was diagnosed with Infectious mononucleosis and myocarditis. Infectious mononucleosis (IM, mono), also known as glandular fever, is an infection usually caused by the Epstein–Barr virus which is a primary causative agent for infectious myocarditis. | [redacted] |

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| | No Medical History information was reported.<br><br>On 15-Jun-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 27-Jul-2021, received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 02-Nov-2021, the patient experienced PFEIFFER SYNDROME (Whistler glandular fever heart muscle inflammation intensive, [redacted] (seriousness criterion hospitalization) and MYOCARDITIS (Pfeifferic glandular fever heart muscle inflammation intensive, [redacted] (seriousness criterion hospitalization).<br>On an unknown date, the patient experienced ARRHYTHMIA (heart rhythm disturbance just before infact or soagar cardiac arrest) (seriousness criterion hospitalization). At the time of the report, ARRHYTHMIA (heart rhythm disturbance just before infact or soagar cardiac arrest) outcome was unknown and PFEIFFER SYNDROME (Whistler glandular fever heart muscle inflammation intensive [redacted] and MYOCARDITIS (Pfeifferic glandular fever heart muscle inflammation intensive, [redacted] had not resolved.<br>The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.<br><br>No concomitant medications were reported.<br>No treatment medications were reported.<br><br>Company comment:<br>This case concerns an 18-year-old male patient with no medical history reported, who experienced the unexpected, serious (hospitalization) events of arrhythmia and Pfeiffer syndrome, and expected event myocarditis, 5 months after the first dose of mRNA-1273 and 4 months after the most recent dose of mRNA-1273. Pfeiffer syndrome's cause, explained by a genetic mutation and autosomal dominant inheritance, are confounders for this event.<br>Information regarding clinical evaluation, diagnostic tests and treatment provided has not been disclosed. The benefit-risk relationship of mRNA-1273 is not affected by this report. | According to the WHO causality assessment this report is considered unlikely and more likely explained by the diagnosis of infectious mononucleosis. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 38-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE2083) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: Comirnaty and Comirnaty.<br>Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.<br><br>On 29-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 29-Dec-2021, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). On 02-Jan-2022, the patient | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | experienced PERICARDITIS (PERICARDITIS) (seriousness criterion medically significant). At the time of the report, COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) had resolved and PERICARDITIS (PERICARDITIS) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 02-Jan-2022, Echocardiogram: abnormal (abnormal) Probable pericarditis..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE).<br><br>No concomitant medication mentioned.<br>No treatment information mentioned.<br>Primary vaccination scheme information: D1 29.06.2021 Comirnaty batch no FE2083, D2 04.08.2021 Comirnaty batch no FC5029 | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDIAL EFFUSION (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome), CARDIOGENIC SHOCK (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome), CAPILLARY LEAK SYNDROME (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome) and MYOCARDITIS (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome) in a 40-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included SARS-CoV-2 test positive on 05-Jan-2022.<br><br>On 02-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Jan-2022, the patient experienced PERICARDIAL EFFUSION (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome) (seriousness criterion hospitalization), CARDIOGENIC SHOCK (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome) (seriousness criterion hospitalization), CAPILLARY LEAK SYNDROME (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome) | 40-year-old, male patient with unknown medical history and use of cocaine, with primary series vaccination with PFIZER COVID-19 VACCINE, who 3 days after the 3rd dose of Spikevax was found to be SARS-CoV-2 test positive, and 2 days later experienced Myocarditis, cardiogenic shock, Pericardial effusion and Capillary leak syndrome. The events occurred approximately 5 days after the 3rd dose mRNA-1273 vaccine. According to the WHO causality assessment this report is considered unlikely and more likely explained by his COVID-19 infection. | [redacted] |

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| | (seriousness criterion hospitalization) and MYOCARDITIS (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome) (seriousness criterion hospitalization). At the time of the report, PERICARDIAL EFFUSION (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome), CARDIOGENIC SHOCK (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome), CAPILLARY LEAK SYNDROME (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome) and MYOCARDITIS (Myopericarditis with pericardial effusion, development of cardiogenic shock picture with lacidemia up to 8mmol/L, oliguria, picture similar capillary leak syndrome) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 11-Jan-2021, Haematology test: inconclusive (Inconclusive) Inconclusive.<br>On 07-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive.<br>On 07-Jan-2022, Haematology test: inconclusive (Inconclusive) Inconclusive.<br>On 07-Jan-2022, SARS-CoV-2 test: inconclusive (Inconclusive) Inconclusive.<br>On 09-Jan-2022, Blood lactic acid: inconclusive (Inconclusive) Inconclusive.<br>On 10-Jan-2022, Echocardiogram: inconclusive (Inconclusive) Inconclusive.<br>On 10-Jan-2022, SARS-CoV-2 test: inconclusive (Inconclusive) Inconclusive.<br>On 11-Jan-2022, Physical examination: inconclusive (Inconclusive) Inconclusive and inconclusive (Inconclusive) Inconclusive.<br>On 11-Jan-2022, Urine analysis: inconclusive (Inconclusive) Inconclusive.<br>On 12-Jan-2022, Haematology test: inconclusive (Inconclusive) Inconclusive.<br>On 12-Jan-2022, Physical examination: inconclusive (Inconclusive) Inconclusive.<br>On 12-Jan-2022, Urine analysis: inconclusive (Inconclusive) Inconclusive.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br>No treatment medications were provided.<br>Company comment: This is a regulatory case concerning a 40-year-old, male patient with a history of SARS-CoV-2 test positive (5-JAN-2021) and use of [redacted] with an interchange of vaccine products (two doses were with PFIZER COVID-19 VACCINE, before current vaccination), who experienced the serious expected according CCDS, AESI of Myocarditis and the serious unexpected, according CCDS, AESI of Cardiogenic shock and the serious unexpected, according CCDS, events of Pericardial effusion and Capillary leak syndrome. The events occurred approximately 5 days after the 3rd dose mRNA-1273 vaccine. The rechallenge was not applicable since no information on other doses was available. The medical history of SARS-CoV-2 test positive tree days after mRNA-1273 vaccine and use of [redacted] reported remains as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by | | |

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| | this report. The case was assessed as serious as per Regulatory Authority´s report due to hospitalization.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 03-Feb-2022: Follow up received that contains No New Information. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation), ASTHENIA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation), MYOCARDITIS (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation) and TACHYCARDIA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 10-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Jun-2021, the patient experienced DYSPNOEA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation) (seriousness criterion medically significant), ASTHENIA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation) (seriousness criterion medically significant), MYOCARDITIS (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation) (seriousness criterion medically significant) and TACHYCARDIA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation) (seriousness criterion medically significant). At the time of the report, DYSPNOEA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation), ASTHENIA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation), MYOCARDITIS (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation) and TACHYCARDIA (- palpitations, drowsy feeling (feeling constantly impotent) shortness of breath, headache, internal restlessness, shaky legs, heart muscle inflammation) had not resolved.<br><br>No concomitant medications were reported.<br><br>No treatment medications were reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Company comment<br>This is a regulatory case concerning a 30-year-old male patient with no medical history reported, who experienced the serious expected AESI event of myocarditis, unexpected events of dyspnoea, asthenia and tachycardia. The events occurred approximately 2 days after the 2nd dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 35-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br>On 29-Sep-2021 at 4:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 30-Sep-2021, the patient experienced CARDIAC DISCOMFORT (PAIN IN HEART REGION), PYREXIA (FEVER), GENERAL PHYSICAL HEALTH DETERIORATION (GENERAL PHYSICAL CONDITION DECREASED) and FATIGUE (EXHAUSTION). On an unknown date, the patient experienced DYSPNOEA (DYSPNEA), DISSOCIATION (FEELING REMOTE), PERICARDITIS (PERICARDITIS) (seriousness criterion medically significant) and BEDRIDDEN (BEDRIDDEN). At the time of the report, DYSPNOEA (DYSPNEA) had not resolved, DISSOCIATION (FEELING REMOTE), PERICARDITIS (PERICARDITIS) and BEDRIDDEN (BEDRIDDEN) outcome was unknown and CARDIAC DISCOMFORT (PAIN IN HEART REGION), PYREXIA (FEVER), GENERAL PHYSICAL HEALTH DETERIORATION (GENERAL PHYSICAL CONDITION DECREASED) and FATIGUE (EXHAUSTION) had resolved with sequelae.<br>No relevant concomitant medications were reported.<br><br>It was reported that pericarditis (the patient reported that the GP was quite certain), bedridden, dyspnea. The patient reported waking up in the middle of the night with strong pain in heart region and total exhaustion. Due to feeling remote, the patient did not call the emergency number. The following days the patient was bedridden with exhaustion. The patient reported to still experience general physical condition decreased and dyspnea. This was the most prominent the first 2 months. Event general physical condition decreased latency was 1-2 days and gradually improvement, for event fever latency was 1-2 days and gradually improvement, for event exhaustion latency was 1-2 days and gradually improvement. The patient also reported that his mother died of heart problems 14 days after administration of dose no. 2, pfizer.<br><br>Treatment medication was not provided by the reporter.<br><br>Company comment: This is a regulatory case concerning a 35-year-old male patient with no medical history reported, who experienced the serious expected AESI event of pericarditis and other non-serious events. The event occurred on an unknown date after the 2nd dose of mRNA- | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | 1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC FAILURE (Cardiac insufficiency) and MYOCARDITIS (Severe myocarditis with heart failure) in a 23-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Patient allergic history and information on risk factors or pre-existing illnesses were reported as None.<br><br>On 18-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Dec-2021, the patient experienced CARDIAC FAILURE (Cardiac insufficiency) (seriousness criterion hospitalization) and MYOCARDITIS (Severe myocarditis with heart failure) (seriousness criterion hospitalization). At the time of the report, CARDIAC FAILURE (Cardiac insufficiency) and MYOCARDITIS (Severe myocarditis with heart failure) outcome was unknown.<br><br>No Concomitant medications were reported.<br><br>It was reported that patient had rel. pre-existing illnesses/occurrence of high fever and low performance, fatigue.<br><br>Company comment: This case concerns a 23-year-old, male patient with no relevant medical history, but pre-existing illnesses/occurrence of high fever, low performance, and fatigue, who experienced the unexpected serious event of Cardiac Failure and expected serious event of Myocarditis. The events occurred approximately 2 days after the second dose of mRNA-1273 (Moderna covid-19 vaccine). The rechallenge was not applicable as events occurred after second dose. This patient's reported pre-existing illness suggestive of underlying medical condition remains a contributory factor. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report.<br><br>No treatment details were reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (confirmed myocarditis after covid booster vaccination with increased troponin level, chest pain) in a 29-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. | 29 years old male patient with no medical history reported. who 2 days after the 3dr dose experienced chest pain. Patient went tot he ED and was found to have elevated troponin, abnormal ECG, abnormal echo, and cMRI. Patient was diagnosed with myocarditis. According to the | [redacted] |

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| | The patient was allergic to Brown patch, raw milk.<br><br>On 16-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Dec-2021, the patient experienced MYOCARDITIS (confirmed myocarditis after covid booster vaccination with increased troponin level, chest pain) (seriousness criterion hospitalization). On 23-Dec-2021, MYOCARDITIS (confirmed myocarditis after covid booster vaccination with increased troponin level, chest pain) outcome was unknown.<br><br>Concomitant medications were not reported.<br><br>Birthday reported as [redacted]1992. Patient had No pre-existing diseases, supposedly through Covid infection 2020 without symptoms. Patient had Chills on 16 Dec 2021 and 17 Dec 2021 after vaccination, none symptoms on 18 Dec 2021, chest pain emitted on 19 Dec 2021 following presentation in the emergency room. Lab Result included: Troponin 136, rising over time and falling from 21 Dec 2021, increased ST output in V1 derivative ECG, echo unobtrusive. MRI known detecting myocarditis. CT without finding to exclude KHK.<br><br>No treatment information was provided by the reporter.<br><br>COMPANY COMMENT : This is a regulatory case concerning a 29 years old male patient with no medical history reported. who experienced the unexpected serious AESI event of myocarditis. The event occurred 3 days after administration of the booster dose of mRNA-1273. . At the time of report event outcome is unknown. Lab reports Troponin is 136, rising over time and falling from 21 Dec 2021, increased ST output in V1 derivative ECG, MRI known detecting myocarditis. The benefit-risk relationship of mRNA-1273 is not affected by this report. The case was assessed as Serious as per Regulatory Authority report due to hospitalization. | WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of TACHYCARDIA (Tachycardia), the first episode of VENTRICULAR INTERNAL DIAMETER ABNORMAL (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume), the second episode of VENTRICULAR INTERNAL DIAMETER ABNORMAL (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume), INFLUENZA (Flu symptoms), DYSPNOEA (Dyspnoea), DILATATION VENTRICULAR (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume), MYOCARDITIS (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and | 31 years old male with unknown medical history who 2 days after the 2nd dose of SPikevax experienced increased sweating, fatigue and retrosternal pressure and shortness of breath. Patient was admitted to the hospital and found to have impaired left ventricular function and dilated left ventricle through MRI heart examination, and impaired cardiac output of only 43%, according to reporter. This is a consumer report. Patient was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as | [redacted] |

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| | correspondingly increased enddiastolic and endsystolic volume), DIZZINESS (Strong pressure on chest with associated shortness of breath and dizziness and sweats), EJECTION FRACTION DECREASED (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume), DIZZINESS (Dizziness), CHEST DISCOMFORT (Strong pressure on chest with associated shortness of breath and dizziness and sweats) and HYPERHIDROSIS (Strong pressure on chest with associated shortness of breath and dizziness and sweats) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004500 and 3004500) for COVID-19 vaccination.<br><br>Patient had House dust allergy Hay fever. Patient had pre-existing diseases as congenital uretertal stenosis.<br><br>On 13-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 03-Jan-2022, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 13-Dec-2021, the patient experienced INFLUENZA (Flu symptoms) (seriousness criterion hospitalization). On 04-Jan-2022, the patient experienced DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization). On 05-Jan-2022, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization), the first episode of VENTRICULAR INTERNAL DIAMETER ABNORMAL (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume) (seriousness criterion hospitalization), the second episode of VENTRICULAR INTERNAL DIAMETER ABNORMAL (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume) (seriousness criterion hospitalization), DILATATION VENTRICULAR (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume) (seriousness criterion hospitalization), MYOCARDITIS (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume) (seriousness criterion hospitalization), DIZZINESS (Strong pressure on chest with associated shortness of breath and dizziness and sweats) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume) (seriousness criterion hospitalization), DIZZINESS (Dizziness) (seriousness criterion hospitalization), CHEST DISCOMFORT (Strong pressure on chest with associated shortness of breath and dizziness and sweats) (seriousness criterion hospitalization) and HYPERHIDROSIS (Strong pressure on chest with associated shortness of breath and dizziness and sweats) (seriousness criterion hospitalization). On 29-Dec-2021, INFLUENZA (Flu symptoms) was resolving. On 09-Jan-2022, TACHYCARDIA (Tachycardia) was resolving. On 12-Jan-2022, last episode of VENTRICULAR INTERNAL DIAMETER ABNORMAL (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic | the EKG results; a causal relationship cannot be excluded | |

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| | volume), DYSPNOEA (Dyspnoea), DILATATION VENTRICULAR (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume), MYOCARDITIS (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume), DIZZINESS (Strong pressure on chest with associated shortness of breath and dizziness and sweats), EJECTION FRACTION DECREASED (Acute diffuse myocarditis, impaired left ventricular function (EF = 43%) and dilated left ventricle and correspondingly increased enddiastolic and endsystolic volume), DIZZINESS (Dizziness), CHEST DISCOMFORT (Strong pressure on chest with associated shortness of breath and dizziness and sweats) and HYPERHIDROSIS (Strong pressure on chest with associated shortness of breath and dizziness and sweats) had not resolved.<br><br>Patient's date of birth: [redacted]1990.<br>Concomitant medications were not reported .<br>Treatment information was provided as sacubitril/valsartan, beta blocker and an aldosterone antagoist.<br><br>Patient reported that in the first two weeks after vaccination, Patient experienced symptoms of a flu-like infection with fatigue, inappetence and sweats and he was feeling better the week before the second vaccination. After the second vaccination with COVID-19, Vaccine Moderna had increased sweating, fatigue and retrosternal pressure and shortness of breath two days after vaccination. Patient was admitted to the hospital from 05.01.2022 for the period from 05 to 11.01.202. The treating physicians diagnosed acute diffuse myocarditis after SARS-CoV-2 vaccination with impaired left ventricular function and dilated left ventricle through MRI heart examination. Impaired cardiac output of only 43% was found. Doctors also noted pericardial effusion. For treatment, he received a guideline sacubitril/valsartan, beta blocker and an aldosterone antagoist. In addition, after his release, he had to wear a Life Vest defibrillator until his condition improves again. He was prescribed physical protection and sports renunciation of at least six months.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 08-Feb-2022: Follow up received contains No New Information. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 21-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced INFLUENZA LIKE ILLNESS (2 days after my Moderna vaccination, where I had headaches, body aches, chest pain, and chills, | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | myocarditis was diagnosed by the family doctor.) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On 24-Dec-2021, INFLUENZA LIKE ILLNESS (2 days after my Moderna vaccination, where I had headaches, body aches, chest pain, and chills, myocarditis was diagnosed by the family doctor.) had not resolved. At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br>Concomitant product use was not provided by the reporter.<br><br>Company comment:<br>This case concerns a 30-year-old male patient with no medical history provided, who experienced serious expected event of Myocarditis (AESI), as well as non serious unexpected event of Influenza like illness. The events occurred two days after the patient had received the mRNA-1273 vaccine (As third dose). As per event description, the patient had headaches, body aches, chest pain, and chills and myocarditis diagnosed by the family doctor. At the time of this report, both reported events were still ongoing and no additional details regarding the clinical course of the events were provided. The rechallenge is not applicable since the patient experienced the events following the third dose of the vaccine. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of the first episode of MYOCARDITIS (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis), CHEST PAIN (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis), the second episode of MYOCARDITIS (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis) and the third episode of MYOCARDITIS (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis) in a 26-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Perimyocarditis in 2014.<br><br>On 16-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 2 dosage form. On 18-Jul-2021, the patient experienced the first episode of MYOCARDITIS (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis) (seriousness criterion hospitalization), the second episode of MYOCARDITIS (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis) (seriousness criteria hospitalization and medically significant) and the third episode of MYOCARDITIS (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis) (seriousness criteria hospitalization and medically significant). On 21-Jul-2021, CHEST PAIN (thoracic pain approximately the third day after [redacted] with troponin increase in the sense of myocarditis) and the last episode of | 26-year-old, male patient with medical history of perimyocarditis, who 3 days after the 2nd dose of Spikevax experienced Chest Pain, flu-like reaction with fever and chills. Patient went to the hospital and lab results showed elevated Troponin. Patient ws diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded. | [redacted] |

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| | MYOCARDITIS (thoracic pain approximately the last day after [redacted] with troponin increase in the sense of myocarditis) had resolved.<br><br>The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient had peri myocarditis on 01/2014, Patient was on Tropnon T hs max. 0.3 ng/ml, exclusion of stenosing CHD on 01/14/. Post vaccination initially patient experienced flu-like reaction with fever and chills. The reaction, even under anti-inflammatory therapy; declined over the course. The 3rd day after vaccination felt recurrent thoracic pain, followed by the hospital for further clarification. Here troponin was 1550 ng/l max.<br>Concomitant medications were not provided by the reporter.<br>Treatment information was not provided.<br><br>Company comment: This case concerns a 26-year-old, male patient with relevant medical history of perimyocarditis, who experienced the expected serious AESI event of Myocarditis and unexpected serious event of Chest Pain. The events occurred approximately 3 days after the second dose of mRNA-1273 (Moderna covid-19 vaccine). Post vaccination, patient initially experienced flu-like reaction with fever and chills. The 3rd day after vaccination, then felt recurrent thoracic pain, followed by the hospital for further clarification. Troponin was 1550ng/l. The rechallenge was not applicable as events occurred after second dose of mRNA-1273. This patient's underlying medical condition remains a confounder. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of INFLUENZA (fever, chills, body aches), MYOCARDITIS (perimyocarditis with typical chest pain) and CHEST PAIN (perimyocarditis with typical chest pain) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004952) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 12-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-Aug-2021, the patient experienced INFLUENZA (fever, chills, body aches) (seriousness criterion medically significant), MYOCARDITIS (perimyocarditis with typical chest pain) (seriousness criterion medically significant) and CHEST PAIN (perimyocarditis with typical chest pain) (seriousness criterion medically significant). At the time of the report, INFLUENZA (fever, chills, body aches), MYOCARDITIS (perimyocarditis with typical chest pain) and CHEST PAIN (perimyocarditis with typical chest pain) was resolving. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.<br><br>No concomitant medication information was mentioned by reporter<br>Patient reported that after vaccination he experienced fever, chills, body aches and marked respiratory dependent chest pain clinic with diagnosis of perimyocarditis. 3 days after vaccination heart enzymes already falling and no symptoms.<br>No treatment medication information was mentioned by reporter | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis) in a 35-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3001945) for COVID-19 vaccination.<br><br>Previously administered products included for Prophylactic vaccination: SpikevaxCOVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax on 29-Apr-2021.<br><br>On 10-Jun-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 2 dosage form. On 13-Jun-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (myocarditis) outcome was unknown.<br>Concomitant medications were not provided by the reporter.<br>The affected person had to be hospitalized and the reaction was life-threatening. She had myocarditis, a myocardial infarction was ruled out. Treatment in the hospital.<br>Treatment information was not provided by the reporter.<br><br>Company comment: This regulatory authority case concerns a 35-year-old male patient with no medical history reported, who experienced the expected serious (medically significant) event/AESI of Myocarditis, approximately 3 days after the second dose of mRNA- 1273 vaccine. Very limited information is available regarding clinical manifestations and diagnostic work-up. The patient was hospitalized and the event was reported as life-threatening, without further details. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report.<br>The seriousness criterion of the event was assessed as per regulatory authority report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 31-Jan-2022. The most recent information was received on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PYREXIA (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | reporting comment), MYOCARDITIS (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see reporting comment), DYSPNOEA (low-grade fever, stabbing chest pains with blockopnea “acute myopericarditis”see reporting comment) and CHEST PAIN (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see reporting comment) in a 26-year-old patient of an unknown gender who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (Subcutaneous) 1 dosage form. On 28-Dec-2021, the patient experienced PYREXIA (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see reporting comment) (seriousness criterion hospitalization), MYOCARDITIS (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see reporting comment) (seriousness criterion hospitalization), DYSPNOEA (low-grade fever, stabbing chest pains with blockopnea “acute myopericarditis”see reporting comment) (seriousness criterion hospitalization) and CHEST PAIN (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see reporting comment) (seriousness criterion hospitalization). At the time of the report, PYREXIA (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see reporting comment), MYOCARDITIS (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see reporting comment), DYSPNOEA (low-grade fever, stabbing chest pains with blockopnea “acute myopericarditis”see reporting comment) and CHEST PAIN (low-grade fever, stabbing chest pains with blockopnea acute myopericarditis see reporting comment) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 29-Dec-2021, Troponin: inconclusive (Inconclusive) Inconclusive.<br><br>For mRNA-1273 (Spikevax) (Subcutaneous), the reporter did not provide any causality assessments.<br><br>No concomitant medication was reported.<br>No treatment medications was reported.<br>Reporter's comment: Do not risk C.V. After vaccination booster COVID 19 III dose, already from the next day malaise, fever and chest pain with blockopnea. Diagnosis: Acute myopericarditis.<br><br>Company Comment:<br>This is a regulatory case concerning a 26-year-old patient of unknown gender with no medical history reported, who experienced the expected serious event of Myocarditis (AESI) and the serious unexpected events of dyspnoea, chest pain and, pyrexia (seriousness criterion hospitalization). The events started one day after the administration of the booster dose of | | |

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| | mRNA-1273 vaccine. Troponin level was reported as inconclusive. The route of administration was subcutaneous. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Feb-2022: Follow-up received where in laboratory result reported. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 31-Jan-2022 and was forwarded to Moderna on 31-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis with fatigue.) in a 30-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 00087A) for COVID-19 vaccination.<br><br>Pre-existing condition included obesity.<br><br>On 21-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced MYOCARDITIS (myocarditis with fatigue.). On 27-Dec-2021, MYOCARDITIS (myocarditis with fatigue.) was resolving.<br><br>Concomitant product use was not provided by the reporter.<br><br>Patient had heart failure therapy with improvement of AP symptoms.<br><br>Company comment:<br>This is a regulatory authority case concerning a 30-year-old, male patient with no reported medical history, who experienced the expected, non-serious, AESI event of myocarditis. The event myocarditis occurred 3 days after the second dose of mRNA-1273 vaccine administration and was accompanied by fatigue. No reported treatment information. The outcome of the event myocarditis with fatigue was resolving from the time of last observation. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>LITERATURE REFERENCE:<br>Kaul R, Sreenivasan. Myocarditis following COVID-19 vaccination. Int J Cardiol Heart Vasc. 2021;36:100872<br><br>No Medical History information was reported.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, after starting mRNA-1273 | Literature report for a 28-year-old male patient with no reported medical history, who 3 days after the second dose of Spikevax the patient presented with chest pain, fever, headache, neck pain and myalgia. Laboratory results showed elevated troponin and CRP, and SARS-CoV-2 negative. Initial echocardiogram showed LVEF of 55% with mid inferolateral wall hypokinesis, normal RV systolic function and no pericardial effusion. Repeat echocardiogram showed LVEF of 55–60%, normal wall motion, normal RV systolic function and no pericardial effusion. Electrocardiogram showed infero-lateral ST elevation with no | [redacted] |

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| | (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 3 days due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Acute myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Angiocardiogram: normal (normal) Normal.<br>On an unknown date, Blood pressure measurement: 118/60 mmhg (abnormal) 118/60 mmHg.<br>On an unknown date, Body temperature: 98.6f 98.6F.<br>On an unknown date, C-reactive protein (Unknown-1.0): 6 mg/dl (High) 6 mg/dL.<br>On an unknown date, Coxsackie virus test: negative (Negative) Negative.<br>On an unknown date, Echocardiogram: lvef 55% (abnormal) LVEF 55%, mid inferolateral wall hypokinesis, normal RV systolic function, no pericardial effusion and lvef 55–60%, normal wall motion (normal) LVEF 55–60%, normal wall motion, normal RV systolic function, no pericardial effusion on repeat echocardiogram.<br>On an unknown date, Electrocardiogram: infero-lateral st elevation with no reciprocal cha (abnormal) Infero-lateral ST elevation with no reciprocal changes.<br>On an unknown date, Heart rate: 75 beats per min 75 beats per min.<br>On an unknown date, Magnetic resonance imaging heart: myocarditis (abnormal) myocarditis, showing diffuse ST segment elevation and delayed hyperenhancement (abnormal) showing delayed hyperenhancement in the lateral epicardium and in the pericardium and epicardial surface of the anterior and lateral wall consistent with myocarditis.<br>On an unknown date, Oxygen saturation: 98 percent on room air 98 percent on room air.<br>On an unknown date, Physical examination: unremarkable Unremarkable.<br>On an unknown date, Red blood cell sedimentation rate (0-15): 15 mm/hr (normal) 15 mm/hr.<br>On an unknown date, SARS-CoV-2 antibody test: negative (Negative) Negative.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.<br>On an unknown date, Troponin I (Unknown-0.03): 7.75 (ng/ml) (High) 7.75 (ng/mL).<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MYOCARDITIS (Acute myocarditis) to be related.<br><br>Concomitant product use was not provided by the reporter. Presenting complaint Other symptoms includes chest pain, fever, headache, neck pain, and myalgia.<br><br>Lab test included Respiratory multiplex negative. Clinical condition at the time of discharge was reported as Asymptomatic.<br><br>Company comment:<br>This is a literature case concerning a 28-year-old male patient with no reported medical history, who experienced the serious expected AESI event of myocarditis. The event occurred 3 days after the second dose of the mRNA-1273 vaccine. The patient presented with chest pain. Other symptoms included fever, headache, neck pain and myalgia. Initial echocardiogram showed | reciprocal changes. The patient was hospitalized for three days and treated with conservative care. At the time of the report, the event resolved. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded. | |

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| | LVEF of 55% with mid inferolateral wall hypokinesis, normal RV systolic function and no pericardial effusion. Repeat echocardiogram showed LVEF of 55–60%, normal wall motion, normal RV systolic function and no pericardial effusion. Electrocardiogram showed infero-lateral ST elevation with no reciprocal changes. The patient was hospitalized for three days and treated with conservative care. At the time of the report, the event resolved. The event was assessed as related to the product administration per temporal association. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 03-Feb-2022: Follow up received by safety 03-Feb-2022 has Email with [redacted] received from [redacted] team and contain information about race, lab data, dose, treatment, events added | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 31-Jan-2022 and was forwarded to Moderna on 31-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Two days after 3 doses I had to go to the emergency room because of severe chest pain, the diagnosis was pericarditis (I had already had pericarditis in 2020 due to cancer)) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006321) for COVID-19 vaccination.<br><br>The patient's past medical history included Pericarditis in 2020 and Hodgkin's lymphoma. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) from 25-Mar-2021 to 03-Jun-2021 for COVID-19 vaccination.<br><br>On 04-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 06-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Two days after 3 doses I had to go to the emergency room because of severe chest pain, the diagnosis was pericarditis (I had already had pericarditis in 2020 due to cancer)) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Two days after 3 doses I had to go to the emergency room because of severe chest pain, the diagnosis was pericarditis (I had already had pericarditis in 2020 due to cancer)) was resolving.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 04-Jan-2022.<br><br>Treatment information was not provided.<br><br>Company comment: This is a regulatory authority case concerning a 37-year-old male patient with medical history of pericarditis in 2020 and Hodgkin's lymphoma, previously vaccinated with two doses of COVID-19 VACCINE NRVV AD (VAXZEVRIA); who experienced serious (medically significant), expected event of pericarditis (AESI). The event occurred | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | approximately 2 days after the administration of third dose of mRNA-1273 vaccine. Diagnostic test results and treatment details were not provided. Patient's medical history remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022. The most recent information was received on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (chest pain) and MYOCARDITIS (myocarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000082A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br>On 06-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced CHEST PAIN (chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (myocarditis) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (chest pain) and MYOCARDITIS (myocarditis) was resolving.<br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No Concomitant medications were reported.<br>No Treatment information was reported.<br>The patient was admitted with chest pain, Underwent MRI and it was showed myocarditis<br>Lab data provided on 09/01/2022 CXR and results provided No lobar collapse consolidation. No pleural effusions or pneumothoraces. The cardiothoracic ratio is within normal limits.<br>Lab data provided On 09/01/2022, ECG, HR77, RR779, PR131, QRSD 94 ,QT 349, QTcB 395, QTcB 395, Axis P68, QRS 53, T 126, Sinus rhythm, abnormal T, consider ischemia, lateral leads, ST elevation probable normal early repol pattern.<br><br>Company Comment - This regulatory authority case concerns a 31 year old male patient with no relevant medical history, who experienced the serious unexpected event of chest pain and the expected AESI of myocarditis. The events occurred 3 days after the third dose of mRNA-1273 vaccine, and was resolving at the time of the report. Patient was admitted due to chest pain, MRI revealed myocarditis. The rechallenge was not applicable as there are no plans for future dosing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>The patient was admitted with chest pain, Underwent MRI ad showed myocarditis. CXR report 09/01/2022 - No lobar collapse consolidation. No pleural effusions or pneumothoraces. The cardiothoracic ratio is within normal limits. ECG HR77 RR779 PR131 QRSD 94 QT 349 QTcB 395 QTcB 395 Axis P68 QRS 53 T 126 Sinus rhythm, abnormal T, consider ischemia, lateral leads, ST elevation probable normal early repol pattern.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Feb-2022: Significant Follow up included added I narrative, updated reporter's and sender's comment. | 31 year old male patient with no reported medical history, who 3 days after the 3rd dose of Spikevax experienced chest pain and was found to have elevated troponin, abnormal ECG, and abnormal cMRI. Patient was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 31-Jan-2022 and was forwarded to Moderna on 31-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Chest pain, myopericarditis) and CHEST PAIN (Chest pain, myopericarditis) in a 15-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214027) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Oct-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Oct-2021, the patient experienced MYOCARDITIS (Chest pain, myopericarditis) (seriousness criterion hospitalization) and CHEST PAIN (Chest pain, myopericarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Chest pain, myopericarditis) and CHEST PAIN (Chest pain, myopericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: negative (Negative) Negative.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>Previous vaccinations for COVID included was first dose on 20 Aug 2021,Spikevax, Lot 3004730.<br><br>Treatment medication was not provided by the reporter.<br><br>Company comment: This is a regulatory case concerning a 15-year-old male patient with no medical history reported who experienced the unexpected and serious (hospitalization) event of chest pain and the expected AESI myocarditis. The events occurred 2 days after a second dose of mRNA-1273 vaccine was administered. No further information was provided. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 01-Feb-2022: Follow-up information included no new information. | 15-year-old male patient with no medical history reported who 2 days after a second dose of Spikevax experienced chest pain and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is conditional based on the lack of information; a causal relationship cannot be excluded due to the lack of information. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of NASOPHARYNGITIS (COMMON COLD SYMPTOMS) and PERICARDITIS | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | (PERICARDITIS) in a 24-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br>On 09-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Sep-2021, the patient experienced NASOPHARYNGITIS (COMMON COLD SYMPTOMS) (seriousness criteria hospitalization and medically significant). On 05-Oct-2021, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PYREXIA (FEVER), DYSPNOEA (DYSPNOEA) and CHEST PAIN (CHEST PAIN). At the time of the report, NASOPHARYNGITIS (COMMON COLD SYMPTOMS) and PERICARDITIS (PERICARDITIS) was resolving and PYREXIA (FEVER), DYSPNOEA (DYSPNOEA) and CHEST PAIN (CHEST PAIN) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: the patient says that "the ecg gave results". (Inconclusive) The patient says that "the ECG gave results"..<br><br>No concomitant medications were reported.<br><br>The first days after vaccination, the patient started to have common cold symptoms. 14 days after vaccination, the patient experienced fever, chest pain and dyspnoea. The patient contacted a physician, who did an ECG, and the patient was sent to the hospital. At the hospital, they did several tests on the patient, and the patient was diagnosed with pericarditis. The patient got [redacted] 600mg and colchicine 0,5 mg as treatment. The patient was then routinely checked by the general physician. 25/Dec/2021 the patient started to feel bad again and was hospitalized. At the hospital the patient went through many tests again, which again came back to pericarditis. The patient got a treatment with [redacted]600mg and Prednisolone 30 mg, which the patient still use today (03/Jan/2022).<br><br>Company comment:<br>This case concerns a 24-year-old male patient with no medical history reported, who experienced the expected, serious (hospitalization) event of pericarditis 1 month after the second dose of mRNA-1273 administration. The patient experienced nasopharyngitis 12 days prior to the event onset, which could be a confounder. After diagnosis at the emergency room, the patient was treated with ibuprofen and colchicine, and was followed up regularly. Due to reappearance of symptoms 3 months after vaccination, the patient was diagnosed with pericarditis once again for which he was hospitalized and treated with ibuprofen and prednisone, which continued at the time of the report. Event outcome was reported as resolving. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of PERICARDITIS (25 Year old actress suffers pericarditis after her second moderna COVID-19 vaccine) in a 25-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No Medical History information was reported.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (25 Year old actress suffers pericarditis after her second moderna COVID-19 vaccine) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (25 Year old actress suffers pericarditis after her second moderna COVID-19 vaccine) outcome was unknown.<br><br>No concomitant medication information was reported.<br>No treatment medication information was reported.<br><br>Company comment: This spontaneous case concerns a 25-year-old, female patient, with no reported medical history, who experienced the expected, serious (Medically significant) AESI pericarditis. The event occurred after an unknown time of interval from receiving the second dose of mRNA-1273 vaccine, as nor vaccination or event dates were reported. No further clinical information was provided for medical reviewing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Jan-2022: Translation document received on 03 Feb 2022 and its included no new information.<br>On 28-Jan-2022: Translation document received on 03 Feb 2022 and its included no new information. | | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 32-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 079F21A) for COVID-19 vaccination.<br><br>Concomitant products included TOZINAMERAN (COMIRNATY) from 26-Nov-2021 to an unknown date for Revaccination with different COVID-19 vaccine.<br><br>On 17-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 04-Jan-2022, the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Treatment information was not provided.<br><br>Company comment. This regulatory authority case concerns a 32– year – old, female patient, with no reported medical history, who experienced the expected serious important medical AESI pericarditis, 18 days after the dose of mRNA-1273 vaccine. The patient previously received a dose of Tozinameran COVID vaccine. At the time of the report the outcome of the event was not recovered. No further clinical information was provided for medical reviewing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214010) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 28-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Jul-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis) had resolved with sequelae.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported.<br><br>Treatment details not provided.<br><br>Company comment include This is a regulatory case concerning a 21-year-old male patient with no medical history reported who experienced the serious, expected AESI myocarditis the same day after a second dose of mRNA-1273 vaccine was administered. The patient required hospitalization; at the time of the report the event had resolved with sequelae. No further information was provided. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyokarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 042G21A) for COVID-19 vaccination. | 22-year-old male patient with unknown medical history and who received the Janssen vaccine who the next day after the booster dose with Spikevax experienced myocarditis. The patient required hospitalization. No other information was provided. Important information is missing in the report including patient's medical history as well | [redacted] |

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| | Previously administered products included for Prophylactic vaccination: COVID-19 VACCINE JANSSEN in May 2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE JANSSEN.<br><br>On 11-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 12-Dec-2021, the patient experienced MYOCARDITIS (Perimyokarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyokarditis) had not resolved.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter. No treatment information was provided.<br><br>Company comment: This is a regulatory case concerning a 22-year-old male patient with no relevant medical history who experienced the serious, expected AESI myocarditis the following day a second dose of mRNA-1273 vaccine was administered. The patient required hospitalization; at the time of the report the event had not resolved. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 02-Feb-2022: Non significant follow-up received includes translation received on 04-Feb-2022 contains event verbatim and translated past drug name. | as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is unassessable based on the lack of information. A causal relationship cannot be excluded due to the lack of other information. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis of viral origin) in a 35-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 21-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Dec-2021, the patient experienced MYOCARDITIS (Perimyocarditis of viral origin) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyocarditis of viral origin) had not resolved. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No concomitant medications were reported.<br>No treatment medications were reported.<br><br>Company Comment: This is a regulatory case concerning a 35-year-old male patient with no reported medical history, who experienced the serious expected AESI of myocarditis. The event occurred 5 days after the third dose of mRNA-1273 vaccine administration. The treatment medications were not reported, and the event was not resolved at the time of this report. The event was assessed as related to the product administration per temporal association. The rechallenge was not applicable since the event occurred after the third dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 02-Feb-2022: Translation received on 03 FEB 2022, event verbatim updated to English. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br>On 20-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>No concomitant medication were provided.<br><br>On 22-Nov-2021, Patient had 1st Spikevax (3004671).<br><br>Patient's troponin up to 560, CK to 490 (CKMB 60) and CRP 60 Coro: exclusion KHK .<br><br>No treatment information were given.<br><br>Company comment: This is a regulatory case concerning a 31-year-old male patient with no medical history reported who experienced the serious, expected AESI myocarditis 2 days after a second dose of mRNA-1273 vaccine was administered. Patient required hospitalization; troponin was up to 560, CK to 490 (CKMB 60), CRP 60. At the time of the report the event was not recovered. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | 31-year-old male patient with no medical history reported who 2 days aftre the 2nd dose of Spikevax was hospitalized and found to have elevated troponin, CK and CRP and was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded | [redacted] |

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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 692F21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Dec-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.<br><br>Concomitant medications were not reported.<br>Patient [redacted] 1. Vaxzevria 20.3.21 (ABV5443), 2. Moderna 12.6.21 (3002334)<br>Treatment medications were not reported.<br>COMPANY COMMENT:<br>This is a Regulatory case concerning 22-years-old male patient with no clinical history who experienced the expected event of MYOCARDITIS (AESI) approximately 8 days after 3rd dose of mRNA-1273.<br>The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br>The case was assessed as serious by the Regulatory Authority's report due to IME<br>Terms and onset dates were captured as provided | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis after vaccination with Moderna vaccine) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Patient had no risk factors or preexisting illnesses.<br><br>On 06-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced MYOCARDITIS (Perimyocarditis after vaccination with Moderna vaccine) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyocarditis after vaccination with Moderna vaccine) was resolving. | 18 years old male with unknown medical history who 3 days after the 3rd dose of Spikevax was hospitalized and found to have elevated troponin. A cMRI was done but results provided are not well described. Patient was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | [redacted] |

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| | No concomitant medications were reported.<br><br>Patient had inpatient admission for troponin elevation, cardio MRT with large areas sub epicardial and low pericardial.<br>Vaccination took place externally in vaccination center.<br>No treatment information was provided.<br><br>Company Comment: This regulatory authority case concerns a 18 year old male with no pre-existing illnesses , who experienced Serious (Hospitalization ) , expected , AESI event of myocarditis which occurred 4 days post -vaccination with the 3rd dose of mRNA-1273 vaccine ( Moderna Covid 19 vaccine ) . This patient was admitted for troponin elevation and was noted to have undergone Cardiac MRI reported result was with large areas sub epicardial and low pericardial. Other details regarding the hospitalization were not reported including treatment information. Outcome of this event was reported as resolving .The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 02-Feb-2022: Translation received on 04-feb-2022 contain no new information. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Obesity.<br><br>On 24-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced INFLUENZA LIKE ILLNESS (Influenza like illness). On 27-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) and INFLUENZA LIKE ILLNESS (Influenza like illness) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided.<br>Treatment information was not provided.<br>COMPANY COMMENT: | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | This is a Regulatory case concerning 21-years-old male patient with clinical history of Obesity who experienced the expected event of MYOCARDITIS (AESI) and the unexpected event of INFLUENZA LIKE ILLNESS approximately 3 days after 1st dose of mRNA-1273.<br>The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br>The case was assessed as serious by the Regulatory Authority's report due to hospitalization<br>Terms and onset dates were captured as provided | | |
| [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On an unknown date, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (myocarditis) was resolving. Not Provided<br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, C-reactive protein: results not reported result not reported.<br>On an unknown date, Electrocardiogram abnormal: abnormal (abnormal) Abnormal (ECG) and (EKG)..<br>On an unknown date, Full blood count: results not reported results not reported.<br>On an unknown date, Metabolic function test: results not reported results not reported.<br>On an unknown date, N-terminal prohormone brain natriuretic peptide: results not reported results not reported.<br>On an unknown date, Red blood cell sedimentation rate: results not reported results not reported.<br>On an unknown date, Respiratory viral panel: results not reported results not reported.<br>On an unknown date, Troponin T: results not reported performed 2 times. results not reported..<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant and treatment medications was provided by the reporter.<br>Patient was admitted to the emergency room last night with chest pain. According to him it was determined that he had developed myocarditis due to the covid booster vaccine he received. He was released today and was at home recovering. On an unknown date, patient had hospital visit and got the doctor's note indicating the cause of his condition.<br><br>Company Comment: This is a spontaneous case concerning a 24-year-old, male patient with no medical history reported, who experienced the expected serious AESI Myocarditis which occurred on an unknown date after the third dose of mRNA-1273 vaccine. Patient was admitted to the emergency room with chest pain. According to him it was determined that he had developed myocarditis due to the covid booster vaccine he received. Investigations like C- | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | reactive protein, Electrocardiogram abnormal, Full blood count, Metabolic function test, N-terminal prohormone brain natriuretic peptide, Red blood cell sedimentation rate, Respiratory viral panel and Troponin T results were not reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report..<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 02-Feb-2022: Patient DOB, lab data and events added. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022.<br>This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS), CHEST PAIN (CHEST PAIN) and PERICARDIAL EFFUSION (PERICARDIAL EFFUSION) in a 19-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005241) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 17-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criterion medically significant), CHEST PAIN (CHEST PAIN) (seriousness criterion medically significant) and PERICARDIAL EFFUSION (PERICARDIAL EFFUSION) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (PERICARDITIS), CHEST PAIN (CHEST PAIN) and PERICARDIAL EFFUSION (PERICARDIAL EFFUSION) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS), CHEST PAIN (CHEST PAIN) and PERICARDIAL EFFUSION (PERICARDIAL EFFUSION) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br><br>No treatment information was provided.<br><br>Notifier qualification: Doctor.<br><br>Time Interval between Beginning of Drug Administration and Start of Reaction reported as 7 days for the events of pericarditis, chest pain and pericardial effusion. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Sender's comment continued.. Questions about coronavaccine and adverse events that cannot be answered by specialist managers locally or in the vaccination supervisor (2) can be directed to [redacted] We ask that no special categories of personal data (health information) be sent by email. If it is impossible to ask a question without including such information, we recommend calling the vaccine phone (tel: [redacted]- open all weekdays at 13-14.30). The Pharmaceutical Agency publishes regular summaries of messages of suspected adverse events following coronary vaccination: [redacted] References: 1) Edwards IR, Aronsen, JK. Adverse reactions: definitions, diagnosis and management. Lancet 2000; 356:1255-1259. 2) The Public Health Institute. The vaccination supervisor: Coronavaccine. [redacted] | | |
| [redacted] | This case was received via [redacted] (Reference number [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) in a 25-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>The patient's past medical history included Suspected COVID-19 (Unsure when symptoms stopped) on 04-Jan-2021, Immunodeficiency (Has an illness or condition, not listed above, which reduces the immune response (e.g. immunodef...) and Immune thrombocytopenic purpura (Mild ITP).<br>On 05-Nov-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 08-Nov-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization), PALPITATIONS (Heart palpitations) (seriousness criterion hospitalization) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving and FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Jan-2021, SARS-CoV-2 test: yes - positive covid-19 test (Positive) Yes - Positive COVID-19 test.<br>On an unknown date, Angiogram: results not provided results not provided.<br>On an unknown date, Echocardiogram: results not provided results not provided.<br>On an unknown date, Electrocardiogram: results not provided results not provided.<br>On an unknown date, Troponin: raised (High) raised. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Concomitant Medication use information was not provided by reporter.<br>Patient experienced Chest pain, breathlessness, very fast heart rate, and troponin levels sky high. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. The report was related to possible inflammation of the heart (myocarditis or pericarditis).<br><br>Diagnosis was made by a medical professional includes Cardiologist, adverse reaction lead to hospitalization, patient was hospitalized for one week.<br><br>The laboratory exam was done that includes ECG, Echocardiogram, and angiogram and the result was unknown. The test includes troponin, and the result was found as raised. The lab data includes chest X-ray, echocardiogram, cardiac MRI, chest computerized tomography and the result was unknown. Blood tests, such as for certain proteins (called troponin) that signal heart muscle damage was carried out.<br>Patient was not tested positive for COVID-19 since the vaccine. Patient was not enrolled in clinical trial. The report was related to possible inflammation of the heart (myocarditis or pericarditis).<br>Treatment Medication includes Colchicine.<br><br>Company comment:<br>This case concerns a 25-year-old male patient with medical history of immunodeficiency, who experienced the expected, serious (hospitalization) event of myocarditis 3 days after the second dose of mRNA-1273. The medical history of immunodeficiency (not specified) is a confounder. The patient experienced fatigue, chest pain, tachycardia, dyspnoea, and palpitations for which the following diagnostic tests were performed: angiogram (result not provided), echocardiogram (result not provided), electrocardiogram (result not provided), troponin (result: raised). Treatment included colchicine. According to the Brighton collaboration criteria, this case is a probable case for myocarditis. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 06-Feb-2022: FU received and Added lab data as Troponin, ECG, Echocardiogram and Angiogram. Updated action taken of Moderna CoviD-19 Vaccine from unknown to not applicable and events updated as per follow-up document. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Especially myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000124A) for COVID-19 vaccination.<br><br>Patient took 1st Comirnaty on 22-APR-2021(ET3045), 2nd Comirnaty on 03-JUN-2021(1C009A). | 33-year-old male patient with heterologous vaccine administration (COVID-19 vaccine, 1st and 2nd dose of Comirnaty) and no previous medical history reported, who 10 days after the 3rd dose of Spikevax experienced Myocarditis. Laboratory results showed elevated troponin and ACS excluded by ECG reported as unremarkable. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the | [redacted] |

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| | On 11-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Dec-2021, the patient experienced MYOCARDITIS (Especially myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Especially myocarditis) had not resolved.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.<br><br>No relevant concomitant medications were reported. Treatment medication was not provided by the reporter. Laboratory data included troponin determination 56, CK norm, ECG and UKG unremarkable DD excluded: ACS.<br><br>Company Comment:<br>This is a Regulatory case concerning a 33-year-old male patient with interchange of vaccine administration (COVID-19 vaccine, 1st and 2nd dose of Comirnaty) and no previous medical history reported, who experienced the serious expected event of Myocarditis. The event occurred 10 days after a dose of mRNA-1273 received as the third dose for COVID-19 Vaccination. Unknown date laboratory data included troponin determination 56 (units not reported) and ACS excluded by ECG reported as unremarkable. Clinical course and treatment details were not provided. Event seriousness assessed as per Regulatory Authority report and retained for consistency. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report. | events, as well as the elevated troponin; a causal relationship cannot be excluded. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 018J21A and 3006323) for COVID-19 vaccination.<br><br>The patient's past medical history included Smoker.<br><br>On 16-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter.<br>On 13-Jan-2022, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 14-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 16-Jan-2022, Angiogram: abnormal (abnormal) Pulmonary CT angiography: Multislice helical examination performed with VSD, (40 ml of Iopamiro 370). No repletion defects in the pulmonary arterial system that suggest acute pulmonary thromboembolism are identified. Pulmonary parenchyma without evidence of alterations. No hilio-mediastinal lymphadenopathies are identified. There is no evidence of pleural or pericardial effusion..<br>On 16-Jan-2022, Blood creatine phosphokinase (30-200): 420 (High) 420. | 29 years old male with unknown medical history who 1 day after the 2nd dose of Spikevax was found to have elevated CK, CRP, fibrin D-dimer, troponin and was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | [redacted] |

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| | On 16-Jan-2022, C-reactive protein (0-5): 44.5 (High) 44.5.<br>On 16-Jan-2022, Fibrin D dimer (0-500): 414 (normal) 414.<br>On 16-Jan-2022, Troponin I (0-34.2): 9639 9639.<br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication was provided by reporter.<br>No treatment drug was provided by reporter.<br><br>Company Comment: This is a regulatory case concerning a 29-year-old male patient with no relevant medical history, who experienced the serious expected AESI of myocarditis. The event occurred 2 days after the second dose of mRNA-1273 vaccine administration. The treatment medications were not reported, and the event was recovering at the time of this report. The event was assessed as related to the product administration per temporal association. The rechallenge was not applicable since the events occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022.<br>This case was received via European Medicines Agency (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 30-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 02-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving.<br><br>No concomitant medication were reported.<br>No treatment medication were reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 03-Feb-2022. The most recent information was received on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and DIZZINESS POSTURAL | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | (Dizziness on standing up) in a 36-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>Concomitant products included ELASOMERAN (MODERNA COVID-19 VACCINE) for COVID-19 vaccination.<br><br>On 21-Jul-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 02-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant) and DIZZINESS POSTURAL (Dizziness on standing up) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and DIZZINESS POSTURAL (Dizziness on standing up) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In November 2021, Electrocardiogram ambulatory: result not reported Result not reported.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>No illnesses or medicines historically that patient felt were relevant. Nothing ongoing. Roughly 4 weeks after vaccination patient noticed he was having random and irregular heart palpitations. He did not normally had these and considered himself relatively fit and healthy for his age. In addition to the palpitations (a couple per week), he would also get very dizzy when standing up from a seated position. This was less frequent than the palpitations (e.g., once per week) but enough for him to realize them and take note. The symptoms were abnormal for him such that he booked a doctor's appointment. The symptoms appeared to stop naturally after a couple of months. Patient had not tested positive for COVID-19 since he had received the vaccine. Tests conducted: Electrocardiogram (ECG). This however was delayed, and he took the ECG for 24 hours in November, after symptoms had stopped. Symptoms did not lead to hospital stay. Diagnosis was made by medical professional. General practitioner (GP). Prescribed an ECG heart monitor. No treatment otherwise. No imaging carried out. No blood tests, such as for certain proteins (called troponin) taken. Shortness of breath, tachycardia. Booster dose: COVID-19 MRNA VACCINE BIONTECH )dose 3b) given 05/01/2022 for COVID-19 vaccination.<br><br>Company Comment:<br>This is a regulatory case concerning a 36-year-old, male patient with no reported medical history, who experienced the expected serious, adverse event of special interest of myocarditis | | |

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| | and the serious unexpected events of dyspnoea, palpitations, tachycardia, and dizziness postural. Approximately 4 weeks after the second of mRNA-1273 vaccine, patient felt papitations and dizziness. Myocaritis was reported with a start date 2 months after the second dose. Symptoms resolved without treatment. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Feb-2022: Significant Follow received and updated case seriousness, added event, event outcome updated, lab data, product, and action taken were updated. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000086A) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 05-May-2021 and COMIRNATY on 12-Jun-2021.<br>Past adverse reactions to the above products included No adverse event with COMIRNATY and Comirnaty BNT162b2.<br><br>On 16-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Dec-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyocarditis) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided by the reporter.<br>No treatment information was provided by the reporter.<br><br>Company Comment: This is a case of interchange of vaccine products for this 33-year-old male patient, with a medical history of previous vaccination with 2 doses of COVID-19 vaccine Comirnaty BNT162b2, who experienced the serious (Seriousness criterion- Caused/prolonged hospitalization) expected event of Perimyocarditis(AESI). The event occurred 9 days after the booster dose of mRNA-1273 vaccine. There is no available information regarding clinical course and treatment medication. At the time of the report, outcome of perimyocarditis was reported as unknown. The patient's age, gender, and medical history of previous vaccination with COVID-19 vaccine Comirnaty BNT162b2 remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On 07-Feb-2022: Follow-up document received and contain no new information. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDIAL EFFUSION (pericardial casting/pericarditis) and PERICARDITIS (pericardial casting/pericarditis) in a 33-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 06-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Dec-2021, the patient experienced PERICARDIAL EFFUSION (pericardial casting/pericarditis) (seriousness criterion medically significant) and PERICARDITIS (pericardial casting/pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDIAL EFFUSION (pericardial casting/pericarditis) and PERICARDITIS (pericardial casting/pericarditis) had not resolved.<br><br>No concomitant medication was reported<br>No treatment medications was reported.<br><br>2 weeks after vaccination: stress dyspnea, increasing in recent weeks, when exercised (in the gym) HF up to 185/min. echocardiographic pericardial effusion -currently approx. 1.7 cm<br><br>Company Comment: This is a regulatory case concerning a 33-year-old female patient with no reported medical history, who experienced the serious expected AESI of pericarditis and serious unexpected event of pericardial effusion. The events occurred 15 days after the third dose of mRNA-1273 vaccine administration. No treatment information available and the events were not resolved at the time of this report. The events were assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the third dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | 33 years old female with no reported medical history who 14 days after the 3rd dose of Spikevax experienced stress dyspnea when exercising and increased heart frequency. Echo showed pericardial effusion and patient was diagnosed with pericarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 30-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Aug-2021, after starting mRNA-1273 (Spikevax), the patient | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br>No concomitant medications reported.<br>No treatment medications provided.<br><br>Company comment: This regulatory authority case concerns a 31-year-old female patient with no medical history reported, who experienced the expected serious (hospitalization) event/ AESI of Myocarditis, approximately 1 day after the second dose of mRNA- 1273 vaccine. No information is available regarding clinical manifestations, diagnostic work-up and treatment provided. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Feb-2022: Translation document received on 08-Feb-2022. Event verbatim was translated. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis + pericarditis + pericardial effusion), PERICARDIAL EFFUSION (myocarditis + pericarditis + pericardial effusion) and PERICARDITIS (myocarditis + pericarditis + pericardial effusion) in a 31-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 01-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 14-Dec-2021, the patient experienced MYOCARDITIS (myocarditis + pericarditis + pericardial effusion) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (myocarditis + pericarditis + pericardial effusion) (seriousness criterion hospitalization) and PERICARDITIS (myocarditis + pericarditis + pericardial effusion) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (myocarditis + pericarditis + pericardial effusion), PERICARDIAL EFFUSION (myocarditis + pericarditis + pericardial effusion) and PERICARDITIS (myocarditis + pericarditis + pericardial effusion) had not resolved.<br><br>The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.<br>No allergies information about risk factors or pre-existing illnesses. No pre-existing conditions. Patient was a nurse and suddenly had heart stumbles which then worsened into breathing problems and circulatory problems. In addition, severe pain later on. Patient still can't go to work and currently in inpatient treatment due to arrhythmias. Ibuprofen and colchicine alone did not help.<br><br>No concomitant medication was reported.<br>No treatment medication was reported. | 31-year-old female patient with no medical history reported, who 13 days after the 3rd dose of Spikevax experienced heart stumbles, breathing problems and severe pain later and was diagnosed with myocarditis and pericarditis. Medication treatment included ibuprofen and colchicine, although outcome has been reported as not resolved. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company comment:<br>This case concerns a 31-year-old female patient with no medical history reported, who experienced the expected, serious (hospitalization) events of myocarditis and pericarditis, and unexpected, serious (hospitalization) event of pericardial effusion. The events occurred 13 days after the third dose of mRNA-1273. The patient experienced heart stumbles, breathing problems and severe pain later. At the time of the report, the patient's working abilities have been impaired and she has had arrhythmia with inpatient treatment. Medication treatment included ibuprofen and colchicine, although outcome has been reported as not resolved. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDIAL EFFUSION (Diagnosed myocarditis with pericardial effusion), PARAESTHESIA (Paresthesia in left leg and hand (vaccination side) wandering up the limb.) and MYOCARDITIS (Diagnosed myocarditis with pericardial effusion) in a 34-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination.<br><br>Patient had Penicillin allergy.<br>Information on risk factors or pre-existing diseases included Heart rhythm disturbances.<br><br>On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Dec-2021, the patient experienced PARAESTHESIA (Paresthesia in left leg and hand (vaccination side) wandering up the limb.) (seriousness criterion medically significant). On 22-Dec-2021, the patient experienced PERICARDIAL EFFUSION (Diagnosed myocarditis with pericardial effusion) (seriousness criterion medically significant) and MYOCARDITIS (Diagnosed myocarditis with pericardial effusion) (seriousness criterion medically significant). At the time of the report, PERICARDIAL EFFUSION (Diagnosed myocarditis with pericardial effusion), PARAESTHESIA (Paresthesia in left leg and hand (vaccination side) wandering up the limb.) and MYOCARDITIS (Diagnosed myocarditis with pericardial effusion) had not resolved.<br><br>Concomitant medications were not reported.<br><br>Paresthesia began on the vaccination side a day after booster vaccination. A week later, circulatory problems began (dizziness, low blood pressure and pulse), as well as severe fatigue. Vitamin B complexes were taken against paresthesia, numbness improved. On 22-Dec-2021, pericardial effusion was diagnosed using ultrasound, blood counts and ECG unobtrusive. On 07-Jan-2022, a cardio MRI took place and myocarditis was detected in addition to pericardial | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | effusion. This was treated with sparing, ibuprofen and Ramipril. Since 06-Jan-2022, numbness has returned on the left side.<br><br>Company Comment: This is a regulatory case concerning a 34-year-old female patient with no reported medical history, who experienced the serious expected AESI of myocarditis and serious unexpected events of pericardial effusion and paraesthesia. The development began with paraesthesia on the next day after the third dose of mRNA-1273 vaccine administration. A week later, circulatory problems started (dizziness, low blood pressure and pulse) with severe fatigue. The events of myocarditis and pericardial effusion occurred 14 days after the vaccination. The ultrasound revealed pericardial effusion and cardio MRI detected myocarditis. The treatment included Vitamin B complexes, sparing, ibuprofen and Ramipril, resulting in improvement; however, the events outcome was reported as not resolved at the time of this report. The events were assessed as related to the product administration per temporal association. The rechallenge was not applicable since the events occurred after the third dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Are you or the person concerned known to have any allergies? If so, which ones?noInformation on risk factors or previous illnessesaortic valve stenosis andAortic arch aneryrisma / Endocarditis developed after heart surgery(Cardiac inflammation)) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Risk factors or pre-existing conditions included aortic valve stenosis and aortic arch aneyrisma.<br><br>On 13-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Aug-2021, the patient experienced PERICARDITIS (Are you or the person concerned known to have any allergies? If so, which ones?noInformation on risk factors or previous illnessesaortic valve stenosis andAortic arch aneryrisma / Endocarditis developed after heart surgery(Cardiac inflammation)) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Are you or the person concerned known to have any allergies? If so, which ones?noInformation on risk factors or previous illnessesaortic valve stenosis andAortic arch aneryrisma / Endocarditis developed after heart surgery(Cardiac inflammation)) had resolved.<br><br>Concomitant product use was not provided by the reporter.<br><br>After heart surgery, endocarditis (pericarditis) occurred. The operating surgeon could not explain endocarditis. The course of [redacted] was 5 weeks instead of planned 2 weeks. The day after surgery, severe pain occurred until painkillers could no longer be given. A heart catheter couldn none resolve. A germ was detected on the sixth day after surgery. This was followed by 16 days of antibiotic therapy. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Company comment: This Regulatory case concerns a 21-year-old, male patient with no relevant medical history, who experienced the expected serious AESI event of Pericarditis. The event occurred approximately 22 days after the second dose of mRNA-1273 (Moderna covid-19 vaccine). Though not clearly stated, it appears the patient had an underlying conditions of aortic valve stenosis and aortic arch aneurysm. A heart surgery was performed with subsequent occurrence of pericarditis. The rechallenge was not applicable as event occurred after second dose of mRNA-1273. This patient's underlying condition along with the subsequent heart surgery remains a confounder. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. | | |
| [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of DYSPNOEA AT REST (Dyspnea at rest), SYNCOPE (Syncope) and PERICARDITIS (Diagnosed with pericarditis) in a 33-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 00031A and 00002A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Hay fever, Grass allergy (ryegrass), Allergy to topical drugs (Allergy to Emla cream) and Allergy to chemicals (Allergy to pesticides).<br>Concomitant products included ASPIRIN [ACETYLSALICYLIC ACID], COLCHICINE, INDOMETHACIN [INDOMETACIN], PANTOPRAZOLE, VITAMIN D [VITAMIN D NOS], MENATETRENONE (VITAMIN K2 [MENATETRENONE]) and UBIDECARENONE (COQ10 [UBIDECARENONE]) for an unknown indication.<br><br>On 03-Oct-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form.<br>On 31-Oct-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced DYSPNOEA AT REST (Dyspnea at rest) (seriousness criterion medically significant), SYNCOPE (Syncope) (seriousness criterion medically significant), PERICARDITIS (Diagnosed with pericarditis) (seriousness criterion medically significant), GAIT DISTURBANCE (Unable to walk for more than 4 months), PALPITATIONS (Heart palpitations), CHEST PAIN (Chest pains / Chest pain – worsen), DYSPNOEA (Shortness of breath), MUSCLE TWITCHING (Severe muscle twitching / Muscle twitching– improved.), TEMPERATURE REGULATION DISORDER (Temperature disregulation), BLOOD PRESSURE ABNORMAL (Sugar and blood pressure instability/variability), TINNITUS (Tinnitus), VEIN DISORDER (Swollen bulging painful veins / Vein pronounced (bulging vein) – it sore and it hurts), MENSTRUAL DISORDER (Menstrual changes), VITREOUS FLOATERS (Eye floaters), NEURALGIA (Nerve pain in teeth and elsewhere / Nerve pain – above her teeth and it does not respond to any pain medication), SKIN BURNING SENSATION (Feeling of burning skin in body / Skin burning on different parts of the body.), IMPAIRED WORK ABILITY (I was also unable to work), DYSPNOEA EXERTIONAL (Dyspnea at rest or during exertional), MUSCULOSKELETAL CHEST PAIN (Rib pain), TACHYCARDIA (Tachycardia – randomly, it happens only during activity), TREMOR (Feeling of too much adrenaline tremors), CONDITION AGGRAVATED (Patient stated all her | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | symptoms worsen and even progress after her second dose), TEMPERATURE REGULATION DISORDER (Temperature dysregulation – less often), BLOOD GLUCOSE FLUCTUATION (sugar and blood pressure instability/variability), HYPOAESTHESIA (Numbness in face and arm / Lift arm above her head – feeling numb felt like there's no circulation), PYREXIA (Fever for a month at the time), ARTHRALGIA (Pain in joints) and FATIGUE (Fatigue). At the time of the report, DYSPNOEA AT REST (Dyspnea at rest), SYNCOPE (Syncope), PERICARDITIS (Diagnosed with pericarditis), GAIT DISTURBANCE (Unable to walk for more than 4 months), DYSPNOEA (Shortness of breath), TEMPERATURE REGULATION DISORDER (Temperature disregulation), BLOOD PRESSURE ABNORMAL (Sugar and blood pressure instability/variability), TINNITUS (Tinnitus), MENSTRUAL DISORDER (Menstrual changes), VITREOUS FLOATERS (Eye floaters), NEURALGIA (Nerve pain in teeth and elsewhere / Nerve pain – above her teeth and it does not respond to any pain medication), SKIN BURNING SENSATION (Feeling of burning skin in body / Skin burning on different parts of the body.), IMPAIRED WORK ABILITY (I was also unable to work), MUSCULOSKELETAL CHEST PAIN (Rib pain), BLOOD GLUCOSE FLUCTUATION (sugar and blood pressure instability/variability), PYREXIA (Fever for a month at the time) and ARTHRALGIA (Pain in joints) outcome was unknown, PALPITATIONS (Heart palpitations), MUSCLE TWITCHING (Severe muscle twitching / Muscle twitching– improved.), TREMOR (Feeling of too much adrenaline tremors) and FATIGUE (Fatigue) was resolving and CHEST PAIN (Chest pains / Chest pain – worsen), VEIN DISORDER (Swollen bulging painful veins / Vein pronounced (bulging vein) – it sore and it hurts), DYSPNOEA EXERTIONAL (Dyspnea at rest or during exertional), TACHYCARDIA (Tachycardia – randomly, it happens only during activity), CONDITION AGGRAVATED (Patient stated all her symptoms worsen and even progress after her second dose), TEMPERATURE REGULATION DISORDER (Temperature dysregulation – less often) and HYPOAESTHESIA (Numbness in face and arm / Lift arm above her head – feeling numb felt like there's no circulation) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 10-Oct-2021, Troponin: troponin level was 4 and went to 3 troponin level was 4 and went to 3.<br>On an unknown date, Cardiac function test: normal (normal) Normal.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Abnormal.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>She was scheduled on 11th of March 2022 for heart MRI.<br>The patient did not know what kind of pesticides she was allergic of and she had never been infected with COVID-19 and was never had any symptoms of it. The patient also stated that she was healthy before having the vaccine and did not have past medical history nor under any medications or supplements. | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company comment:This case concerns a 33-year-old female patient, with no medical history reported, who experienced the unexpected serious (seriousness criterion- Other medically important condition) event of Dyspnoea at rest, expected serious (seriousness criterion- Other medically important condition) events of Syncope and Pericarditis (AESI), and multiple non serious events reported as Dysautonomia, Gait disturbance (unable to walk for more than 4 months), Heart palpitations, Fast heart rate, Chest pains, Shortness of breath, Severe muscle twitching, Temperature dysregulation, Sugar and blood pressure instability/variability, Tinnitus, Swollen bulging painful veins, Menstrual changes, Eye floaters, Nerve pain in teeth and elsewhere, Feeling of burning skin in body, Unable to work, Numbness in face and arm, Fever for a month at the time, Pain in joints, and Fatigue. The events occurred on an unknown date after the second dose of mRNA-1273. Rechallenge was positive for event of dysautonomia as event occurred after first dose, resolved for a day, then recurred after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>This case was linked to [redacted](Patient Link).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Feb-2022: Significant follow up received included reporter information, new reporter, medical history, lab details suspect dosing details, patient details, treatment information,new events was added and case country updated from Philippines to Australia and events dysautonomia and fast heart rate was removed from the case as occurred after first dose. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Heart pain with a high pulse (possibly myocarditis)) and ANGINA PECTORIS (Heart pain with a high pulse (possibly myocarditis)) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214008) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Allergy included house dust, mites, and grass.<br><br>On 16-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Nov-2021, the patient experienced CHEST PAIN (Heart pain with a high pulse (possibly myocarditis)), MYOCARDITIS (Heart pain with a high pulse (possibly myocarditis)) (seriousness criterion medically significant) and ANGINA PECTORIS (Heart pain with a high pulse (possibly myocarditis)) (seriousness criterion medically significant). On 29-Nov-2021, CHEST PAIN (Heart pain with a high pulse (possibly myocarditis)), MYOCARDITIS (Heart pain with a high pulse (possibly myocarditis)) and ANGINA PECTORIS (Heart pain with a high pulse (possibly myocarditis)) was resolving. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br><br>This case concerns a 22-year-old male patient with no relevant medical history, who experienced the unexpected serious event of Angina Pectoris, and expected serious adverse event of special interest, Myocarditis. The events were medically significant as reported by the regulatory authority. The events occurred in 8 days after receiving the third dose of mRNA-1273 Vaccine. No clinical or treatment details were given. It was reported that the outcome of the event was resolving. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003603) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 19-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Jun-2021, the patient experienced PERICARDITIS (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade) (seriousness criterion medically significant), ASTHENIA (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade), HEART RATE INCREASED (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade), IMMUNE SYSTEM DISORDER (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade) and FATIGUE (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade). On 02-Nov-2021, PERICARDITIS (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade), ASTHENIA (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade), HEART RATE INCREASED (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade), IMMUNE SYSTEM DISORDER (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade) and FATIGUE (pericarditis, weakness, increased heart rate, until September Chronic exhaustion, immune system continues to persuade) had not resolved. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | No concomitant medications were reported.<br><br>Patient had extreme weakness from 22.6.2021. Then pericarditis, increased heart rate were detected. This lasted until September. In addition, chronic exhaustion and an overreaction of the immune system are still present. Approximately 75% of previous state of health reached. Patient had good days and bad days.<br><br>No treatment medications were reported.<br><br>Company Comment:<br>This regulatory case concerns a 20-year-old male patient, with no medical history reported, who experienced the expected serious (medically significant) AESI event of Pericarditis, the unexpected events of Asthenia, Heart rate increased, Immune system disorder, and the expected event of Fatigue. The events started approximately 4 days after receiving the second dose of mRNA-1273 Vaccine. At the time of the report the outcome of the events was not resolved. Event seriousness assessed as per Regulatory Authority report and retained for consistency. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocardium inflammation) in a 23-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Patient had no allergies and information on risk factors or pre-existing conditions were reported as none.<br><br>On 25-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Sep-2021, the patient experienced MYOCARDITIS (myocardium inflammation) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (myocardium inflammation) had not resolved.<br><br>Concomitant medication was not provided.<br><br>Patient pre-existing illnesses was reported as Heart muscle disease/increase in values was detected in a blood test.<br><br>No treatment details were reported.<br><br>Company Comment: | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | This regulatory case concerns a 23-year-old female patient, with no medical history reported, who experienced the expected serious AESI event of Myocarditis. The event occurred approximately 2 months 9 days after receiving the second dose of mRNA-1273 Vaccine. At the time of the report the outcome of the event was not resolved. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>LITERATURE REFERENCE:<br>Manfredi R, Bianco F, Bucciarelli V, Ciliberti G, Guerra F, Schicchi N et al. Clinical profiles and CMR findings of young adults and pediatrics with acute myocarditis following mRNA COVID-19 vaccination: A case series. Vaccine. 2022;10(2):169<br><br>No Medical History information was reported.<br><br>On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was treated with COLCHICINE for Myocarditis, at a dose of 0.5 milligram; IBUPROFEN for Myocarditis, at a dose of 600 milligram every eight hours and IBUPROFEN for Myocarditis, at a dose of 200 milligram once a week. At the time of the report, MYOCARDITIS (Myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood pressure measurement: 120/70 mmhg 120/70 mmHg.<br>On an unknown date, Body temperature: 38 degree celcius 38 degree celcius.<br>On an unknown date, Brain natriuretic peptide (2-75): 5 pg/ml (normal) 5 pg/mL.<br>On an unknown date, C-reactive protein: 7.3 mg/dl (High) 7.3 mg/dL.<br>On an unknown date, Ejection fraction: 57 % 57 %.<br>On an unknown date, Heart rate: 57 bpm 57 bpm.<br>On an unknown date, Magnetic resonance imaging heart: no significant cmr findings no significant CMR findings were documented after a three-month medical treatment follow-up and late gadolinium enhancement (lge) was found At the CMR imaging the late gadolinium enhancement (LGE) was found and mostly in right ventricular.<br>On an unknown date, Troponin I: 40568 ng/l admission-40568 ng/L and 12500 ng/l Nadir-12500 ng/L.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be related. | Patient 3 of this case report series - 25 years old male - Literature report on a case series report from [redacted] on 6 patients (four males and two females, 16.5 years old (Q1, Q3: 15, 18)) that experienced mRNA-COVID-19-vaccines side effects. All patients were hospitalized due to fever and troponins elevation following the second dose of an mRNA-based COVID-19 vaccine. Cardiovascular magnetic resonance (CMR) was performed 72–96 h after vaccination. All patients were treated with colchicine and ibuprofen. Myocarditis was prevalent in males. It was characterized by myocardial edema and late gadolinium enhancement (LGE) in the lateral wall of the left ventricle (LV). One patient showed sole right ventricular involvement, while the females presented with myopericarditis (myocarditis + pericardial effusion). All patients had preserved LV ejection fraction and remained clinically stable during a relatively short inpatient hospital stay. One case presented with atrial tachycardia. At the follow-up, no significant CMR findings were documented after a three-month medical treatment. According to other recently published case series, our report suggests a possible association between acute myocarditis and myopericarditis with mRNA COVID-19 vaccination in healthy young adults and pediatric patients. Not only males are involved, while some arrhythmic manifestations are possible, such as atrial tachycardia. Conversely, the authors highlight the benign nature of such complications and the absence of CMR findings after a three-month medical treatment with colchicine and ibuprofen. | [redacted] |

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| | Concomitant medication was not reported. All patients were hospitalized due to fever and troponins elevation.<br><br>Triple-IR was also found. Left ventricular end-diastolic volume was found to be 77 ml. All the CMRs were performed 72–96 h after receiving the second dose of an mRNA based COVID-19 vaccine. No CRP or Hs-TnI elevation was found on followup.<br><br>Colchicine was 0.5 mg once (<70 kg) or 0.5 mg b.i.d. (≥70 kg) was administered for the whole ibuprofen treatment.<br><br>Company comment: This is a literature-non-study case concerning a 25-year-old, male patient with no reported medical history, who experienced the expected serious event of myocarditis. The event occurred on an unknown day after the second dose of mRNA-1273 COVID 19 Vaccine. Laboratory test results showed Ejection fraction- stable, Magnetic resonance imaging heart - no significant findings, Troponin - elevated results. Treated with colchicine and Ibuprofen with unspecified dose and frequency. The event outcome was unknown. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 10-Feb-2022: Follow-up received by safety on 10-Feb-2022 included an Email with [redacted] received from [redacted] team includes significant information contains reporters details and lab data | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004959) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis). On 28-Dec-2021, MYOCARDITIS (Myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 26-Dec-2021, Troponin: increased (High) INCREASED.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not reported.<br>Treatment information was not reported. | 22-year-old male patient, with unknown medical history, who 3 days aftre the 3rd dose of Spikevax was found to have elevated troponin and was diagnosed with MYOCARDITIS. The event was resolved two days later. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company comment: This regulatory case of concerns a 22-year-old male patient, with no relevant medical history, who experienced the non-serious expected AESI of MYOCARDITIS. The event occurred 3 days after the third dose of mRNA-1273 vaccine. On the same day, a troponin dosage was performed with an elevated result. Treatment information was not provided. The event was resolved two days later. The benefit-risk relationship of the mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 08-Feb-2022 and was forwarded to Moderna on 08-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 008G21A) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19.<br>Previously administered products included for Product used for unknown indication: Pfizer Comirnaty (Dose 1: Pfizer Comirnaty-30 adult vaccine, 27/07/2021, Left arm, Intramuscular injection and Batch No.: FE1573) on 27-Jul-2021.<br>Past adverse reactions to the above products included No adverse event with Pfizer Comirnaty.<br><br>On 04-Jan-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) I dosage form. On 10-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant and treatment medication was not reported.<br>Company Comment<br>This is a regulatory case concerning a 31-year-old male patient with previous administration of one dose of Pfizer Comirnaty (Dose 1: Pfizer Comirnaty-30 adult vaccine, 27/07/2021,with past medical history of COVID-19,who experienced the serious expected AESI event of Pericarditis.The event occurred 6 day safter administration of the second dose of mRNA-1273 (Spikevax).The benefit-risk relationship of mRNA-1273 (Spikevax) Vaccine is not affected by this report<br>Limited information regarding this event has been provided at this time.reports of diagnostic tests,confirmation by the heath care provider and hospital records not reported | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 32-year-old female patient who received mRNA-1273 | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | (Spikevax) (batch no. 302542) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Postpartum thyroiditis (Postpartum thyroiditis), Polycystic ovaries (Polycystic ovary syndrome.), Gestational diabetes and Pericarditis (pericarditis in 2019.).<br><br>On 21-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced INFLUENZA LIKE ILLNESS (Influenza like illness). On an unknown date, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, INFLUENZA LIKE ILLNESS (Influenza like illness) and PERICARDITIS (Pericarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 02-Feb-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>Concomitant medications were not reported.<br><br>Treatment information was not provided.<br><br>Company comment: This is a regulatory case concerning a 32 year-old, female patient with a history of Pericarditis in 2019, who experienced the serious (due to medically important condition) expected, AESI of pericarditis, approximately 2 days after the second dose of mRNA-1273 vaccine. The outcome of the event was reported as recovered. The mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| MOD-2022-477661 | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>The patient's past medical history included End stage renal disease (End-stage renal disease s/p PD), Bone fissure (skull fissure s/p operation during infant.), Right inguinal hernia (right inguinal herniation 5 yrs ago), Peritoneal dialysis and Cranial operation (operation during infant).<br>Concurrent medical conditions included Hypertension and Polycystic kidney (Polycystic kidney disease.).<br><br>On 11-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 16-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion death). It is unknown if an autopsy was performed. Not Provided | 38-year-old, male patient, with medical history of hypertension, end-stage renal disease, polycystic kidney disease, and who had the primary series vaccination with the AstraZeneca vaccine and who 5 days after the 3rd dose with Spikevax experienced shortness of breath for two days and could not be woken up at home. Emergency service arrived and patient was found in cardiac arrest, and Ventricular fibrillation, was taken to the hospital however, due to multiple organ failure, the patient was pronounced dead 9 days after vaccination. Autopsy report is not available. The medical history of hypertension, end-stage renal disease, polycystic kidney disease remain as confounders. Pericardial disease is common in patients with renal disease. Approximately 20% of | TW-MODERNATX, INC.-MOD-2022-477661 |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication was reported by patient.<br>Patient treatment medication was reported as BOSMIN, with left hand IV, Adrenalin inj. 1mg/ml 1 ml, N/S 500 ml, TRANSAMIN inj. 5% 5ml, Pantoloc Inj. 40mg, Gipamine inj. 3mg/ml 200ml injection and Bokey 100 mg, Brilinta 90 mg for oral use.<br>On 20 Jan 2022 patient was pronounced dead by physician [redacted] due to multiple organ failure.<br>The outcome of the event Myocarditis was recovery or handling<br>Company comment:<br>This Fatal Regulatory Authority case concerns a 38-year-old, male patient, with medical history of hypertension, end-stage renal disease, polycystic kidney disease, who experienced the unexpected, serious (death) and AESI of Myocarditis. The patient received as first and second dose of his COVID-19 vaccination schedule two doses of "AZ" 's vaccine and developed Myocarditis 5 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of his vaccination schedule. The patient suffered shortness of breath for two days and could not be woken up at home. Emergency service arrived for cardiac arrest, electric shock was administered due to Ventricular fibrillation, along with Bosmin and was sent to hospital where administered Adrenalin, Transamin, Pantoloc, Gipamine, Bokey and Brilinta. The patient underwent a cardiac catheterization and was admitted to ICU for observation. Extracorporeal membrane oxygenation (ECMO) was required, however, due to multiple organ failure, the patient was pronounced dead 9 days after vaccination. Autopsy report is not available. The medical history of hypertension, end-stage renal disease, polycystic kidney disease remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | uremic patients requiring chronic dialysis develop uremic pericarditis or dialysis pericarditis. In all forms of uremic pericarditis, cardiac tamponade is the main danger, and can be life-threatening. No other information was provided. Important information is missing in the report including patient clinical course of the current conditions, as well as any laboratory test conducted. The concurrent history of hypertension, end-stage renal disease, polycystic kidney disease are important risk factors that provide a more plausible explanation for the occurrence of the reported events. According to the WHO causality assessment this report is considered unlikely. | |
| [redacted] | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 07-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 12-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 14-Jan-2022, the patient experienced HEADACHE (Headache) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, HEADACHE (Headache) and MYOCARDITIS (Myocarditis) was resolving. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication was provided by reporter.<br>No treatment drug was provided by reporter.<br><br>On 01/15/2022 and 07/29/2021, the first dose of COVID-19 Vaccine (AZ) was administered to the patient at [redacted]<br>On 10/15/2021, the second dose of COVID-19 Vaccine (AZ) was administered to the patient at [redacted]<br>On 01/12/2022, the third dose of COVID-19 Vaccine (Moderna) was administered to the patient at [redacted]<br>On 01/15/2022, patient complained in the emergency department that his headache started on 1/13 and his chest pain started on 1/14. His blood drawing draws showed an increase in Troponin T, and it was suspected that Moderna caused Acute myocarditis to be transferred to SICU for follow-up visit.<br>On 01/16/2022, the value of Cardio enzyme decreased, and he was transferred to the general ward without discomfort.<br>On 01/18/2022, patient was discharged in stable condition without special discomfort.<br>The follow-up care is as follows. He was connected by telephone on 01/19/2022, but no one answered. and x0D; Case summary was not uploaded.<br>Company Comment<br>This is a regulatory case concerning a 21-year-old male patient with no medical history reported, with previous administration of two does of COVID-19 Vaccine (AZ) ,who experienced the serious unexpected event of Headache and serious expected AESI event of Myocarditis,, .The events occurred on 2 days after administration of the third dose of mRNA-1273 (Spikevax).It was reported that patient complained in the emergency department that his headache started on 1/13 and his chest pain started on 1/14. His blood drawing draws showed an increase in Troponin T, transferred to SICU .,On 01/16/2022, the value of Cardio enzyme decreased, and he was transferred to the general ward without discomfort.,On 01/18/2022, patient was discharged in stable condition without special discomfort, The benefit-risk relationship of mRNA-1273 (Spikevax) Vaccine is not affected by this report | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (fever), MYOCARDITIS (Myocarditis) and MUSCULAR WEAKNESS (Weakness of limbs) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 22-Jan-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Jan-2022, the patient experienced PYREXIA (fever) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization) and MUSCULAR WEAKNESS (Weakness of limbs) (seriousness | 25-year-old male patient, with unknown medical history, who 4 days after the 2nd dose of Spikevax experienced chest pain, chest tighness, pyrexia and muscular weakness in both hands and was found to have elevated troponin, CK-MB, and abnormal EGC and was diagnosed with MYOCARDITIS. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | criterion hospitalization). At the time of the report, PYREXIA (fever), MYOCARDITIS (Myocarditis) and MUSCULAR WEAKNESS (Weakness of limbs) was resolving. Not Provided<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 26-Jan-2022, Blood creatine phosphokinase MB: 6.0 6.0, 6:12, 15.6 9:29 , 15.6 and 13.8 13:51,13.8.<br>On 26-Jan-2022, Troponin I: 0.474 5:26; 0.474, 2.296 9:29; 2.296 and 2.287 13:51; 2.287.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not provided by the reporter.<br><br>Patient took first dose of Moderna vaccine on 23 Nov 2021,<br>The second dose of the Moderna COVID vaccine was administered on 26 Jan 2022 and the patient had a fever for about two days.<br>On 26 Jan 2022 at around 4:00 in the morning, the patient experienced chest tightness, chest pain, and weakness in both hands, and went to the emergency department of the hospital for medical treatment. The emergency physician gave intravenous injection of NaCl 500ml/pack1 pk ST. After the EKG was completed, it was suspected that the myocarditis was caused by the vaccine and the patient was hospitalized by the Cardiology Department.<br><br>Company comment. This regulatory case concerns a 25-year-old, male patient with no reported medical history, who experienced the unexpected, serious events of muscular weakness, and pyrexia, and the expected serious AESI of myocarditis. The events occurred after administration of the second dose of mRNA-1273 vaccine. The report stated that after vaccination, the patient had a fever for about two days. Four days after the mRNA – 1273 dose, he consulted to the emergency department due to chest pain and weakness in hands. After the electrocardiogram was performed, he was hospitalized with suspected diagnose of myocarditis. Blood tests (creatine phosphokinase MB and Troponin I) were reported, but the results lack dates, units, and specifications, hence, they cannot be interpreted in the context of the patient. No further clinical information was provided for medical reviewing. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of ENDOCARDITIS (ENDOCARDITIS) and MYOCARDITIS (MYOCARDITIS) in a 25-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002546) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: SPIKEVAX and SPIKEVAX. | 25-year-old female patient, with unknown medical history, who 40 days after the 3rd dose of Spikevax experienced endocarditis and myocarditis and was found to have elevated troponin and CRP. The prolonged TTO and the diagnosis of endocarditis are a confounder for this report. According to the WHO causality assessment this report is conditional based on the | [redacted] |

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| | Past adverse reactions to the above products included No adverse event with SPIKEVAX and SPIKEVAX.<br>Concomitant products included ETHINYLESTRADIOL, FERROUS FUMARATE, LEVONORGESTREL [redacted] from 30-Jun-2020 to an unknown date for Contraception.<br><br>On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) I dosage form. In December 2021, the patient experienced HEAVY MENSTRUAL BLEEDING (HEAVY MENSTRUAL BLEEDING). On 18-Jan-2022, the patient experienced ENDOCARDITIS (ENDOCARDITIS) (seriousness criterion hospitalization) and MYOCARDITIS (MYOCARDITIS) (seriousness criterion hospitalization). At the time of the report, ENDOCARDITIS (ENDOCARDITIS) and MYOCARDITIS (MYOCARDITIS) was resolving and HEAVY MENSTRUAL BLEEDING (HEAVY MENSTRUAL BLEEDING) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In January 2022, C-reactive protein: 100 (High) Elevation to 100.<br>In January 2022, Influenza A virus test: negative (Negative) Negative.<br>In January 2022, Influenza B virus test: negative (Negative) Negative.<br>In January 2022, Respiratory syncytial virus test: negative (Negative) Negative.<br>In January 2022, SARS-CoV-2 test: negative (Negative) Negative.<br>In January 2022, Troponin T: 33 (High) Maximum 33.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Treatment information was not provided.<br><br>Company comment:<br>This is a regulatory authority case concerning a 25-year-old, female patient with no reported medical history and vaccine history of receiving mRNA-1273 vaccine as primary doses and with concomitant medication of levonorgestrel and ethinylestradiol [redacted] for contraception, who experienced the unexpected, serious event of endocarditis, the expected, serious, AESI event of myocarditis and unexpected non-serious event of heavy menstrual bleeding. The event heavy menstrual bleeding exact occurrence unknown but stated that the event occurred with the same month of third dose of mRNA-1273 vaccine administration while the events endocarditis and myocarditis occurred 40 days after the third dose of mRNA-1273 vaccine administration which resulted to hospitalization. Diagnostics were done as follows, C-reactive protein: Elevation to 100, Influenza A virus test: negative, Influenza B virus test: negative, Respiratory syncytial virus test: negative, SARS-CoV-2 test: negative, and Troponin T: Maximum 33. No reported treatment information. The outcome of the event heavy menstrual bleeding was unknown while the events endocarditis and myocarditis the outcome were | lack of information; a causal relationship cannot be excluded due to the lack of information. | |

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| | resolving from the time of last observation. The concomitant medication of Levonorgestrel and ethinylestradiol [redacted] remain confounder for the event heavy menstrual bleeding. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Feb-2022: Translation received on 11-Feb-2022 which contains no new information. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 14-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 25-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication information was not provided by the reporter.<br><br>Treatment information was not provided by the reporter.<br><br>Company comment: This is a regulatory case concerning a 29-year-old male patient with no reported medical history, who experienced the serious expected event myocarditis, that occurred approximately 11 days after the third dose of mRNA-1273 and lead to hospitalization. Clinical course and treatment details were not provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Heart muscle inflammation) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004670) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 immunisation (Spikevax dos 1) on 21-Jul-2021.<br>Concurrent medical conditions included Exercise induced asthma.<br>Concomitant products included MONTELUKAST SODIUM (MONTELUKAST EG) for an unknown indication. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On 24-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Nov-2021, the patient experienced MYOCARDITIS (Heart muscle inflammation) (seriousness criteria hospitalization and life threatening). At the time of the report, MYOCARDITIS (Heart muscle inflammation) was resolving.<br><br>Con med MONTELUKAST EG for Exercise induced asthma<br><br>Company Comment: This is a Regulatory Authority case concerning a 22-year-old male patient, with no relevant medical history for this case, who experienced the serious unexpected AESI of Myocarditis (serious criteria Life-threatening and Hospitalized), approximately 2 months and 20 days the day after the administration of the second dose of the mRNA-1273 vaccine. The outcome of the event was Recovering/Resolving. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022.<br>This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PERICARDIAL EFFUSION (Pericardial effusion) and PERICARDITIS (Recurrent pericarditis, mental fog, balance problems, dizziness, tinnitus, dyspnea, neuropathic pain, muscle and joint pain, paresthesia fatigue, difficulty swallowing, testicular and groin pain, digestive problems.) in a 40-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001656 and 3002541) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 24-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 22-May-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 02-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Recurrent pericarditis, mental fog, balance problems, dizziness, tinnitus, dyspnea, neuropathic pain, muscle and joint pain, paresthesia fatigue, difficulty swallowing, testicular and groin pain, digestive problems.) (seriousness criterion hospitalization). On 25-Oct-2021, the patient experienced PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criterion hospitalization). At the time of the report, PERICARDIAL EFFUSION (Pericardial effusion) and PERICARDITIS (Recurrent pericarditis, mental fog, balance problems, dizziness, tinnitus, dyspnea, neuropathic pain, muscle and joint pain, paresthesia fatigue, difficulty swallowing, testicular and groin pain, digestive problems.) had not resolved.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 22-May-2021. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No concomitant medications were reported.<br><br>No treatment medications were reported.<br><br>Company comment:<br>This regulatory case concerns a 40-year-old, male patient with no medical history reported, who experienced serious unexpected event of pericardial effusion and serious expected AESI event of pericarditis. The event pericardial effusion occurred after 5 months 4 days and pericarditis after 12 days of vaccination with second dose of mRNA-1273 Vaccine. The patient reported that he experienced recurrent pericarditis, mental fog, balance problems, dizziness, tinnitus, dyspnea, neuropathic pain, muscle and joint pain, paresthesia, fatigue, difficulty swallowing, testicular and groin pain and digestive problems. At the time of the report, the events had not resolved. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting. | | |
| [redacted] | This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 39-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 50 microgram. On 21-Jan-2022, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria medically significant and life threatening). At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related.<br><br>No treatment medication information provided<br><br>This spontaneous report was received from a Physician from [redacted] and concerned a patient (Female), age: 39 Year (born: 1982-[redacted] This report is serious - life threatening, other. The patient's medical history and concurrent conditions included: no relevant medical history reported. The patient's weight was not reported, and height was not reported. The patient received COVID-19 Vaccine Moderna (Spikevax) 3rd vaccination (COVID-19 vaccine), a dosage of 50 microgram. Concomitant medications were: no concomitant medication reported. On 21.01.2022 the patient experienced Pericarditis. The patient's outcome was: not recovered/not resolved for Pericarditis. | 39-year-old female patient, with no reported medical history, who 7 days after the 3rd dose of Spikevax experienced PERICARDITIS. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is unassessable due to the complete lack of information. A causal relationship cannot be excluded due to the lack of other information. | [redacted] |

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| | Company comment: This regulatory authority case concerns a 39-year-old female patient, with no reported medical history, who experienced the expected serious (medically significant and life threatening) event of PERICARDITIS (AESI), which occurred approximately 7 days after receiving the third dose of mRNA-1273 vaccine. At the time of the report, PERICARDITIS had not resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 32-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214018) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 03-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 03-Sep-2021.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br>Treatment medication was not provided by the reporter.<br><br>Company comment:This regulatory authority case concerns a 32-year-old, female patient with no medical history reported, who experienced the expected serious AESI event of Pericarditis (seriousness criterion Medically significant) which occurred 2 months 29 days after the second dose of mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022.<br>This case was received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On 31-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Sep-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion medically significant) and TACHYCARDIA (myocarditis). On 04-Sep-2021, MYOCARDITIS (myocarditis) and TACHYCARDIA (myocarditis) had resolved.<br><br>No concomitant medications were reported.<br>The patient was hospitalized for myocarditis.<br>Patient received One time administration of Ibuprofen afterwards patient showed spontaneous improvement, good course function. Uncomplicated course.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 10-Feb-2022: Translation received on 15 Feb 2022 contains no new information. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022.<br>This case was received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis (heart muscle inflammation)) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214012) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 20-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jul-2021, the patient experienced MYOCARDITIS (myocarditis (heart muscle inflammation)) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (myocarditis (heart muscle inflammation)) was resolving.<br><br>Company comment:This is a regulatory case concerning a 31-year-old male patient with no medical history reported, who experienced the serious expected event of Myocarditis(seriousness criteria hospitalization and medically significant).This event occurred one day after the patient received the second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form, resulting in hospitalization. At the time of the report, Myocarditis was resolving.The rechallenge was unknown since there's only information about the second dose. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.<br>No concomitant product was provided.<br>Causality of event was reported as D. Unclassifiable by regulatory authority [redacted] | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | A day (21-Jul-2021) after vaccination occurred after normal symptoms such as chills and fever, severe chest pain, which was why the patient was taken to hospital. Due to increased troponin levels, myocarditis (heart muscle inflammation) was quickly suspected as a result of vaccination and confirmed by an MRI (Magnetic resonance imaging) scan. The LV-EF (Left ventricular ejection fraction) here was only 49%. Then he was hospitalized for two weeks, first a week in the monitoring station, then a week in the cardiology ward. Since tachycardia occurred and the troponin level was still increased after two weeks, he could only be released with a 'LifeVest'. In the meantime, he took ramipril, ibuprofen and pantoprazole. He was able to take off the 'LifeVest' after two weeks but was still on sick leave until the end of August. Climbing stairs and sports were banned until the end of 2021, physical protection was announced, which was often difficult for a daughter born in [redacted]2021 - not to mention the psychological strain. Improvement was only in sight after a new MRI in Dec-2021 (LV-EF now 57%). Nevertheless, he was still limited and sports as before (football in a club, gym, jogging several times a week) was still unthinkable. Until now, only light cycling had been possible. He was also strong on my job in the meantime and now still slightly restricted. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (third dose vaccination covid19 Moderna on 07/1/2022 the 14\ 01\ 2022evaluated in ps for chest pain and hospitalized for acute pericarditis postvaccine covid19 resigned on 17\ 01\ 2022) and CHEST PAIN (third dose vaccination covid19 Moderna on 07/1/2022 the 14\ 01\ 2022evaluated in ps for chest pain and hospitalized for acute pericarditis postvaccine covid19 resigned on 17\ 01\ 2022) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 030G21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 07-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 14-Jan-2022, the patient experienced PERICARDITIS (third dose vaccination covid19 Moderna on 07/1/2022 the 14\ 01\ 2022evaluated in ps for chest pain and hospitalized for acute pericarditis postvaccine covid19 resigned on 17\ 01\ 2022) (seriousness criterion hospitalization) and CHEST PAIN (third dose vaccination covid19 Moderna on 07/1/2022 the 14\ 01\ 2022evaluated in ps for chest pain and hospitalized for acute pericarditis postvaccine covid19 resigned on 17\ 01\ 2022) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (third dose vaccination covid19 Moderna on 07/1/2022 the 14\ 01\ 2022evaluated in ps for chest pain and hospitalized for acute pericarditis postvaccine covid19 resigned on 17\ 01\ 2022) and CHEST PAIN (third dose vaccination covid19 Moderna on 07/1/2022 the 14\ 01\ 2022evaluated in ps for chest pain and hospitalized for acute pericarditis postvaccine covid19 resigned on 17\ 01\ 2022) was resolving.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. | 19-year-old, male patient with no medical history reported, who 7 days after the 3rd dose of Spikevax experienced chest pain and was diagnosed with Pericarditis. Patient was treated with colchicine therapy, ibuprofen, and lansoprazole. At the time of report, the outcome for the events was reported as recovering. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is conditional based on the lack of information; a causal relationship cannot be excluded due to the lack of information. | [redacted] |

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| | For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information provided.<br><br>Company comment:<br>This is a regulatory authority case concerning a 19-year-old, male patient with no medical history reported, who experienced an expected serious AESI event of Pericarditis (seriousness hospitalization) and unexpected, serious (hospitalization) event of chest pain. The events occurred 8 days after the third dose of mRNA-1273 vaccine. Patient was treated with colchicine therapy, ibuprofen, and lansoprazole. At the time of report, the outcome for the events was reported as recovering. The benefit-risk relationship of mRNA-1273 in not affected by this report. The events are assessed as serious per regulatory authority reporting as events resulted in hospitalization.<br><br>Patient reported third dose vaccination of COVID-19 Moderna on 07-Jan-2022.On 14-Jan-2022 chest pain evaluated in ps and then hospitalization acute pericarditis post vaccine covid19 got discharged on 17-Jan-2022, colchicine therapy 1mg 1\ 2 cp ibuprofen 600mgcp lansoprazole 15mg cp in the visit scheduled under cardiological control. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Acute myocarditis presenting with chest pain VAS 10/10; blood tests with significant enzymatic breakdown (TnHS > 8000)) and MYOCARDITIS (Acute myocarditis presenting with chest pain VAS 10/10; blood tests with significant enzymatic breakdown (TnHS > 8000)) in a 12-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000033A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Jan-2022, the patient experienced CHEST PAIN (Acute myocarditis presenting with chest pain VAS 10/10; blood tests with significant enzymatic breakdown (TnHS > 8000)) (seriousness criterion hospitalization) and MYOCARDITIS (Acute myocarditis presenting with chest pain VAS 10/10; blood tests with significant enzymatic breakdown (TnHS > 8000)) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Acute myocarditis presenting with chest pain VAS 10/10; blood tests with significant enzymatic breakdown (TnHS > 8000)) and MYOCARDITIS (Acute myocarditis presenting with chest pain VAS 10/10; blood tests with significant enzymatic breakdown (TnHS > 8000)) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): | 12-year-old male patient, with no reported medical history, who 2 days after the 2nd dose of Spikevax experienced chest pain and was diagnosed with myocarditis. Laboratory results showed Increased red blood cell sedimentation rate and echocardiogram, and troponin T were performed but no results were provided. A cardiac magnetic resonance imaging was pending at the time of the report. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is conditional based on the lack of information; a causal relationship cannot be excluded due to the lack of information. | [redacted] |

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| | On 20-Jan-2022, Echocardiogram: inconclusive Inconclusive.<br>On 20-Jan-2022, Red blood cell sedimentation rate increased: inconclusive Inconclusive.<br>On 20-Jan-2022, Troponin T: inconclusive Inconclusive.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>The patient had acute myocarditis onset clinically 48 hours after administration of the second dose of antiSarsCov2 vaccine with typical clinical and major enzyme withdrawal.<br>Patient waiting for MRI of heart without and with contrast<br>Treatment information was not provided.<br><br>Company comment: This regulatory authority case concerns a 12-year-old male patient, with no reported medical history, who experienced the serious (hospitalization) expected AESI of MYOCARDITIS that occurred 2 days after receiving the second dose of mRNA-1273 and had not recovered by the time of the report. Increased red blood cell sedimentation rate and significant enzymatic withdrawal were reported. Additionally, echocardiogram, and troponin T were performed but no results were provided. A cardiac magnetic resonance imaging was pending at the time of the report. No further information regarding hospitalization and treatment provided were reported. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 37-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000110A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 28-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 01-Jan-2022, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.<br><br>Patient initials were reported as [redacted]<br>No concomitant medications were reported.<br>On 17-Jul-2021, patient received first dose of spikevax and second dose on 31-Jul-2021. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No treatment medications were provided.<br>Laboratory investigations included ECG at rest, troponin was negative and CRP was 5.6 (Normal<5).<br>Company comment: This regulatory case of concerns a 37-year-old female patient, with no medical history reported, who experienced the serious (medically significant) expected AESI of MYOCARDITIS. The event occurred 4 days after the third dose of mRNA-1273 vaccine. An electrocardiogram was performed with no reported result, a troponin dosage was negative, and a C-reactive protein test was elevated. Treatment information was not provided. The benefit-risk relationship of the mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of VENTRICULAR TACHYCARDIA (Non-persistent ventricular tachycardia), PERICARDITIS (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load capacity, stress dyspnea NYHA III, thoracic pain), CARDIAC FAILURE CHRONIC (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load capacity, stress dyspnea NYHA III, thoracic pain) and DYSPNOEA EXERTIONAL (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load capacity, stress dyspnea NYHA III, thoracic pain) in a 29-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002614) for COVID-19 vaccination.<br><br>Patient had No allergies and Information on risk factors or pre-existing illnesses was reported as to date patient was without health restrictions, especially none.<br>Previously administered products included for Prophylactic vaccination: SPIKEVAX (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax) on 05-May-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br><br>On 09-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Sep-2021, the patient experienced PERICARDITIS (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load capacity, stress dyspnea NYHA III, thoracic pain) (seriousness criterion hospitalization), CARDIAC FAILURE CHRONIC (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load capacity, stress dyspnea NYHA III, thoracic pain) (seriousness criterion hospitalization) and DYSPNOEA EXERTIONAL (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load capacity, stress dyspnea NYHA III, thoracic pain) (seriousness criterion hospitalization). On 01-Oct-2021, the patient experienced VENTRICULAR TACHYCARDIA (Non-persistent ventricular tachycardia) (seriousness criterion hospitalization). At the time of the report, VENTRICULAR TACHYCARDIA (Non-persistent ventricular tachycardia), PERICARDITIS (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | capacity, stress dyspnea NYHA III, thoracic pain), CARDIAC FAILURE CHRONIC (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load capacity, stress dyspnea NYHA III, thoracic pain) and DYSPNOEA EXERTIONAL (pericarditis (secured by cardio-MRI) under medical therapy with colchizine 0.5 mg 2x daily reduced load capacity, stress dyspnea NYHA III, thoracic pain) had not resolved.<br>No Concomitant medication details were reported.<br><br>Patient had pre-existing cardiac illnesses and in the temporal context of 2nd modern vaccination, cardiac complaints (left thoracic complaints and clearly red. resilience). In an LZ ECG non-persistent ventricular tachycardia. Inpatient examination revealed pericarditis.<br><br>No Treatment information was provided.<br><br>Company Comment: This is a Regulatory Authority case concerning a 29-year-old female patient, with no relevant medical history, who experienced the unexpected and serious (hospitalization) events of Ventricular tachycardia (AESI), Cardiac failure chronic, and Dyspnoea exertional, and the expected, serious (hospitalization), and AESI of Pericarditis. The events of Pericarditis, Cardiac failure chronic, and Dyspnoea exertional started 2 months and 24 days after the second dose of mRNA-1273 vaccine, and one month after these events, ventricular tachycardia occurred (revealed in an ECG). Treatment received: Colchicine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000109A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 31-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 01-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>No concomitant medication information was provided.<br><br>On 6-Jul-21, Patient had taken 1st dose comirnaty (FE7011).<br><br>On 17-Aug-21, Patient had taken 2nd dose comirnaty (1F036A).<br><br>It was reported that ECG, coronary angiography with exclusion CHD, cardio-MRI finding compatible with myocarditis DD excluded: stenosing CHD. | 31-year-old male patient, with no medical history reported, who the next day after his 3rd dose with Spikevax (previous 2 doses with Cominarty) experienced MYOCARDITIS. A cardiovascular magnetic resonance imaging was performed and perimyocarditis was diagnosed. Treatment information was not provided. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is conditional based on the lack of information; a causal relationship cannot be excluded due to the lack of information. | [redacted] |

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| | No treatment medication were provided.<br>Company comment: This regulatory case of concerns a 31-year-old male patient, with no medical history reported, who experienced the serious (hospitalization) expected AESI of MYOCARDITIS. The event occurred on the following day the dose of mRNA-1273 vaccine, patient previous vaccination schedule included two doses of Comirnaty. A cardiovascular magnetic resonance imaging was performed and perimyocarditis was diagnosed. Treatment information was not provided. The benefit-risk relationship of the mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE3064) for COVID-19 vaccination.<br><br>Previously administered products included for Vaccination: Comirnaty and Comirnaty.<br>Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.<br><br>On 03-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Jan-2022, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (PERICARDITIS) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 24-Jan-2022, Cardiac telemetry: frequent ventricular extrasystoles (trigeminy). Frequent ventricular extrasystoles (trigeminy)..<br>On 24-Jan-2022, Echocardiogram: no pericardial fluid. No pericardial fluid..<br>On 24-Jan-2022, Electrocardiogram: no signs of ischemia. No signs of ischemia..<br>On 24-Jan-2022, Troponin: negative (in three sets of blood tests). (Negative) Negative (in three sets of blood tests)..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related.<br><br>Concomitant product use was not provided by reporter.<br>Treatment information was not provided. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis.) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216038) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19.<br>Previously administered products included for COVID-19 immunisation: Spikevax on 01-Jul-2021 and Spikevax on 31-Jul-2021.<br>Past adverse reactions to the above products included No adverse event with Spikevax and Spikevax.<br>Concurrent medical conditions included Smoker.<br><br>On 27-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Jan-2022, the patient experienced PERICARDITIS (Pericarditis.) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis.) was resolving.<br><br>No concomitant medications reported.<br>No treatment information was provided.<br><br>Company comment:<br>This is a regulatory authority case concerning a 23-year-old, male patient with no relevant medical history and with vaccine history of receiving mRNA-1273 vaccine as primary doses, who experienced the expected serious (medically significant according to regulatory authority), AESI event of pericarditis. The event pericarditis occurred approximately 5 days after the third dose of mRNA-1273 vaccine administration. No reported treatment information. The outcome of the event pericarditis was resolving from the time of last observation. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Treatment - Ja Evolution of the ADR - Herstellende Examinations - Bloedanalyse, EKG, ECG, CT scan. ADR description - Pericarditis. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 40-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Previously administered products included for Vaccination: SPIKEVAX and COMIRNATY. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Past adverse reactions to the above products included No adverse event with COMIRNATY and SPIKEVAX.<br><br>On 13-Jan-2022 at 12:00 PM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Jan-2022, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (PERICARDITIS) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related.<br><br>No concomitant medications reported.<br><br>No treatment information was provided. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (myocarditis with performance reduction, arrhythmia, shortness of breath), MYOCARDITIS (myocarditis with performance reduction, arrhythmia, shortness of breath) and ARRHYTHMIA (myocarditis with performance reduction, arrhythmia, shortness of breath) in a 35-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003609) for COVID-19 vaccination.<br><br>Patient's concurrent condition includes chronic inflammatory bowel disease.<br><br>On 29-Jun-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 2 dosage form. On 26-Jul-2021, the patient experienced DYSPNOEA (myocarditis with performance reduction, arrhythmia, shortness of breath) (seriousness criterion medically significant), MYOCARDITIS (myocarditis with performance reduction, arrhythmia, shortness of breath) (seriousness criterion medically significant) and ARRHYTHMIA (myocarditis with performance reduction, arrhythmia, shortness of breath) (seriousness criterion medically significant). On 19-Jan-2022, DYSPNOEA (myocarditis with performance reduction, arrhythmia, shortness of breath), MYOCARDITIS (myocarditis with performance reduction, arrhythmia, shortness of breath) and ARRHYTHMIA (myocarditis with performance reduction, arrhythmia, shortness of breath) had not resolved.<br><br>The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.<br><br>No concomitant medications were provided.<br>It was reported that, patient's date of birth was [redacted]1986 and no allergies were known.<br>Patient's had slow improvement until the end of Dec-2021 while preserving incapacity for work, drugs colchicine and bisoprolol from the beginning of 2022. Patient's general condition | 35 year old female patient with medical history of chronic inflammatory bowel disease who 28 days after the 2nd dose of SpikevX experienced Dyspnoea and Arrhythmia and was diagnosed with Myocarditis with performance reduction, arrhythmia and shortness of breath. Patient had slow improvement over the next few months. She was reported to be on colchicine and bisoprolol after 7 months of vaccination. Patient's general condition deteriorated again with shortness of breath under stress and significant reduction in performance was reported. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is unassessable based on the lack of information. A causal relationship cannot be excluded due to the lack of other information. | [redacted] |

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| | deteriorated again with shortness of breath under stress and significant reduction in performance.<br>No treatment medications were provided.<br><br>Company comment : This regulatory authority case concerns a 35 year old female patient with no reported medical history who experienced the unexpected serious (important medical event) events of Dyspnoea and Arrhythmia(AESI) and expected serious (important medical event) event of Myocarditis (AESI) on the 28th day of receiving the second dose of mRNA-1273 vaccine. According to the verbatim, the patient had myocarditis with performance reduction, arrhythmia and shortness of breath. Patient had slow improvement over the next few months. She was reported to be on colchicine and bisoprolol after 7 months of vaccination. Patient's general condition deteriorated again with shortness of breath under stress and significant reduction in performance was reported. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority reporting | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), CARDIOVASCULAR DISORDER (Cardiovascular problem), IMPAIRED WORK ABILITY (Disability at least until 23/01) and MYOCARDITIS (Perimyocarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216038) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 immunisation: Comirnaty on 13-Jul-2021 and Comirnaty on 17-Aug-2021.<br>Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.<br>Concurrent medical conditions included Smoker.<br><br>On 06-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced CARDIOVASCULAR DISORDER (Cardiovascular problem) (seriousness criterion hospitalization), IMPAIRED WORK ABILITY (Disability at least until 23/01) (seriousness criterion disability) and MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). At the time of the report, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), CARDIOVASCULAR DISORDER (Cardiovascular problem), IMPAIRED WORK ABILITY (Disability at least until 23/01) and MYOCARDITIS (Perimyocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Concomitant product use was not provided by the reporter.<br><br>Laboratory tests included TTE and ECG (result not reported).<br><br>Treatment included NSAIs and colchicine | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (myocarditis) in a 38-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Myocarditis in March 2019.<br>Concurrent medical conditions included Muscle atrophy (Spinal muscle atrophy).<br><br>On 26-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Subcutaneous) 1 dosage form. On 30-Nov-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Subcutaneous), the reporter considered MYOCARDITIS (myocarditis) to be probably related.<br><br>No concomitant medication was reported.<br><br>Treatment of side effect 1: improving under NSAIDs. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number [redacted] on 08-Feb-2022 and was forwarded to Moderna on 17-Feb-2022.<br><br>This case, initially reported to the [redacted] by a physician, was received via the [redacted] (Ref, [redacted]. On an unknown date, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 03-Sep-2021, the patient received the 2nd dose of the vaccine. On 07-Sep-2021, at 02:20, acute myocarditis developed. The patient was aware of chest pressure sensation and dyspnea at bedtime and called an ambulance. On arrival at the reporting hospital, extensive ST elevations and an increase in troponin were noted. In addition, reduction in the left ventricular ejection fraction was also found in the echocardiography. The patient was hospitalized for acute myocarditis. On 08-Sep-2021, blood test showed increases in troponin I of 75,730 ng/mL, CK of 2,411 U/L, CK-MB of 208.1 U/L, and CRP of 1.23 mg/dL. Echocardiography showed left ventricular ejection fraction of 45%. The patient had local or diffuse malfunction of the right ventricle or the left ventricle. Electrocardiography showed ST segment elevation or negative T wave. In the differential diagnosis, other diseases that could explain the findings have been ruled out regarding clinical symptoms Ob 14-Sep-2021, the | 18 year old male patient with no reported medical history who 4 days after the 2nd dose of Spikevax experienced chest pressure sensation and dyspnoea at bedtime for which he was hospitalized. Lab work up revealed an increase in troponin, abnromal echo, abnormal ECG. . According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | symptoms were resolving, and the patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship.<br><br>Company comment: This case received from Business partner- Takeda case concerns an 18 year old male patient with no reported medical history who experienced the expected serious (seriousness criteria-hospitalization and important medical event), AESI of Myocarditis on the 5th day of receiving the second dose of mRNA-1273 vaccine. It was reported that the patient developed chest pressure sensation and dyspnoea at bedtime for which he was hospitalized. Lab work up revealed an increase in troponin. In addition, echocardiography showed reduction in the left ventricular ejection fraction(45%). As per the report, there was local or diffuse malfunction of the right ventricle or the left ventricle. Electrocardiography showed ST segment elevation or negative T wave. He was diagnosed with acute myocarditis. In the differential diagnosis, other diseases that could explain the clinical symptoms and findings had been ruled out. The patient was subsequently discharged from the hospital. At the time of the report, the event was resolving. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 15-Feb-2022 and was forwarded to Moderna on 15-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.) and ARRHYTHMIA (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 20T214015) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 17-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Nov-2021, the patient experienced MYOCARDITIS (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.) (seriousness criterion medically significant), SOMNOLENCE (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.), ARRHYTHMIA (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.) (seriousness criterion medically significant), CHEST DISCOMFORT (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.), SUPRAVENTRICULAR EXTRASYSTOLES (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | "supraventricular bending minus", dyspnea on exertion and exhaustion.) and DYSPNOEA EXERTIONAL (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.). On 01-Dec-2021, MYOCARDITIS (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.), SOMNOLENCE (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.), ARRHYTHMIA (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.), CHEST DISCOMFORT (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.), SUPRAVENTRICULAR EXTRASYSTOLES (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.) and DYSPNOEA EXERTIONAL (Classic picture of a myocarditis with a feeling of pressure in the chest, cardiac arrhythmias in the sense of a "supraventricular bending minus", dyspnea on exertion and exhaustion.) had not resolved.<br><br>The patient did not have any allergies and there was no risk factors or pre-existing illnesses.<br>Concomitant medication were not reported.<br>Patient was currently on physical protection as therapy.This included subjectively emofound suspending of HRST and a decrease in the thoracic feeling of pain.<br>Laboratory investigation of echocardiographic showed Good systolic LV and RV EF, no pericardial effusion, none higher grade vitia, none wall movement disorders. LZ ECG report was pending. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 15-Feb-2022 and was forwarded to Moderna on 15-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of the first episode of MYOCARDITIS (myocarditis) and the second episode of MYOCARDITIS (myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004953) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 04-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Dec-2021, the patient experienced the first episode of MYOCARDITIS (myocarditis) (seriousness criterion medically significant) and the second episode of MYOCARDITIS (myocarditis) (seriousness criterion medically significant). On 09-Dec-2021, last episode of MYOCARDITIS (myocarditis) had not resolved. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No concomitant medications were reported.<br>No treatment medications were reported.<br>Patient experienced breathing discomfort and chest pain from Monday to Tuesday. Doctor diagnoses suspicion of heart muscle inflammation.<br><br>Are you or the person concerned aware of allergies? If yes, which one? No Information about risk factors or pre-existing conditions No/According to the classic symptoms, breathing discomfort and chest pain occurred on from Monday to Tuesday. doctor diagnoses suspicion of heart muscle inflammation observation in hospital, running outpatient | | |
| [redacted] | This case, initially reported to the [redacted] by a physician, was received via the [redacted] (Ref, [redacted]. Myocarditis was assessed as serious by the MAH. On 19-May-2021, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 09-Jun-2021, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 24-Jan-2022, the patient received the 3rd vaccination with this vaccine. At night, myocarditis developed. Generalized malaise, pyrexia of 39.3 degrees Celsius, and chest tightness developed. On 25-Jan-2022, pyrexia developed. On 26-Jan-2022, pyrexia subsided. Around the time of dinner, pyrexia of 38 degrees Celsius and chest pain developed again. As the heart rate gradually increased, the patient experienced pain like being grabbed by the heart, palpitations, respiratory discomfort, and malaise. On 27-Jan-2022, palpitations developed. The patient visited a medical institution. Chest X-ray and electrocardiography were performed. PCR test was performed because the patient had pyrexia of 37.5 degrees Celsius. There was no abnormality, and the patient was treated with loxoprofen sodium hydrate and rebamipide. On 28-Jan-2022, the patient visited the reporting hospital. There was no abnormality in electrocardiogram or chest X-ray. Blood test showed increases in white blood cell count of 5,000, CRP of 2.29 mg/dL, and CPK of 471 U/L. GOT: 63, and LDH: 299. Electrocardiogram revealed PR prolongation of 0.241 seconds. Differential diagnosis excluded other disorders that could explain clinical symptoms/findings. On 03-Feb-2022, the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship. | 22 years old male with unknown medical history and who previously received 2 doses of Cominarty as his primary series vaccination and who 4 days after his 3rd dose with Spikevax developed chest pain, palpitations. Patient went to the hospital and was found to have to have a normal chest x-ray and EKG. The next day the pateint went back to the hospital and this time his CRP, CPK were elevated and his EKC was abnormal. Patient was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated enzymes and EKG results; a causal relationship cannot be excluded. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted]) on 15-Feb-2022 and was forwarded to Moderna on 15-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocardium inflammation) in a 38-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 10-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced MYOCARDITIS (myocardium inflammation) (seriousness criterion medically significant). On 21-Dec-2021, MYOCARDITIS (myocardium inflammation) had not resolved. | 38-year-old female patient, with no medical history reported in this case, who 5 days after the 3rd dose of Spikevax experienced Myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is unassessable based on the lack of information. A causal relationship cannot be excluded due to the lack of other information. | [redacted] |

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| | No concomitant products were reported.<br>No treatment drugs were reported<br><br>after [redacted] between the duration felt tired,patient is feeling like prick in the chest when exerted. high pulse and blood pressure. no more movement is possible, patient is on sick leave without intensifying the stinging. myocarditis would be attested. birthday [redacted]83. treatment was bed rest and how long this symptoms goes no person know<br><br>Company Comment: This is a Regulatory Authority case concerning a 38-year-old female patient, with no medical history reported in this case, who experienced the serious expected AESI of Myocarditis (serious criteria Medically Significant), approximately 5 days after the administration of the 3rd dose of the mRNA-1273 vaccine. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000110A) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 06-Mar-2021 and Comirnaty BNT162b2 on 29-May-2021.<br>Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.<br><br>On 16-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported.<br>No treatment medications provided.<br><br>Company Comment:<br>This regulatory authority case of Interchange of vaccine products concerns a 35-year-old male patient, with relevant medical history of previous vaccinations of Comirnaty BNT162b2, who experienced the expected/ serious (medically significant) AESI of Myocarditis. The event occurred approximately 5 days after receiving a dose of mRNA-1273 Vaccine. At the time of | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | the report the outcome of the event was not resolved. Event seriousness assessed as per Regulatory Authority report. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 39-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 17-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Dec-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter. No treatment information was provided.<br><br>Company comment: This regulatory authority case concerns a 39-year-old male patient, with no medical history reported, who experienced the expected event of myocarditis, which required hospitalization. The event occurred approximately 5 days after the third dose of mRNA-1273 and was ongoing at the time of report. No further information regarding the event or diagnostic findings was provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via [redacted] (Reference number: [redacted] on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), CHEST DISCOMFORT (Chest pressure) and PAIN IN EXTREMITY (Pain in arm) in a 24-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005889) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 16-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 17-Dec-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant) and CHEST | 24-year old male experienced chest pressure 1 day after receiving the 3rd dose of Spikevax. | [redacted] |

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| | DISCOMFORT (Chest pressure) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization and medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization and medically significant) and PAIN IN EXTREMITY (Pain in arm) (seriousness criteria hospitalization and medically significant). On 20-Jan-2022, PERICARDITIS (Pericarditis) had resolved with sequelae. At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), CHEST DISCOMFORT (Chest pressure) and PAIN IN EXTREMITY (Pain in arm) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Chest X-ray: results not provided Results not provided.<br>On an unknown date, Electrocardiogram: results not provided Results not provided.<br>On an unknown date, Troponin: reported by consumer as raised<br><br>Patient did not take any medicines routinely.<br>Patient had constant uncomfortable pressure in chest the day after vaccine for a week and a half. Patient developed crushing pain in chest and radiated into left arm. Exacerbated by low intensity exercise (walking) and travelling in a car. Went to A&E where patient had positive markers for a heart attack, but the markers were present due to the diagnosis of pericarditis. Patient took ibuprofen for a couple of weeks, then prescribed colchicine for up to 3 weeks as ibuprofen had limited effects. Reduced from the crushing pain to the uncomfortable pressure ,this persisted for another 3 weeks after going to A&E. Occasionally the constant pressure Iinitially felt came back and patient had minimal stress Patient had chest pain which never happened before booster. Patient stayed 5 to 6 hours in A and E for investigations. Patients troponin level raised ,high enough to alert of a potential heart attack.<br><br>Company Comment: This is a Regulatory Authority case concerning a 24-year-old male patient, with no relevant medical history, who experienced the expected, serious (hospitalization and medically significant), and AESI of Pericarditis, and the unexpected and serious (hospitalization and medically significant) events of Chest discomfort, Dyspnoea, among others. The events started 1 day after the third dose of mRNA-1273 vaccine. Patient went to A&E due to symptoms, were ECG, chest x-ray, and multiple blood tests were performed. With troponin values raised, pericarditis was diagnosed, and after 5-6 hours at A&E, patient was sent home with ibuprofen (taken this for 3 weeks, and then prescribed colchicine). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Feb-2022: Follow up received contains additional events and updated action taken. | | |

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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Hospitalized with Chest pain) and MYOCARDITIS (Perimyocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 immunisation: SPIKEVAX on 23-Jul-2021 and SPIKEVAX on 20-Aug-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX and SPIKEVAX.<br><br>On 06-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In January 2022, the patient experienced CHEST PAIN (Hospitalized with Chest pain) (seriousness criterion hospitalization). On 18-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Hospitalized with Chest pain) and MYOCARDITIS (Perimyocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In January 2022, Electrocardiogram: ekg changes EKG changes.<br>In January 2022, Myocardial necrosis marker: increased coronary enzymes (High) Increased coronary enzymes.<br>In January 2022, Troponin T: increased (High) Increased.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Company comment :<br>This regulatory authority case concerns a 21 year old male patient with no reported medical history who experienced the expected serious (hospitalization) AESI of Myocarditis and unexpected serious (hospitalization) event of Chest pain after receiving the third dose of mRNA-1273 vaccine. Chest pain developed on an unspecified day and Perimyocarditis was reported on the 13th day of vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 16-Feb-2022: Upon Internal Review on 07-Mar-2022, Non Significant correction was performed to update product event details tab by recalculating the causality. | | [redacted] |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 20-Feb-2022. The most recent information was received on 05-Mar-2022 and was forwarded to Moderna on 05-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of PLEUROPERICARDITIS (Pleuro-pericarditis with | Case with prolonged time to onset reported. The temporal relationship between vaccine administration and onset of the reactions is unclear. The date of the third dose of COVID-19 | [redacted] |

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| | pericardial fluid, breathlessness, fatigue, chest pain, fever, dyspnoea and syncope) in a 34-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>Co-suspect products included non-company products IBUPROFEN for an unknown indication and PREDNISOLONE for an unknown indication.<br><br>The patient's past medical history included Epigastric pain (started 2 weeks after the third vaccine) and Hospitalisation (13 days and the readmitted for further 5 days) since an unknown date.<br>Concomitant products included COLCHICINE for an unknown indication.<br><br>On 31-Jan-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 15-Jan-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PLEUROPERICARDITIS (Pleuro-pericarditis with pericardial fluid, breathlessness, fatigue, chest pain, fever, dyspnoea and syncope) (seriousness criterion hospitalization). At the time of the report, PLEUROPERICARDITIS (Pleuro-pericarditis with pericardial fluid, breathlessness, fatigue, chest pain, fever, dyspnoea and syncope) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 22-Jan-2022, Chest X-ray: Bilateral pleural effusions and the heart shadow is enlarged<br>On 22-Jan-2022, Echocardiogram: Features suggestive of haemodynamic compromise, Suggestive of cardiac tamponade, Diastolic compression of the right ventricle and mod global pericardial effusion(rv 1.6& lv 1.7 cm)<br>On 22-Jan-2022, Electrocardiogram: ST saddle elevation % PR depression in some leads, reciprocal changes in avr, Isolated T inversion III and acute pericarditis changes.<br>On 23-Jan-2022, Computerised tomogram: Imaged upper abdominal viscera are normal, No concerning bone lesions, No rib fractures or pneumothorax, Good opacification of pulmonary arteries achieved, No pulmonary embolism, Pericardial effusion & maximal depth approx 12mm, Bilat pleural effusion with associated atelectasis, Mediastinal& hilar lymph nodes are consid reactive, No coronary artery calcification and No calcification to suggest ischemic heart disease.<br>On 22-Feb-2022, Troponin: normal (normal) Normal.<br>On an unknown date, Heart sounds: Presence of pericardial rub<br>On an unknown date, Viral test: negative (Negative) Negative.<br><br>Company Comment: This regulatory case concerns a 34-year-old, male patient with no reported relevant medical history, who was hospitalized due to the unexpected event of Pleuropericardits. The event was reportedly diagnosed approximately a year after receiving mRNA-1273 as third dose of COVID-19 vaccine. The patient initially presented with epigastric pain followed by breathlessness a few days later. Other symptoms reported were fatigue, chest pain, fever, dyspnoea and syncope although the onset dates were not mentioned. Information was not provided on what happened to the patient during the interval period between start of | VACCINE MODERNA is 31-Jan-2021 and the narrative provided states that symptoms stared 2 weeks and a few days after the third vaccine. | [redacted] |

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| | symptoms and event diagnosis. Reported results of ECG, echocardiogram, chest computed tomography, and hearts sounds were supported a diagnosis of pleuropericarditis. On unknown dates, the patient was started on colchine, ibuprofen, and prednisolone. At the time of reporting, the outcome was unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority's report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Mar-2022: Significant Follow-up information received on 05-MAR-2022: Relevant medical history added. Pleuropericarditis added as event.<br>On 06-Mar-2022: Significant Follow-up information received on 06-MAR-2022: Laboratory investigation added and lab test result update. Concomitant medication added. Except Pleuropericarditis rest all events were deleted. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 21-Feb-2022 and was forwarded to Moderna on 21-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000137A) for COVID-19 vaccination.<br><br>Patient had asthma.<br><br>On 04-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Jan-2022, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). On 25-Jan-2022, PERICARDITIS (Pericarditis) had not resolved.<br><br>Concomitant drugs were not reported.<br>It was reported that patient had dizziness and chest pain for a few days after vaccination that did not got better. Therefore, patient visited the doctor and diagnosis after MRI.<br>Treatment medications were not provided.<br><br>Company comment:<br>This regulatory authority case concerns a 27-year-old male patient, with no relevant medical history reported, who experienced the serious (hospitalization) expected AESI of pericarditis 5 days after the third dose of mRNA-1273. The patient reported dizziness and chest pain, a MRI was performed and pericarditis was diagnosed. Event outcome was not resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via [redacted] (Reference number: [redacted]) on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) in a 33-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. | 33-year old male patient developed chest pain 10 days after a 3rd dose of Spikevax (primary series with AstraZeneca). Three days after symptom onset, the patient was evaluated at the hospital where pericarditis was confirmed by abnormalities on ECG and an echocardiogram which showed "swelling of the heart". The patient had a history of COVID-19 infection one year before the event. | [redacted] |

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| | The patient's past medical history included Suspected COVID-19 from 12-Dec-2020 to 23-Dec-2020.<br><br>On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 19-Dec-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization, disability and medically significant), CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization, disability and medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization, disability and medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved and FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 11-Dec-2020, SARS-CoV-2 test: positive<br><br>The patient initially had 2 COVID vaccines in Feb 2021 and May 2021.The patient believed that these were Astra Zeneca vaccines. On 8th December, the patient had booster vaccine of the Moderna type. The patient did not feel ill after this. On the weekend of the 18th of December 2021, patient noticed chest pain when breathing and didn't felt quite right. On the morning of the 21st of December, patient was woken early hours by intense chest pain which was horrendous when breathing in. Pain was left side of chest and would radiate to the left shoulder and collarbone. The patient attended hospital , he stayed 1 day. Relevant investigations or tests conducted include ECG which discovered pericarditis and an echocardiogram (swelling of the heart, irregular heartbeat).<br><br>Company Comment:<br>This is a regulatory case concerning a 33-year-old male patient with no relevant medical history reported, who experienced the expected serious (medically significant, hospitalization and disability criteria) AESI of pericarditis. The patient reported initially chest pain while breathing, 10 days after a dose of mRNA-1273 vaccine, received as the third dose for COVID-19 Vaccination. Chest pain was localized on the left side and radiated to left shoulder and collarbone. As it worsened, approximately 13 days after vaccination, the patient visited his GP and went to hospital, where he stayed for 1 day. A diagnosis of pericarditis was confirmed by a Cardiologist, electrocardiogram findings (not disclosed) and an echocardiogram that evidenced heart swelling and an irregular heartbeat. Blood tests were not suggestive of viral infection. In addition to chest pain, the patient also experienced fatigue, dyspnoea, palpitations and tachycardia, that could be related to pericarditis. The patient received treatment, which was not detailed; however, pericarditis was reported as not resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | The causality is assessed as possible for this case due to the close temporal relationship with event onset 10 days following the 3rd dose of Spikevax; however, it is unknown whether other potential etiologies were ruled out based on the report received. | |

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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 21-Feb-2022 and was forwarded to Moderna on 21-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis (heart muscle inflammation)) in a 27-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 22-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Dec-2021, the patient experienced MYOCARDITIS (myocarditis (heart muscle inflammation)) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (myocarditis (heart muscle inflammation)) was resolving.<br><br>No relevant concomitant medications were reported.<br>Patient reported that on 26-DEC-2021 discovery of myocarditis. Patient was admitted. Treatment with beta blockers and rest. Ibuprofen for anti-inflammatory. ECG, ultrasound, MRI, heart catheter examination were reported as done, but results were not provided.<br><br>Company comment: This Regulatory Authority case concerns a 27-year-old, male patient with no relevant medical history, who experienced the expected serious AESI event of Myocarditis. The event occurred approximately 4 days after the third dose of mRNA-1273 (Moderna covid-19 vaccine). Patient was admitted into the hospital; ECG, ultrasound, MRI, heart catheter examination were done, but results were not provided. The patient was treated with beta blockers, rest, and ibuprofen for anti-inflammatory. Outcome was reported as recovering. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 22-Feb-2022. The most recent information was received on 24-Feb-2022 and was forwarded to Moderna on 24-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of DIZZINESS (dizziness), DYSPNOEA (breathlessness), FEELING ABNORMAL (spaced out), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and PALPITATIONS (Heart palpitations) in a 30-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 18-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 21-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced DIZZINESS (dizziness) (seriousness criterion medically significant), DYSPNOEA (breathlessness) (seriousness criterion medically significant), FEELING ABNORMAL (spaced out) (seriousness | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant) and PALPITATIONS (Heart palpitations) (seriousness criterion medically significant). At the time of the report, DIZZINESS (dizziness), DYSPNOEA (breathlessness) and FEELING ABNORMAL (spaced out) was resolving, MYOCARDITIS (Myocarditis) had not resolved and CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and PALPITATIONS (Heart palpitations) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: results not provided Results not provided.<br>On an unknown date, Chest X-ray: results not provided Results not provided.<br>On an unknown date, Electrocardiogram: results not provided Results not provided.<br><br>Patient experienced tightness of the chest and occasional sharper pains, occasional breathlessness and occasional seemingly random increases in heart rate. In the first two to three weeks following patient's booster jab, patient would also experienced slight dizziness and feeling spaced out, although this did not continued. With the exception of a period of perhaps a week, patient continue to experienced the above symptoms. On the recommendation of the doctor at the hospital, and later patient's GP. Patient occasionally took Ibroprufen, but this does not seem to have help that much.<br>Patient did not tested positive for COVID-19 after taking the vaccine. Patient was not enrolled in clinical trial.<br>Company Comment: This regulatory case concerns a 30-year-old, male patient with no medical history reported, who experienced the serious unexpected events of Dizziness, Dyspnoea, Feeling abnormal, Chest pain, Dyspnoea, Palpitations and serious expected AESI event of Myocarditis (Medically significant). The event Myocarditis occurred after 2 days and further events dizziness, dyspnoea, feeling abnormal, chest pain, dyspnoea, palpitations occurred unspecified days after receiving third dose of mRNA-1273 vaccine. Patient experienced tightness of the chest and occasional sharper pains, breathlessness and seemingly random increases in heart rate. In the first two to three weeks following patient's booster dose, patient also experienced slight dizziness and feeling spaced out, although this did not continue. Within a week, patient again continue to experience the above symptoms. Patient was treated with Ibroprufen. On an unknown date Blood test, Chest X-ray, Electrocardiogram were performed results were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Feb-2022: Follow-up received, added lab tests (chest X-ray, blood test and electrocardiogram). | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 16-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000135A) for COVID-19 vaccination. | 16 year old male patient with no reported medical history and who received Cominarty as the two primary dosis for COVID-19 prevention, and who 1 day after the 3rd dose with Spikevax was diagnosed with myocarditis. No other information | [redacted] |

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| | Previously administered products included for Prophylactic vaccination: COMIRNATY on 16-Aug-2021 and COMIRNATY on 13-Sep-2021.<br><br>On 12-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 13-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and life threatening). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>No concomitant details were provided. No treatment details were provided.<br><br>Company Comment - This regulatory authority case concerns a 16 year old male patient with no relevant medical history, who experienced the serious expected event of myocarditis. The event occurred 1 day after a dose of mRNA-1273 vaccine, and had not resolved at the time of the report. The rechallenge was not applicable. Patient's sex remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. | was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is conditional based on the lack of information; a causal relationship cannot be excluded due to the lack of information. | |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis), MYALGIA (Myalgia), ASTHENIA (Asthenia), PLEURITIC PAIN (Pleuritic pain), PYREXIA (Febricula), DYSPNOEA (Dyspnea) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 29-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3006276) for COVID-19 vaccination.<br><br>Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) from 14-Feb-2021 to 06-Jun-2021 for COVID-19 vaccination.<br><br>On 27-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 27-Dec-2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion medically significant). On 08-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), MYALGIA (Myalgia) (seriousness criterion medically significant) and ASTHENIA (Asthenia) (seriousness criterion medically significant). On 10-Jan-2022, the patient experienced PLEURITIC PAIN (Pleuritic pain) (seriousness criterion medically significant) and PYREXIA (Febricula) (seriousness criterion medically significant). On 18-Jan-2022, the patient experienced DYSPNOEA (Dyspnea) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis), MYALGIA (Myalgia), ASTHENIA (Asthenia), PLEURITIC PAIN (Pleuritic pain), PYREXIA (Febricula) and DYSPNOEA (Dyspnea) was resolving and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 11-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative.<br>On 13-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative. | Lack of information in the case, particularly diagnostic exam results. Initial COVID-19 vaccine series was Vaxzevria and booster dose was Spikevax. | [redacted] |

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| | On 18-Jan-2022, Fibrin D dimer (0-500): 108 (normal) 108 ng/mL (nanogram per millliiter).<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Treatment medications were not reported.<br>No medical history was reported.<br><br>Company comment: This is a regulatory case concerning a 29 year-old, female patient with no reported medical history, who experienced the serious (medically important condition) expected, AESI of myocarditis and the serious (medically important condition) unexpected events of pleuritic pain, dyspnoea, myalgia, asthenia and pyrexia; approximately 13 to 23 days after the mRNA-1273 vaccine, received as the third dose of COVID-19 vaccination. Additionally, Revaccination with different COVID-19 vaccine was also reported in the case (vaccination with two doses of COVID-19 vaccine AstraZeneca approximately 6 months prior). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 23-Feb-2022. The most recent information was received on 23-Feb-2022 and was forwarded to Moderna on an unknown date.<br>This regulatory authority case was reported by a physician and describes the occurrence of CARDIOVASCULAR DISORDER (Cardiovascular problem), MYOCARDITIS (Myocarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000057A) for COVID-19 vaccination.<br><br>Previously administered products included Comirnaty on 19-Jun-2021 and Comirnaty on 04-Aug-2021.<br><br>On 21-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Jan-2022, the patient experienced CARDIOVASCULAR DISORDER (Cardiovascular problem) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). At the time of the report, CARDIOVASCULAR DISORDER (Cardiovascular problem), MYOCARDITIS (Myocarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications was not provided by the reporter.<br><br>Treatment includes Antiphlogistics and Rest. | Lack of information in the case, particularly diagnostic exam results. Troponin level of 6093 ng/L with no additional lab/diagnostic exam results. Prrimary COVID-19 vaccination series with Comirnaty, 3rd vaccination with Spikevax. | [redacted] |

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| | Restorative Examinations includes Troponins 6093 ng/L. Ppreserved LV function in echocardiography.<br><br>Company comment: This regulatory case concerns a 19-year-old male patient with history of interchange of vaccine products (two doses of Comirnaty Covid19 vaccine), who experienced the unexpected serious event Cardiovascular disorder and expected serious AESI event Myocarditis, one day after a dose of mRNA-1273 (taken as third dose). Additionally, Covid 19 immunization was also reported. The patient was hospitalized for the events. Reports showed Troponins 6093 ng/L. preserved LV function in echocardiography. At the time of reporting, the events were resolving. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Feb-2022 and was forwarded to Moderna on 25-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) and CHEST PAIN (Chest pain) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000054A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 25-Jan-2022 at 5:34 PM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Jan-2022 at 5:34 PM, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 26-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced PYREXIA (Pyrexia), MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization), FATIGUE (Fatigue) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). On 25-Jan-2022 at 5:34 PM, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. At the time of the report, PYREXIA (Pyrexia), MYOCARDITIS (Myopericarditis), FATIGUE (Fatigue) and CHEST PAIN (Chest pain) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 28-Jan-2022, Blood creatine phosphokinase MB (<5): 31.28 ng/L<br>On 28-Jan-2022, Troponin I (Unknown-53): 10696 ng/L<br>On 30-Jan-2022, Blood creatine phosphokinase MB (Unknown-5): 15.75 ng/L<br>On 30-Jan-2022, Troponin I (Unknown-53): 16644 ng/L.<br>On 31-Jan-2022, Magnetic resonance imaging heart: Left ventricle dilatation with preserved ejection fraction, visible signs of morphological changes in left ventricle anterior and lateral wall whole length in myocardial middle and subepicardial layer, which corresponds with oedema associated with acute myocarditis.<br>On 01-Feb-2022, Angiogram: normal Initial left ventricle dilatation (borderline measurements),no signs of coronary artery branching or path variations, pathologic changes in artery walls or signs of artery stenoses..<br>On 02-Feb-2022, Blood creatine phosphokinase MB (Unknown-5): 0.5 0.5 ng/L<br>On 02-Feb-2022, Troponin I (Unknown-53): 185 ng/L | 32-year-old male patient experienced chest pain, fatigue, and pyrexia 1 day after receiving Spikevax as a 3rd/booster dose. Three days after vaccination CK-MB was elevated at 31.28 ng/L (normal <5) and Troponin I was elevated at 10,696 ng/L (normal unk-53). Six days after receiving Spikevax, cardiac imaging showed left ventricle dilation and evidence of myocardial oedema. Medical history and concomitant medication information, or the lack thereof, was not provided, impeding complete medical assessment of the case to determine causality. Addtionally, it was reported that the patient had received a different COVID-19 vaccine prior to receiving Spikevax. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company comment:<br>This case concerns a 32-year-old male patient with no medical history reported, who experienced the expected, serious (hospitalization) event of myocarditis (AESI) 1 day after the third dose of mRNA-1273. Diagnostic tests included elevated CK-MB and Troponin I, as well as a heart MRI which showed abnormal left ventricle dilatation with preserved ejection fraction, visible signs of morphological changes in left ventricle anterior and lateral wall whole length in myocardial middle and subepicardial layer, which corresponds with oedema associated with acute myocarditis. Outcome was reported as resolving. Interchange of vaccine products could be a confounder for the case. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 24-Feb-2022 and was forwarded to Moderna on 24-Feb-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 13-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216045) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 30-Aug-2021 and Comirnaty BNT162b2 on 20-Sep-2021.<br>Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.<br><br>On 23-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported.<br>No treatment information reported.<br><br>This is a regulatory case concerning a 13-year-old male patient with previous COVID-19 vaccination of non-company product Comirnaty BNT162b2, who experienced the expected serious adverse event of special interest, Myocarditis. The event led to the hospitalization of the patient as reported by the regulatory authority and occurred 3 days after receiving the third dose of mRNA-1273 Vaccine. No clinical or treatment details were given. It was reported that the outcome of the event has not resolved. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | 13-year-old male patient with unknown medical history and previous COVID-19 vaccination of non-company product Comirnaty BNT162b2, who 3 days after a 3rd dose with Spikevax was diagnosed with Myocarditis. The event led to the hospitalization of the patient. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is conditional based on the lack of information; a causal relationship cannot be excluded due to the lack of information. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. | Lack of information in the case, particularly diagnostic exam results and there is no mention of medical history or concomitant medications or the lack thereof. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 11-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) outcome was unknown.<br><br>No concomitant medication details was provided.<br>No treatment medication details was provided.<br><br>Company comment: This regulatory case concerns a 20-year-old male patient with no reported medical history who experienced the expected serious AESI event of Myocarditis (Myopericarditis) 2 days after the receipt of third dose of mRNA-1273 Vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the event retained as per Regulatory Authority reporting. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 25-Feb-2022 and was forwarded to Moderna on 25-Feb-2022.<br>This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PALPITATIONS (HARD PALPATION), MYOCARDITIS (??? MYOCARDITIS/ PERICARDITIS AS A S/E TOTHE BOOSTER), MALAISE (FELT UNWELL AFTER THE VACCINE), EXERCISE TOLERANCE DECREASED (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT), AXILLARY PAIN (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) - PAIN/PRESSURE), IMPAIRED WORK ABILITY (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT), CHEST PAIN (BIGGER CHEST PAIN / SHARP HARD PAIN / LEFT SIDED CHEST PAIN), DISCOMFORT (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) - PAIN/PRESSURE), INSOMNIA (AT THE NIGHT I COULDN'T SLEEP FOR BIG CHEST PAIN, DIFFICULTY TO BREATHE AND HARD PALPATION), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT), SWELLING (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) / BIG SWELLING ON THE LEFT SIDE OF THE CHEST AND UNDER THE ARM (10-15 CM)), DYSPNOEA (BIGGER DIFFICULTY TO BREATH / SOME SOB - INTERMITTENT), BEDRIDDEN (COULDN'T GO OUT OF THE BED), PERICARDITIS (??? MYOCARDITIS/ PERICARDITIS AS A S/E TOTHE BOOSTER), COSTOCHONDRITIS (OTHER CAUSE OF CHEST PAIN? COSTOCHONDRITITIS), LYMPHADENOPATHY (SWOLLEN LYMPH GLANDS), FATIGUE (FATIGUE / MORE FATIGUE EARLIER THIS WEEK), HYPERHIDROSIS (SWEATING QUITE A LOT AT THE MOMENT), HEART RATE INCREASED (RESTING HEARTBEAT USUALLY STARTS AT 38 BPM, NOW IS AROUND 50 BPM / WOULD NORMALLY HAVE | Lack of information in the case, particularly diagnostic exam results. Due to the prolonged time to onset of 190 days, this report is assessed as unlikely related to Spikevax. with symptoms starting two days after the third dose of mRNA 1273 COVID-19 vaccine. The patient reported having an electrocardiogram and bloodwork done, but no results were provided. | [redacted] |

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| | AROUND 50BPM WHEN I SIT AND REST NOW AROUND 70BPM), MUSCULOSKELETAL CHEST PAIN (SOME TENDERNESS LEFT CHEST WALL) and FATIGUE (TIREDNESS - ALL THE TIME / HAVE TO REST ALL THE TIME / SLIGHTLY TIRED) in a 37-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Patient reported to be in good health with no family history of cardiac disease.<br><br>On 04-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Jan-2022, the patient experienced MALAISE (FELT UNWELL AFTER THE VACCINE) (seriousness criterion medically significant), EXERCISE TOLERANCE DECREASED (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT) (seriousness criterion disability), IMPAIRED WORK ABILITY (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT) (seriousness criterion disability), DISCOMFORT (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) - PAIN/PRESSURE) (seriousness criterion disability), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT) (seriousness criterion disability), SWELLING (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) / BIG SWELLING ON THE LEFT SIDE OF THE CHEST AND UNDER THE ARM (10-15 CM)) (seriousness criterion disability), LYMPHADENOPATHY (SWOLLEN LYMPH GLANDS) (seriousness criterion medically significant), HEART RATE INCREASED (RESTING HEARTBEAT USUALLY STARTS AT 38 BPM, NOW IS AROUND 50 BPM / WOULD NORMALLY HAVE AROUND 50BPM WHEN I SIT AND REST NOW AROUND 70BPM) (seriousness criterion medically significant) and FATIGUE (TIREDNESS - ALL THE TIME / HAVE TO REST ALL THE TIME / SLIGHTLY TIRED) (seriousness criterion disability). 06-Jan-2022, the patient experienced AXILLARY PAIN (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) - PAIN/PRESSURE) (seriousness criterion disability) and CHEST PAIN (MILD CHEST PAIN). On 13-Jan-2022, the patient experienced PALPITATIONS (HARD PALPATION) (seriousness criterion disability), INSOMNIA (AT THE NIGHT I COULDN'T SLEEP FOR BIG CHEST PAIN, DIFFICULTY TO BREATHE AND HARD PALPATION) (seriousness criterion medically significant) and DYSPNOEA (BIGGER DIFFICULTY TO BREATH / SOME SOB - INTERMITTENT) (seriousness criterion medically significant). 13-Jan-2022, the patient experienced CHEST PAIN (BIGGER CHEST PAIN / SHARP HARD PAIN / LEFT SIDED CHEST PAIN) (seriousness criterion disability). On 14-Jan-2022, the patient experienced MUSCULOSKELETAL CHEST PAIN (SOME TENDERNESS LEFT CHEST WALL) (seriousness criterion medically significant). On an unknown date, the patient experienced MYOCARDITIS (??? MYOCARDITIS/ PERICARDITIS AS A S/E TOTHE BOOSTER) (seriousness criterion medically significant). an unknown date, the patient experienced BEDRIDDEN (COULDN'T GO OUT OF THE BED) (seriousness criterion disability), PERICARDITIS (??? MYOCARDITIS/ PERICARDITIS AS A S/E TOTHE BOOSTER) (seriousness criterion medically significant), COSTOCHONDRITIS (OTHER CAUSE OF CHEST PAIN? COSTOCHONDRITITIS) (seriousness criterion medically significant), | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | FATIGUE (FATIGUE / MORE FATIGUE EARLIER THIS WEEK) (seriousness criterion disability) and HYPERHIDROSIS (SWEATING QUITE A LOT AT THE MOMENT) (seriousness criterion medically significant). At the time of the report, PALPITATIONS (HARD PALPATION), MYOCARDITIS (??? MYOCARDITIS/ PERICARDITIS AS A S/E TOTHE BOOSTER), MALAISE (FELT UNWELL AFTER THE VACCINE), EXERCISE TOLERANCE DECREASED (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT), AXILLARY PAIN (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) - PAIN/PRESSURE), IMPAIRED WORK ABILITY (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT), CHEST PAIN (BIGGER CHEST PAIN / SHARP HARD PAIN / LEFT SIDED CHEST PAIN), DISCOMFORT (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) - PAIN/PRESSURE), INSOMNIA (AT THE NIGHT I COULDN'T SLEEP FOR BIG CHEST PAIN, DIFFICULTY TO BREATHE AND HARD PALPATION), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (I AM NOT ABLE TO DO ANYTHING. WORK, TAKE A CARO OF FAMILY, DO SPORT), DYSPNOEA (BIGGER DIFFICULTY TO BREATH / SOME SOB - INTERMITTENT), PERICARDITIS (??? MYOCARDITIS/ PERICARDITIS AS A S/E TOTHE BOOSTER), COSTOCHONDRITIS (OTHER CAUSE OF CHEST PAIN? COSTOCHONDRITITIS), HYPERHIDROSIS (SWEATING QUITE A LOT AT THE MOMENT), HEART RATE INCREASED (RESTING HEARTBEAT USUALLY STARTS AT 38 BPM, NOW IS AROUND 50 BPM / WOULD NORMALLY HAVE AROUND 50BPM WHEN I SIT AND REST NOW AROUND 70BPM), MUSCULOSKELETAL CHEST PAIN (SOME TENDERNESS LEFT CHEST WALL) and FATIGUE (TIREDNESS - ALL THE TIME / HAVE TO REST ALL THE TIME / SLIGHTLY TIRED) had not resolved and SWELLING (ENORMES SWOLLENNESS OF LEFT UNDERARM (10 CM) / BIG SWELLING ON THE LEFT SIDE OF THE CHEST AND UNDER THE ARM (10-15 CM)), BEDRIDDEN (COULDN'T GO OUT OF THE BED), CHEST PAIN (MILD CHEST PAIN), LYMPHADENOPATHY (SWOLLEN LYMPH GLANDS) and FATIGUE (FATIGUE / MORE FATIGUE EARLIER THIS WEEK) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Jan-2022, Blood pressure measurement: 130/84 130/84.<br>On 14-Jan-2022, Heart rate: 50 regular 50 regular.<br>On 14-Jan-2022, Heart sounds: hs1&2 - no murmur HS1&2 - no murmur.<br>In January 2022, Heart rate: resting heartbeat - now around 50 bpm Resting heartbeat - now around 50 BPM and when sit and rest - now around 70 bpm. When sit and rest - now around 70 BPM..<br>On 24-Jan-2022, Blood test: results not provided. Results not provided..<br>On 24-Jan-2022, Electrocardiogram: results not provided Results not provided..<br><br>It was reported that the patient Kept a very healthy lifestyle. Was a [redacted] Still train 4 times and eat a healthy diet to maintain health. Was a [redacted] now exercise regularly, cycling/running/weight. No heart problems in the family. No concomitant medications were reported. No treatment medications were reported. | | |

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| | Company comment: This regulatory authority case concerns a 37-year-old female patient, with no reported medical history, who experienced the unexpected, serious (medically significant) events of malaise, insomnia, dyspnea, costochondritis, lymphadenopathy, musculoskeletal chest pain, and unexpected, serious (disability) palpitations, exercise capacity, axillary pain, inability to work, chest pain, discomfort, loss of personal independence in daily activities, swelling, bedridden, fatigue, sweating, heart rate increased, fatigue; expected, | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 24-Feb-2022 and was forwarded to Moderna on 24-Feb-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 39-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006270) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 immunisation (Spikevax dos 1) on 08-Jul-2021 and COVID-19 immunisation (Spikevax dos 2) on 26-Aug-2021.<br><br>On 26-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Jan-2022, the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (MYOCARDITIS) was resolving.<br><br>No concomitant medications were reported. No treatment medications were reported.<br><br>company comment-This regulatory case concerns a 39-year-old male patient with no relevant medical history, who experienced expected serious (medically significant) AESI event of Myocarditis one day after vaccination with third dose of mRNA-1273. No clinical or treatment details were given. The event was resolving at the time of report. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report | Lack of information in the case, particularly diagnostic exam results and there is no mention of medical history or concomitant medications, or the lack thereof. | [redacted] |
| [redacted] | This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 25-Feb-2022. The most recent information was received on 25-Feb-2022 and was forwarded to Moderna on 18-Mar-2022.<br><br>This case, initially reported to the [redacted]) by a physician, was received via the [redacted] (Ref, [redacted]. Pericarditis was assessed as serious by the MAH. On 19-May-2021, the patient received the 1st dose of coronavirus-modified uridine RNA vaccine (SARS-CoV-2). On 09-Jun-2021, the patient received the 2nd dose of coronavirus-modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 11-Feb-2022, at 10:00, the patient received the 3rd vaccination with this vaccine. On 13-Feb-2022, at 20:00, pericarditis developed. During the night, chest pressure sensation, referred pain in both mandibles, and shortness of breath developed. On 14-Feb-2022, the patient visited a hospital. Electrocardiogram showed ST change, and blood collection showed elevations in high-sensitivity troponin T, CRP, and D-dimer. The vital signs were stable, and echocardiography | 30-year-old, pregnant, female patient experienced chest pressure and shortness of breath 2 days after receiving a 3rd dose of Spikevax. Although general abnormalities were reported on ECG, troponin T, CRP, and D-dimer, it was also reported that vital signs were stable and echocardiography showed good cardiac contractions and no pericardial effusion. Follow-up was conducted 5 days later and the symptoms and diagnostic results were reported as improved, including a normal ECG. Pregnancy itself is a confounder in this case and the lack of clear diagnostic data impairs the medical assessment of this case. Additional information is needed for a proper assessment. | [redacted] |

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| | showed good cardiac contractions and no pericardial effusion. The patient was followed up for possible mild pericarditis. On 18-Feb-2022, the patient returned to the hospital. Improvement of the symptoms, normalization of ST in the electrocardiogram, and improvement of troponin in the blood collection were noted. The symptoms were resolving. The outcome of pericarditis was reported as resolving. Follow-up investigation will be made. A data correction was performed on 17-MAR-2022. The need for a correction was identified on 16-MAR-2022. "Gravida" was added as Current Condition to Other Relevant History. | | |
| [redacted] | This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 01-Mar-2022. The most recent information was received on 23-Mar-2022 and was forwarded to Moderna on 30-Mar-2022.<br>This case was reported by a physician via a medical representative. Suspected myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 26-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 01-Mar-2022, pyrexia, chest pain, and suspected myocarditis were observed. The outcome of pyrexia, chest pain, and suspected myocarditis was reported as ongoing and unchanged. Follow-up investigation was tried, but it was not possible because of non-cooperation of the reporter. Follow-up received on 23-MAR-2022 Updated: Narrative<br>Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | Lack of information in the case, particularly diagnostic exam results provided. Reporter refused to provide additional information. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 02-Mar-2022 and was forwarded to Moderna on 02-Mar-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CARDIOVASCULAR DISORDER (Cardiovascular problem), MYOCARDITIS (Myocarditis with tropo+) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214064) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: Comirnaty on 23-Jun-2021 and Comirnaty on 14-Jul-2021.<br><br>On 18-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Jan-2022, the patient experienced CARDIOVASCULAR DISORDER (Cardiovascular problem), MYOCARDITIS (Myocarditis with tropo+) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 31-Jan-2022, CARDIOVASCULAR DISORDER (Cardiovascular problem), MYOCARDITIS (Myocarditis with tropo+) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) was resolving.<br><br>Treatment included NSAIDs with improvement of symptoms.<br><br>No concomitant medications reported. | Lack of information in the case, particularly diagnostic exam results and there is no mention of medical history or concomitant medications, or the lack thereof. Additionally, the patient received 2 dosed of Comirnaty as the primary COVID-19 vaccine series and Spikevax for dose 3. | [redacted] |

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| | No allergies reported.<br><br>Company Comment: This is a regulatory case of revaccination with different COVID-19 vaccine for this 18-year-old, male patient with past drug history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine), who experienced the expected, non-serious AESI of myocarditis and the unexpected, non-serious event of cardiovascular disorder. The events occurred 1 day after administration of the third dose of the Moderna mRNA-1273 vaccine. The report stated that the patient had a positive Troponin (value not provided). No other details were provided regarding laboratory test/s. Unspecified non-steroidal anti-inflammatory drugs (unspecified dosage, frequency and duration) were used for treatment. The events were resolving at the time of the report. The patient's gender remains a confounder for the event myocarditis. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 12-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. Not Provided<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant products were reported.<br><br>Patient received 3rd Moderna COVID-19 vaccine on 14-Feb-2022, chest pain. On 16-Feb-2022, ER. Troponin-I: 0.9- 1.7- 1.4. EKG: normal. On 17-Feb-2022, patient admitted to CCU. Add colchicine on 18-Feb-2022, Cardiac CTA: patent Suspect Moderna vaccine related myocarditis. Treatment included colchicine. supportive care. Follow up on 21-Feb-2022, The patient mentioned that he had been transferred to a general ward and underwent echocardiography today: normal. After the physician's evaluation, it was expected that the patient would be discharged tomorrow.<br><br>Company comment: This Regulatory Authority case concerns a 35-year-old, male patient with no relevant medical history, who experienced the expected serious (Hospitalization) AESI event of Myocarditis. The event occurred approximately 2 days after the third dose of mRNA-1273 (Moderna covid-19 vaccine). EKG and ECG testing performed was normal; patient treated with Colchicine and supportive care. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. | Although symptom of chest pain and subsequent hospitalization for suspected myocarditis was reported, all diagnostic and lab data in the case appear to be normal. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>Patient took AstraZeneca vaccine on 17JUN2021.<br><br>On 16-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion life threatening). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>Patient diarrhea was noted for one week (February 9) and accompany with fever. Progressive dyspnea and orthopnea were also noted. She visits to ER for evaluation. At ER her consciousness was clear and vital sign show BP: 100 / 68 mmHg; HR: 135/min; RR:16; BT:38.9. Lab data reveal elevation of troponin-I and BNP. Beside echo show rapidly decreased ejection fraction and hypotension. ECMO was indicated. The ECMO was implacement. Under impression of myocarditis, she was admitted to CCU for further management since February 16. On February 22, her condition improved and ECMO was removed. Ventilator treatment was continued, GCS: E3VeM6, vital signs were stable. Tests were carried out to determine if myocarditis is due to bacterial infection. On February 25, 2022, the patient's family mentioned that the patient has been weaned off ECMO and ventilator and is expected to be transferred to an ordinary ward tomorrow.<br><br>C C: This Regulatory Authority case concerns a 21-year-old, female patient with no relevant medical history, who experienced the unexpected serious (Life threatening) AESI event of Myocarditis. The event occurred approximately 25 days after the third dose of mRNA-1273 (Moderna covid-19 vaccine). Patient experienced diarrhea accompany by fever post vaccination with third dose of mRNA-1273; progressive dyspnea and orthopnea were also noted. Laboratory data revealed elevated Troponin-I and BNP; Echo showed rapidly decreased ejection fraction and hypotension. The patient was admitted into the hospital, treated with ECMO and ventilator. There's a discrepancy as hospitalization wasn't reported as a seriousness criteria but mentioned in the RA SD. Of note, patient had previous dose with AstraZeneca covid-19 vaccine. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. | 21-year-old female patient experienced dyspnoea and orthopnoea beginning 24 days after receiving a 3rd dose of Spikevax. Investigations showed elevation of troponin-I and BNP and echocardiogram showed decreased ejection fraction and hypotension. There is no mention of medical history or concomitant medications, or the lack thereof. The patient required critical care admission with ECMO and mechanical ventilation. The causality assessment is conditional based on the information in the report indicating that other underlying etiologies were under investigation. | [redacted] |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 10-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 10-Feb-2022, the patient experienced | Lack of information in the case, particularly clinical signs and symptoms and diagnostic exam results. There is no mention of medical history or concomitant medications, or the lack thereof. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had resolved.<br><br>On 21-Feb-2022, the patient's mother informed that the patient currently had no discomfort reaction in physical condition.<br><br>Concomitant Medication use information was not provided by reporter.<br><br>Treatment information was not provided by reporter.<br><br>Company comment: This Regulatory Authority case concerns a 21-year-old, female patient with no relevant medical history, who experienced the expected serious (Hospitalization) event of Myocarditis. The event occurred approximately 1 day after the third dose of mRNA-1273 (Moderna covid-19 vaccine). The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis) and TACHYCARDIA (heart palpitations, heart palpitations) in a 40-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214022) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 04-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion medically significant) and TACHYCARDIA (heart palpitations, heart palpitations) (seriousness criterion medically significant). On 21-Jan-2022, MYOCARDITIS (myocarditis) and TACHYCARDIA (heart palpitations, heart palpitations) had resolved.<br><br>No concomitant medications were provided by the reporter.<br>No treatment information was provided by the reporter.<br><br>No known allergies. Information on risk factors or previous illnesses was reported as none. 10 days after vaccination feeling of pressure in the thorax area left. Reinforced by physical stress and strain. palpitations, tachycardia. Radiation to the left arm and neck area on the left.<br><br>Company Comment: This is a Regulatory Authority case concerning a 39-year-old male patient, with no medical history reported in this case, who experienced the serious expected AESI of Myocarditis and the unexpected serious adverse event of Tachycardia (serious criteria Medically Significant), approximately 12 days after the administration of the 3rd dose of the mRNA-1273 vaccine. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event´s seriousness assessed as reported. | Lack of information in the case, particularly diagnostic exam results. There is no mention of medical history or concomitant medications, or the lack thereof. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of the first episode of FATIGUE (fatigue exhaustion.), DYSPNOEA (Then the heart racing came. Heart pressure. added shortness of breath), MYOCARDITIS (Probably heart muscle inflammation), TACHYCARDIA (Then the heart racing came. Heart pressure. added shortness of breath), the second episode of FATIGUE (fatigue exhaustion.) and CHEST DISCOMFORT (Then the heart racing came. Heart pressure. added shortness of breath) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000139A) for COVID-19 vaccination.<br><br>The patient was allergic to cat and hay fever.<br><br>On 12-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Jan-2022, the patient experienced the first episode of FATIGUE (fatigue exhaustion.) (seriousness criterion medically significant), DYSPNOEA (Then the heart racing came. Heart pressure. added shortness of breath) (seriousness criterion medically significant), MYOCARDITIS (Probably heart muscle inflammation) (seriousness criterion medically significant), TACHYCARDIA (Then the heart racing came. Heart pressure. added shortness of breath) (seriousness criterion medically significant), the second episode of FATIGUE (fatigue exhaustion.) (seriousness criterion medically significant) and CHEST DISCOMFORT (Then the heart racing came. Heart pressure. added shortness of breath) (seriousness criterion medically significant). At the time of the report, DYSPNOEA (Then the heart racing came. Heart pressure. added shortness of breath), MYOCARDITIS (Probably heart muscle inflammation), TACHYCARDIA (Then the heart racing came. Heart pressure. added shortness of breath), the last episode of FATIGUE (fatigue exhaustion.) and CHEST DISCOMFORT (Then the heart racing came. Heart pressure. added shortness of breath) had not resolved.<br><br>No relevant concomitant medication information provided.<br><br>There was no information on risk factors or previous illnesses. Patient experienced tiredness or exhaustion, then came the racing heart, heart pressure and added shortness of breath.<br><br>No treatment information provided.<br><br>Company Comment: This regulatory case concerns a 34-year-old male patient, with no relevant medical history reported, who experienced the unexpected, serious medically significant events of Dyspnoea, Tachycardia, Chest discomfort as well as the expected, serious medically significant events of Fatigue (two events of fatigue exhaustion.) and Myocarditis (AESI) 5 days after the mRNA-1273 vaccine. No further information was reported regarding the clinical course or treatment details. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority's report. | Lack of information in the case, particularly diagnostic exam results. There is no mention of concomitant medications, or the lack thereof. | [redacted] |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 03-Mar-2022. The most recent information was received on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. | Lack of information in the case, particularly supporting abnormal diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Diagnosed heart muscle inflammation) and PALPITATIONS (Diagnosed heart muscle inflammation) in a 35-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216044) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 15-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced MYOCARDITIS (Diagnosed heart muscle inflammation) (seriousness criterion hospitalization) and PALPITATIONS (Diagnosed heart muscle inflammation) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Diagnosed heart muscle inflammation) and PALPITATIONS (Diagnosed heart muscle inflammation) had not resolved.<br><br>No Concomitant medications were reported.<br>The patient had no previous illness. It was reported that on the evening of vaccination (15-Dec-2021), patient had heart stinging, strong heart rate during exertion. Diffuse heart stings/chest pressure for weeks on 10-Jan-2022 after exertion, heart rate, high, fluctuating pulse and severe heart pain. Patient had doctor visit on 11-Jan-2022, ECG was inconspicuous, blood count was inconspicuous, blood pressure was inconspicuous. Patient again Visited the doctor on 13-Jan-2022 and was referred to the cardiologist, there ultrasound (unobtrusive), ECG (unobtrusive), blood test (unobtrusive) and exercise ECG cardiac arrhythmias, tachycardia at rest after exercise ECG. On 14-Jan-2022, patient had MRI and diagnosing reported as heart muscle inflammation.<br>No treatment information was provided.<br><br>Company comment:<br>This regulatory authority case concerns a 35-year-old, female patient with no medical history reported, who experienced the serious (Hospitalisation) expected AESI event of Myocarditis with serious (Hospitalisation) unexpected event of Palpitations, approximately 25 days after receiving third dose of mRNA 1273 Vaccine. Patient reported on the evening of vaccination (15-Dec-2021), patient had heart stinging and strong heart rate during exertion. On 10-Jan-2022 after exertion, patient had diffuse heart stings/chest pressure for weeks, high heart rate, fluctuating pulse and severe heart pain. Patient's investigations showed cardiac arrhythmias, tachycardia at rest after exercise ECG. He was admitted and based on MRI he was diagnosed of heart muscle inflammation. At the time of reporting, events had not resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting as hospitalization and retained for consistency with the RA report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Mar-2022: Follow up information received and included Clinical course of events, patient lab data results and diagnosis details. | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYALGIA (Muscle pain) and MYOCARDITIS (Myocarditis) in a 31-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A_1110124-CDC) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 08-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 27-Jan-2022, the patient experienced MYALGIA (Muscle pain) and MYOCARDITIS (Myocarditis). At the time of the report, MYALGIA (Muscle pain) and MYOCARDITIS (Myocarditis) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br>Treatment drug information was not provided.<br><br>Patient has experienced Chest pain, palpitations, mild asthma.<br>On 02/22/2022, Due to improved symptoms, the patient was not necessary to return to the hospital for follow-up and to take medication.<br><br>Company Comment: This regulatory case concerns a 31-year-old, female patient with no medical history reported, who experienced the unexpected, non-serious, AESI of Myocarditis 19 days after the third dose of mRNA-1273. No relevant lab data or details regarding clinical course and treatment received were reported. At the time of report, outcome of the event was Resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. There is no mention of medical history or concomitant medications, or the lack thereof. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 04-Mar-2022 and was forwarded to Moderna on 04-Mar-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (chest pain) and MYOCARDITIS (myocarditis, without focal changes) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 immunisation: SPIKEVAX on 15-Jul-2021 and SPIKEVAX on 16-Aug-2021.<br><br>On 14-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Jan-2022, the patient experienced CHEST PAIN (chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (myocarditis, without focal changes) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (chest pain) outcome was unknown and MYOCARDITIS (myocarditis, without focal changes) had not resolved. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Company comment: This is a regulatory case concerning a 31-year-old male patient with no known medical conditions, who experienced the serious (hospitalization) expected event myocarditis, approximately 14 days after the third dose of mRNA-1273. Myocarditis without focal changes and chest pain were reported. Clinical course, diagnostic tests and treatment details were not provided. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>The patient did not have any known medical conditions.<br>No concomitant information was provided.<br>No treatment information was given. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 08-Mar-2022 and was forwarded to Moderna on 08-Mar-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Fever), MYALGIA (Muscle pain), INJECTION SITE REACTION (Injection site response), COVID-19 IMMUNISATION (2x Comirnaty and 1x Spikevax), MALAISE (Feeling unwell), FATIGUE (fatigue), ARTHRALGIA (Joint pain) and PERICARDITIS (Pericarditis) in a 31-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216038) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: COMIRNATY on 28-Jun-2021 and COMIRNATY on 23-Jul-2021.<br><br>On 07-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Jan-2022, the patient experienced PYREXIA (Fever) (seriousness criterion medically significant), MYALGIA (Muscle pain) (seriousness criterion medically significant), INJECTION SITE REACTION (Injection site response) (seriousness criterion medically significant), COVID-19 IMMUNISATION (2x Comirnaty and 1x Spikevax) (seriousness criterion medically significant), MALAISE (Feeling unwell) (seriousness criterion medically significant), FATIGUE (fatigue) (seriousness criterion medically significant), ARTHRALGIA (Joint pain) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PYREXIA (Fever), MYALGIA (Muscle pain), INJECTION SITE REACTION (Injection site response), COVID-19 IMMUNISATION (2x Comirnaty and 1x Spikevax), MALAISE (Feeling unwell), FATIGUE (fatigue), ARTHRALGIA (Joint pain) and PERICARDITIS (Pericarditis) was resolving.<br><br>No concomitant medications were reported.<br><br>Treatment medication was reported as received, but no additional details provided. On 13-Jan-2022, pericarditis was diagnosed with the GP through an EKG and blood test. The complaints started the night of vaccination (07-Jan-2022) and worsen during the following days. Pericarditis has not been fully cured yet.<br><br>Company comment: | Non-specific report stating that diagnosis was through EKG and blood test. Patient received Comirnaty for first 2 doses of COVID-19 vaccination and Spikevax as 3rd dose. There is no mention of medical history or concomitant medications, or the lack thereof. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | This Regulatory Authority case concerns a 31-year-old, female patient with no reported medical history, who experienced the expected, serious (Medically significant) AESI of pericarditis and the unexpected, serious (Medically significant) events of pyrexia, myalgia, injection site reaction, COVID-19 immunization, malaise, and fatigue, arthralgia. The events occurred on the same day after receiving the third dose of mRNA-1273 vaccine. Pericarditis was diagnosed with the GP through an EKG and blood test. Treatment medications were not provided. The benefit-risk relationship of the mRNA-1273 is not affected by this report. At the time of the report, the events were resolving. Vaccination with Comirnaty suggest interchange of vaccine products. Event seriousness assessed as per Regulatory Authority reporting. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 39-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216041) for COVID-19 vaccination.<br><br>Patient concomitant elements was asymptomatic.<br><br>On 29-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milligram. On 31-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and disability). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>No concomitant medication was reported.<br>Treatment medication was not provided by the reporter.<br><br>Company Comment: This regulatory authority case concerns a 39 year old female with no relevant medical history reported, who experienced the Serious ( Hospitalization , Disability ) , expected event of myocarditis which occurred 2 days post vaccination with the 3rd dose of mRNA-1273 vaccine . The information regarding the primary series Covid 19 vaccine of this patient was not reported. The details of the hospitalization like treatment information, results of laboratories /diagnostic procedure results were not included in this report. At the time of this report event outcome was unknown. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. Events seriousness assessed per regulatory report. | Lack of information in the case, particularly clinical signs and symptoms and diagnostic exam results. The medical history is unclear and there is no mention concomitant medications, or the lack thereof. | [redacted] |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 02-Mar-2022 and was forwarded to Moderna on 08-Mar-2022.<br><br>This spontaneous case was reported by a consumer and describes the occurrence of PYREXIA (Pyrexia of 40.3 degrees Celsius (After the third vaccination)), CHILLS (Chills (After the third vaccination)), DYSPNOEA (Respiratory discomfort (After the third vaccination)) and MYOCARDITIS (Suspected myocarditis (After the third vaccination)) in a 21-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination.<br><br>Previously administered products included: Comirnaty and Comirnaty. | Lack of information in the case, particularly diagnostic exam results. There is no mention of medical history or concomitant medications, or the lack thereof. Patient's primary series of COVID-19 vaccines was with Comirnaty for first 2 doses and Spikevax was received as 3rd dose. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 01-Mar-2022, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 01-Mar-2022, the patient experienced PYREXIA (Pyrexia of 40.3 degrees Celsius (After the third vaccination)) (seriousness criterion hospitalization), CHILLS (Chills (After the third vaccination)) (seriousness criterion hospitalization), DYSPNOEA (Respiratory discomfort (After the third vaccination)) (seriousness criterion hospitalization) and MYOCARDITIS (Suspected myocarditis (After the third vaccination)) (seriousness criteria hospitalization and medically significant). At the time of the report, PYREXIA (Pyrexia of 40.3 degrees Celsius (After the third vaccination)), CHILLS (Chills (After the third vaccination)), DYSPNOEA (Respiratory discomfort (After the third vaccination)) and MYOCARDITIS (Suspected myocarditis (After the third vaccination)) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 01-Mar-2022, Body temperature: 40.3 40.3 degree Celsius.<br><br>Company comment: This regulatory authority case concerns a 21-year-old male with a medical history of 2 doses of Comirnaty who experienced the serious (hospitalization), unexpected events of pyrexia, chills and dysponea and the serious (hospitalization and medically significant), expected event myocarditis the day of the booster dose of mRNA-1273. Testing revealed an elevated temperature and treatment mentioned as medication without specifics. Outcome is ongoing. The history of previous doses of Comirnaty is a confounder as it could have sensitized the patient to other vaccines. The narrative states that the patient "was not hospitalized because of mild symptoms" so only the event of myocarditis may be serious as the criterion of hospitalization may be invalid. The risk-benefit relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 17-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Polyarthritis and Autoinflammatory disease.<br><br>On 09-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-Feb-2022, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 15-Feb-2022, C-reactive protein: 63 mg/L.<br>On 15-Feb-2022, Echocardiogram: Normal echocardiogram. Study without abnormalities.<br>On 15-Feb-2022, Electrocardiogram: Sinus rhythm at 92 bpm, with PR segment depression of 1-2 mm on the anterolateral surface with narrow QRS at 30°. No ST changes. | 17-year old female patient with reported myocarditis 4 days after receiving a 3rd dose of Spikevax. Clinical signs and symptoms leading to investigations were not reported. ECG did not show abnormalities consistent with myocarditis and echocardiogram results were normal. hs-Troponin T was reported as 225.7 ng/L. Medical history of polyarthritis and autoinflammatory disease are confounders. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On 15-Feb-2022, Troponin:hs-TnT 225.7 ng/L.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant products were reported.<br><br>No treatment information was reported.<br><br>This is a regulatory case concerning a 17-year-old female patient with reported medical history of Autoinflammatory Disease, who experienced the expected serious adverse event of special interest, Myocarditis. The event led to the hospitalization of the patient as reported by the regulatory authority and occurred 5 days after receiving the third dose of mRNA-1273 Vaccine. As reported, C-reactive protein and Troponin levels were increased while ECG and Echocardiography showed normal results, no other clinical or treatment details were given. It was reported that the outcome of the event was resolving. The medical history of Autoinflammatory Disease remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 07-Mar-2022. The most recent information was received on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PAIN IN EXTREMITY (Pain in arm), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), AMENORRHOEA (Amenorrhea), AMNESIA (Loss of memory), PERICARDITIS (pericarditis), PARAESTHESIA (Paraesthesia) and CONFUSIONAL STATE (Confusion) in a 40-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 01ES07V1F7B5DE193A1D3ACB158D1) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 on 06-Mar-2020 and Mastectomy bilateral.<br>Concurrent medical conditions included Barrett's esophagus, Ferropenic anemia, Autoimmune hypothyroidism and BRCA2 gene mutation assay.<br>Concomitant products included LEVOTHYROXINE SODIUM (EUTIROX) and LEVOTHYROXINE SODIUM (EUTIROX) for Autoimmune hypothyroidism, TOZINAMERAN (COMIRNATY) from 01-Jul-2021 to 22-Jul-2021 for COVID-19 vaccination, FERROUS SULFATE (FERO GRADUMET) for Ferropenic anemia, CYANOCOBALAMIN, FOLIC ACID, POTASSIUM IODIDE ([redacted] from 2020 to an unknown date for Folic acid supplementation, CHORIOGONADOTROPIN ALFA (OVITRELLE) from 12-Jan-2022 to 12-Jan-2022 for Management of reproduction.<br><br>On 19-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Jan-2022, the patient experienced PAIN IN EXTREMITY (Pain in arm) (seriousness criterion medically significant), COVID-19 IMMUNISATION (Revaccination | Lack of information in the case, particularly clinical signs and symptoms and diagnostic exam results. Previous vaccination with a different COVID-19 vaccine (not specified) before the 3rd dose of Spikevax associated with this report was noted. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | with different COVID-19 vaccine) (seriousness criterion medically significant), AMENORRHOEA (Amenorrhea) (seriousness criterion medically significant), AMNESIA (Loss of memory) (seriousness criterion medically significant), PERICARDITIS (pericarditis) (seriousness criterion medically significant), PARAESTHESIA (Paraesthesia) (seriousness criterion medically significant) and CONFUSIONAL STATE (Confusion) (seriousness criterion medically significant). At the time of the report, PAIN IN EXTREMITY (Pain in arm), AMENORRHOEA (Amenorrhea), AMNESIA (Loss of memory), PARAESTHESIA (Paraesthesia) and CONFUSIONAL STATE (Confusion) had not resolved and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) and PERICARDITIS (pericarditis) outcome was unknown.<br><br>It was reported that COVID-19 had passed.<br><br>Treatment information was not provided.<br><br>Company comment:<br>This regulatory authority case concerns a 40-year-old female patient with medical history of Autoimmune hypothyroidism and Ferropenic anemia, who experienced serious (medically significant) unexpected events of Pain in extremity, Amenorrhoea, Amnesia, Paraesthesia and Confusional state, as well as serious (medically significant) expected event of Pericarditis. The events occurred approximately one week after the patient had received the mRNA-1273 vaccine (as third vaccination). Information regarding clinical course of the events was not provided. At the time of this report, the outcome of the event of Pericarditis was unknown, while the remaining reported events were still ongoing. In addition, the event of COVID-19 immunisation (Revaccination with different COVID-19 vaccine) was coded as serious event according to the Regulatory Authority and was retained as such, having in mind that the patient previously had received two doses of Comirnaty vaccine. The company causality for this event is not applicable. The underlying medical history of Autoimmune hypothyroidism remains a confounder for Amenorrhoea, Amnesia and Confusional state, while underlying Ferropenic anemia remains a confounder for Amnesia and Confusional state. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Mar-2022: Ongoing status updated for Autoimmune hypothyroidism. Dose deleted for Eutirox and [redacted] New dosing regimen added for Comirnaty. Except Pericarditis and Revaccination with different COVID-19 vaccine rest all events were added.Suspect dechallenge results updated to not applicable. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Dilatin cardiomyopathy) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000109A) for COVID-19 vaccination. | Lack of information in the case, particularly clinical signs and symptoms and diagnostic exam results. There is no mention of medical history or concomitant medications, or the lack thereof. Patient previously received one dose of Vaxzevria | [redacted] |

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| | Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) from 11-May-2021 to an unknown date and TOZINAMERAN (COMIRNATY) from 21-Jul-2021 to an unknown date for Prophylactic vaccination.<br><br>On 15-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 08-Jan-2022, the patient experienced MYOCARDITIS (Dilatin cardiomyopathy) (seriousness criteria hospitalization and life threatening). At the time of the report, MYOCARDITIS (Dilatin cardiomyopathy) had not resolved.<br><br>The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.<br><br>Treatment details was not reported by the reporter.<br><br>Company comment:<br>This regulatory authority case concerns a 32-year-old male patient, with no medical history reported, previously vaccinated with three doses of COVID-19 vaccine from different companies, who experienced the serious (life threatening and hospitalization) unexpected AESI of myocarditis, which occurred 25 days after a dose of mRNA-1273 vaccine (dose number 3 in the COVID-19 vaccine schedule). Event outcome was not resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | and one dose of Comirnaty, then received a 3rd dose of Spikevax 24 days prior to event onset. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 36-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018J21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) had resolved.<br><br>No concomitant medications were provided by the reporter.<br><br>No treatment information was provided by the reporter.<br><br>Company comment: This regulatory authority case concerns a 36-year-old male patient with no reported medical history, who experienced the expected serious (hospitalization and important medical event) AESI event of Acute myocarditis 5 days after third dose of mRNA-1273 vaccine. There is no information available regarding first 2 doses and treatment of the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the event retained as per Regulatory Authority reporting. | Lack of information in the case, particularly clinical signs and symptoms and diagnostic exam results. There is no mention of medical history or concomitant medications, or the lack thereof. | [redacted] |

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| [redacted] | This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 10-Mar-2022. The most recent information was received on 04-Apr-2022 and was forwarded to Moderna on 12-Apr-2022.<br>This case, initially reported to the [redacted] by a physician, was received via the [redacted] (Ref, [redacted]. On 04-Apr-2022, follow-up information was received from a physician. On 24-Jul-2021, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 21-Aug-2021, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 07-Mar-2022, the patient received the 3rd vaccination with this vaccine. On 08-Mar-2022, before dawn, pyrexia of 37.5 degrees Celsius or higher developed. Around 22:00, pericarditis and myocarditis developed, and the patient experienced pain in the left precordial region. The patient was followed up and was not recovering. On 09-Mar-2022, at 07:00, an ambulance was called, and the patient went to the emergency department of the reporting hospital. There was no physical examination finding suggestive of pericardial effusion. An electrocardiogram showed a decreased PR in aVR and ST elevation in other leads. Blood tests showed positive troponin T of 180 ng/mL and elevated CRP of 3.91 mg/dL. BNP was 5.8 pg/mL or lower, and there was no increase in D-dimer. Coronary CT showed no coronary artery lesions or significant stenosis. Echocardiography showed a left ventricular ejection fraction of 65.7% and no decrease in wall motion, but focal wall motion abnormalities. No pericardial effusion, no pericardial inflammatory findings. Chest CT showed no abnormal pericardial effusion or pericardial inflammatory findings. Chest X-ray showed no findings of cardiomegaly. At 15:00, the patient was considered to have pericarditis and was urgently admitted to the hospital. After admission, the patient's blood tests showed increases in CPK to 280 U/L and CK-MB to 28.0 U/L. Acetaminophen and colchicine were administered, and chest pain was resolving. On 10-Mar-2022, electrocardiogram showed decreased PR. On 11-Mar-2022, cardiac MRI (gadolinium contrast) showed findings of pericardial inflammation and late gadolinium enhancement image on T1-weighted images. Pericarditis and myocarditis could not be ruled out, and the findings were consistent. On 14-Mar-2022, electrocardiogram showed decreased PR. On 16-Mar-2022, chest pain was no longer noted, and the decreased PR on the electrocardiogram returned to baseline. The symptoms were resolving, and the patient was discharged from the hospital. The outcome of pericarditis and myocarditis was reported as resolving. No follow-up investigation will be made. Reporter comments continuation: Electrocardiogram abnormalities recovered normally with resolving symptoms, and the examination for congenital heart disorder was completed by the patient's family physician, so the occurrence of adverse events was not related to any pathological factors such as underlying diseases or complications. Although intellectual development disorder and pulmonary valve stenosis were noted, two echocardiograms were performed at the reporting hospital, and pulmonary valve stenosis was not significant. The patient has no coronary risk, and there appears to be no history of cardiac disease on the maternal side, although details are unknown on the paternal side regarding family history of coronary artery involvement. This time, the patient had no common cold-like symptoms prior to the onset of adverse events and was tested for influenza, adenovirus, and other viruses, all of which were negative. The patient was 19 years old, and the kind of the third dose of the vaccine was changed from that of the precious one, so the risk of perimyocarditis as an adverse reaction was judged to be high. The risk of the | 19-year old male experienced myocarditis 1 day after receiving a 3rd dose of Spikevax (first two doses were Comirnaty) which presented with the initial symptom of left precordial chest pain, leading to hospital evaluation and admission 2 days after vaccination. EKG revealed ST elevations, troponin T was positive at 180 ng/mL, CK-MB to 28.0 U/L, and CRP was elevated at 3.91 mg/dL. Echocardiogram showed focal wall motion abnormalities, preserved LVEF of 65.7%, and no pericardial effusion. Cardiac MRI showed findings of pericardial inflammation and late gadolinium enhancement on T1-weighted images. An examination for congenital heart disorders was completed and ruled out underlying diseases or complications as alternate etiologies. The patient had no coronary risk and there was no history of cardiac disease on the maternal side, although details are unknown on the paternal side. The patient had no common cold-like symptoms prior to the onset of adverse events and was tested for influenza, adenovirus, and other viruses, all of which were negative. Within one week, chest pain had resolved and ECG returned to normal and the patient was discharged from the hospital. Treatment included acetaminophen and colchicine. | [redacted] |

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| | third dose of vaccine, where the different kind of vaccine from the previous one was administered, was not clear, but the possibility of adverse reactions was judged to be high based on the adverse reactions to the first two doses of vaccine. Follow-up received on 04-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments<br>Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | | |
| [redacted] | This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 10-Mar-2022. The most recent information was received on 04-Apr-2022 and was forwarded to Moderna on 04-Apr-2022.<br><br>This case was reported by a physician via a medical representative. On 11-Mar-2022, follow-up information, reported to the [redacted]) by a physician, was received via the [redacted] (Ref, [redacted] On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, the patient received the 2nd dose of this vaccine. On 06-Mar-2022, the patient received the 3rd dose of this vaccine. Pyrexia of 39 degrees Celsius and respiratory discomfort developed during the night-time hours. On 07-Mar-2022, myocarditis developed. Pyrexia of 39 degrees Celsius persisted. Prickling pain in the chest was observed. The patient took antipyretic analgesics orally. On 08-Mar-2022, in the afternoon, the patient visited a previous hospital because chest pain persisted. Blood test was performed. Electrocardiogram showed ST elevation. The patient was prescribed analgesics and retuned home. On 09-Mar-2022, the blood test showed increases in CK of 525 and CRP of 8, and the patient visited another hospital with a referral. Although the degree of wall motion decrease was mild, CK increase was noted. The patient was hospitalized for follow-up. On admission, pain and pyrexia disappeared. The symptoms were resolving. On 10-Mar-2022, CK tended to improve. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. The duplicate was identified on 22-Mar-2022 on review of data; all information from [redacted] has been merged into [redacted] No new information has been received on this case. Case [redacted] has been identified as a duplicate case of case [redacted] Case [redacted] will stand as the case of record. All information from case [redacted] has been incorporated into case [redacted] Case [redacted] will be deleted from the safety database. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship. | 22-year old male experienced chest pain and respiratory discomfort, later diagnosed as myocarditis, one day after receiving the 3rd dose of Spikevax. Two days after vaccination ECG showed ST elevation and three days after vaccination CK was 525 and CRP was 8. Mild wall motion decrease is mentioned, however there is no mention of cardiac imaging studies. There is no report of troponin or CK-MB testing. The event is assessed as possibly related to Spikevax due to the onset of symptoms one day after the 3rd dose, however, the report is missing important information concerning the patient's medical history/concurrent illnesses or concomitant medication use, if any. The report does not indicate whether there were additional investigations into other causes for the events. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number [redacted] on 14-Mar-2022 and was forwarded to Moderna on 14-Mar-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 056G21A, 300042460 and 300042722) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Pleuropericarditis.<br><br>On 29-Jan-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. | Lack of information in the case, particularly clinical signs and symptoms and diagnostic exam results. The medical history is unclear and there is no mention concomitant medications, or the lack thereof. | [redacted] |

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| | On 01-Mar-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter.<br>On 14-Jan-2022, received third dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .25 milliliter. On 25-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis) was resolving.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 01-Mar-2021.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication reported.<br><br>No treatment details reported.<br><br>Company comment. This regulatory case concerns a 31 – year – old, male patient with relevant medical history of pleuropericarditis, who experienced the unexpected, serious (due to hospitalization) AESI of pericarditis, 11 days after the administration of the third dose of mRNA-1273 vaccine. No further details such as hospitalization dates, myocardial biomarkers or imaging study diagnosis tests were provided for medical review. Patient´s medical history remains as confounder. Regulatory authority reported the rechallenge as positive; however, it is unknown the outcome of patient´s medical history of pleuropericarditis. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 26-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Mar-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. Not Provided<br><br>No concomitant medication details were provided. No treatment medication details were provided.<br><br>Patient received Moderna vaccine at [redacted] on 26-Feb-2022 and got a slight fever at night. 28-Feb-2022 In the morning, mild chest discomfort developed. 01-Mar-2022, ongoing chest pain and discomfort. He went to the hospital and reported a diagnosis of acute myocarditis. He was admitted to the hospital and was discharged the following day. 04-Mar-2022 the discomfort had been improved a lot. However, if he did strenuous exercise, he would still feel chest tightness and discomfort. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Company comment:<br>This regulatory authority case concerning 22-year-old, male patient with no reported medical history, who experienced the expected serious AESI event of Myocarditis (seriousness criteria hospitalization) which occurred 3 days after the third dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. It was reported that Patient developed a slight fever at night after receiving the vaccine and eventually developed pain in the arm at the injection site and mild heart discomfort and heart pain. He was hospitalized and discharged in one day and advised for rest and follow up. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority's report. | | |
| [redacted] | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 14-Mar-2022 and was forwarded to Moderna on 16-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache), PAIN IN EXTREMITY (Limb pain) and MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>The patient did not have a history of chronic disease.<br><br>On 04-Mar-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Mar-2022, the patient experienced HEADACHE (Headache) (seriousness criterion hospitalization), PAIN IN EXTREMITY (Limb pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, HEADACHE (Headache), PAIN IN EXTREMITY (Limb pain) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>On March 4, 2022 patient received the 3rd dose of the Moderna vaccine. On March 7, 2022 patient complained of chest tightness, chest pain, nausea, and headache and sought medical attention at the emergency department. Patient had done tests CK:652 U/L, CK-MB:68.4 ng/mL, Troponin I:8276.4 pg/mL. The patient was admitted to the hospital due to suspected myocarditis.<br><br>Company Comment: This is a Regulatory Authority case concerning a 35-year-old male patient, with no medical history reported, who experienced the expected, serious (hospitalization), and AESI of Myocarditis, and the unexpected and serious (hospitalization) events of Headache and Pain in extremity. The events occurred 3 days after the third dose of mRNA-1273 vaccine. No information about previous doses was disclosed. Patient experienced chest tightness, chest pain, headache, limb pain, and nausea. Cardiac enzymes were evaluated, with high results. With suspected myocarditis, patient is under observation at the intensive care unit. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | 35-year old male patient with no history of chronic disease experienced chest tightness and pain 3 days after receiving the 3rd dose of Spikevax and was subsequently hospitalized with suspected myocarditis. Laboratory results showed CK-MB of 68.4 ng/mL and Troponin I of 8276.4 pg/mL. There was no report of cardiac imaging or ECG. No additional information was provided. The causality assessment is considered possible for this case, as there is a close temporal relationship with event onset 3 days following the 3rd dose of Spikevax. However, there is a lack of information concerning rule out of other potential etiologies. | [redacted] |

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| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>Concurrent medical conditions included Smoker (one packet per day for about 10 years).<br><br>On 21-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>Concomitant medications were not reported by the reporter.<br>Treatment information was not provided.<br><br>It was reported that on 27/09/2021 Patient received the first dose of BNT and on 11/05/2021 received the second dose of BNT. On 21/02/2022 received the third dose of Moderna. It was reported that on 23/02/2022 due to paroxysmal chest pain for three days and fever, he went to the hospital for treatment, and was admitted to the hospital because of abnormal myocardial enzymes. On 24/02/2022 patient entered the intensive care unit of Cardiology Department for observation. On 26/02/2022 The condition was stable and he was transferred to general ward. On 01/03/2022 followed up with echocardiography and Troponin-T, the condition was stable without special discomfort, discharged from the hospital after being assessed by doctors and followed up by outpatient service.<br><br>Company comment:This is a regulatory authority case concerning a 22-year-old, male patient, with concurrent medical conditions of Smoker (one packet per day for about 10 years), who experienced the expected serious (hospitalization) event of myocarditis. The event occurred on the same day after the third dose of mRNA-1273 COVID 19 Vaccine. Treatment information was not provided. The events were reported as resolving. The concurrent medical conditions of Smoker (one packet per day for about 10 years)remains a confounder. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. The patient's primary two-dose COVID-19 vaccine series was with Comirnaty prior to receiving a 3rd vaccine with Spikevax. The patient's concurrent history of smoking with a 10-year history of smoking 1 pack per day is a confounder in this case. | [redacted] |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 21-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 23-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>No concomitant medication was reported. | 26-year old male patient experienced chest pain 2 days after receiving the 3rd dose of Spikevax and was subsequently hospitalized with suspected myocarditis. Laboratory results showed elevated Troponin I max of 5.13. Coronary angiogram was normal with LVEF of 63%. Cardiac enzymes declined gradually and EKG dislosed no ST-T deviation. Cardiac echo showed normal left ventricular size with mild concentric left ventricular hypertrophy; normal left ventricular systolic function; LVEF: 61%. The patient was discharged from the hospital with planned outpatient follow-up with Cardiology. The | [redacted] |

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| | On 21-Feb-2022, The patient received the third dose of COVID-19 Moderna vaccine and felt sore all over on the night. On 23-Feb-2022, The patient began to have cold sweat and chest pain at about 21:00 on the night. There were no fever with chills, cough with sputum, orthopnea, paroxysmal nocturnal dyspnea, nausea/vomiting, diarrhea, skin rashes or dysuria. Due to persisting symptoms, he presented to the ED and on arrival his vital signs we BP: 117/62mmHg, PR: 81/min, RR: 20/min, and BT: 35.6 degree, Laboratory exam showed serial elevated cardiac enzyme,CK:307/Trop-I:5.13, CK:439/Trop-I:4.19, CK:416/Trop-I:4.72, Physical examination disclosed no obvious jugular vein engorgement, no clubbing finger, no obvious basal rales, regular heart beat without obvious murmur, no lower limbs pitting edema. Due to above symptoms, the patient was admitted for further evaluation and treatment due to suspected Myocarditis. On 27-Feb-2022, coronary angiography was performed and showed normal CAG; Left Ventriculogram: Normal LV systolic function, LVEF 63%. Cardiac enzymes declined gradually and EKG dislosed no ST-T deviation. Cardiac echo showed Normal left ventricular size with mild concentric left ventricular hypertrophy; Normal left ventricular systolic function; LVEF: 61%. Under stable condition, the patient was discharged and Cardiology Clinic outpatient department follow-up. No treatment information was provided.<br><br>Company comment: This case concerns a 26-year-old male patient, with no reported medical history, who experienced the serious (hospitalization), expected AESI of Myocarditis. The patient received third dose of mRNA 1273 COVID-19 vaccine, on the same day, patient had soreness all over, then headache and chest tightness the day after. Two days after the vaccine, patient began to have cold sweat and chest pain. Due to persisting symptoms, patient consulted in the Emergency Department (ED). On ED arrival, his vital signs were normal, laboratory exam showed elevated cardiac enzyme, CK/Trop-I, and primary PCI showed normal coronary angiography, Normal LV (left ventricular) systolic function, LVEF (left ventricular ejection fraction) 63%. The patient was admitted for further evaluation and treatment of suspected Myocarditis. Coronary angiography was normal. Repeat laboratory data showed cardiac enzymes declined gradually and EKG (electrocardiogram) disclosed no ST-T deviation. Cardiac echocardiogram showed Normal left ventricular size with mild concentric left ventricular hypertrophy. Patient was discharged on unknown date under stable conditions. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. | causality assessment is considered possible for this case, as there is a close temporal relationship with event onset 2 days following the 2nd dose of Spikevax. However, there is a lack of information concerning rule out of other potential etiologies. | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>Patient had first two doses of Medigen vaccine. The patient had no past medical history.<br><br>On 09-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization prolonged). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>On 28-Feb-2022, patient visited the Emergency Room for fever and abdominal pain (blood pressure 114/58 mmHg; pulse 109 beats/min; temperature 38.4 C; pain index 5, oxygen | 26-year old male patient experienced abdominal pain and fever 50 days after receiving a 3rd dose of COVID-19 vaccine with Spikevax (first 2 doses were with Medigen vaccine). After visiting the emergency room, he was sent home with prescriptions for ciprofloxacin, mebeverine, acetaminophen, and diclofenac, but returned the next day due to fever and breathlessness and was subsequently hospitalized. Laboratory results showed elevated hs-Troponin I of 3033.3 pg/mL. He was treated for suspected acute coronary artery disease. Echocardiogram estimated LVEF of (M-mode) 50.60% and (m. Simpsons) 40.73%, with | [redacted] |

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| | concentration 100%) and was sent home with prescriptions for ciprofloxacin 250mg/tab 2 Q12H PO x3 days, acetaminophen 500 mg/tab 1 TIDAC PO, mebeverine 100 mg/tab 1 BIDAC PO, and diclofenac 25mg/tab 1 PRNBIDAC PO. On 01-Mar-2022, patient returned to the Emergency Room with a fever and sudden breathlessness (pain index: 0, oxygen concentration: 100%). Laboratory tests showed hs-TnI: 3033.3 pg/ml, suspected acute coronary artery disease and given Acetylsalicylic Acid 1, Ticagrelor 2, Morphine 3mg IM, Heparin 4000U IV, Heparin 5000U+0.9% NaCl 100ml IV pump (14ml/hr). The patient was given a non-invasive positive pressure mask for wheezing and transferred to the ICU for observation. On March 2, Echo LVEF (M-mode) 50.60%, LVEF (m. Simpsons) 40.73%, Mild MR, Mild TR. The consulting cardiac surgeon recommended IVIG for 2 days. From March 2 to March 4, monitoring of the ECG showed a rise in the ST segment. On 04-Mar-2022 vital signs stabilized, patient was transferred to general ward. On 08-Mar-2022 patient was discharged in a stable condition.<br><br>Company comment: This regulatory case concerns a 26-year-old male patient with no medical history reported, who experienced the expected serious (medically significant according to authority report), event of Myocarditis (adverse event of special interest), 1 month 20 days after the third dose of mRNA-1273 vaccine. The patient visited the Emergency Room for fever and abdominal pain with blood pressure 114/58 mmHg; pulse 109 beats/min; temperature 38.4 C; oxygen concentration 100%. The patient was treated with diclofenac, ciprofloxacin for 3 days. The patient returned home with a fever and suddenly became breathless and visited the Emergency Room (pain index: 0, oxygen concentration: 100%). Test hsTnI: 3033.3pg/ml, suspected acute coronary artery disease and was treated with acetylsalicylic acid, Ticagrelor, Morphine, and Heparin. The patient was given a non-invasive positive pressure mask for wheezing and transferred to the ICU for observation. While the patient was in the medical intensive care unit, the consulting cardiac surgeon tested the patient for myocarditis and recommended IVIG for 2 days. Subsequent monitoring of the ECG showed a rise in the ST segment. Echo showed LVEF (M-mode) 50.60%, LVEF (m. Simpsons) 40.73%, Mild MR, Mild TR. Subsequently vital signs stabilized, patient was transferred to general ward. Subsequently the patient was discharged in a stable condition. Outcome reported as not resolved at the time of reporting. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | mild mitral regurgitation, and mild tricuspid regurgitation. ECG showed a rise in the ST segment. The consulting cardiac surgeon recommended IVIG for 2 days. On the 4th day of hospitalization, vital signs stabilized. On the 8th day of hospitalization, the patient was discharged in a stable condition. The causality assessment is considered unlikely for this case, as there was a prolonged time to onset of 50 days following Spikevax administration with concurrent fever, indicating a more likely infectious etiology. | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain and chest tightness) and CHEST DISCOMFORT (Chest pain and chest tightness) in a 22-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 25-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Mar-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization), CHEST PAIN (Chest pain and chest tightness) (seriousness criterion hospitalization) and CHEST DISCOMFORT (Chest pain and chest tightness) (seriousness criterion hospitalization). At the time of the report, | Lack of information in the case, particularly diagnostic exam results and clinical course. Additionally, there was no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain and chest tightness) and CHEST DISCOMFORT (Chest pain and chest tightness) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication information was provided.<br><br>On 26 Feb 2022, the patient experienced fever and chills. On 28 Feb 2022, the patient had chest tightness and chest pain, and went to the emergency department for treatment.<br><br>No treatment medication was provided.<br><br>Company comment:<br>This regulatory case concerns a 22-year-old female patient with no medical history reported, who experienced the expected serious adverse event of special interest of myocarditis that led to hospitalization, 4 days after receiving the third dose of mRNA-1273 vaccine in the COVID-19 vaccination series (no information disclosed on previous doses or vaccination schedule). The patient experienced fever and chills one day after vaccination, followed by the unexpected serious events of chest tightness and chest pain 3 days after vaccination, so she went to the emergency department for treatment. Diagnostic evaluations and treatment not reported. Outcome reported as resolving at the time of reporting. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events´ seriousness assessed as reported. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 13-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 25-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>The patient received the booster vaccine on 13-Feb. He visited the Emergency Department of hospital on 25-Feb-2022 and subsequently was hospitalized. The patient was discharged on 02-Mar-2022.<br><br>No concomitant product use was provided by the reporter. | Lack of information in the case, particularly clinical signs/symptoms, diagnostic exam results and clinical course. Additionally, there was no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Follow-up care on 11-Mar-2022: The patient complained of chest distress in case of excessive activity, and had a follow-up visit on 10-Mar-2022 and was prescribed with 1-month medication.<br><br>Company comment: This regulatory authority case concerns a 34-year-old male patient, with no medical history reported, who experienced the expected AESI of myocarditis. It was reported that the event of myocarditis was non serious, however it was also stated that the patient was hospitalized for 5 days after presenting to emergency department on the day of event onset. The event occurred approximately 12 days after the third dose of mRNA-1273. No information regarding any diagnostic findings or laboratory results was provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was retained as per Regulatory Authority reporting. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>Previously administered products: COVID-19 MRNA VACCINE BNT162B2 and COVID-19 MRNA VACCINE BNT162B2<br><br>On 28-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood creatine phosphokinase MB (0-5): 1.3<br>On an unknown date, Electrocardiogram: Sinus bradycardia probably due to early repolarization.<br>On an unknown date, Troponin I (<0.02): 0.085.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Patient denied any underlying disease.<br><br>After receiving a dose of Moderna (booster) on February 28, 2022, the patient developed chest pain. On March 2, 2022, the symptoms did not improve, so the patient went to the Emergency Department of Hospital. The patient was given Cataflam (diclofenac) and Panadol (paracetamol) to take orally. The patient refused to be hospitalized for further examination.The patient got much improved after NSAID usage.<br><br>This is a regulatory authority case concerning a 23-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event occurred on the same day after the third dose of mRNA-1273 COVID 19 Vaccine. Patients laboratory test | 23-year old male patient experienced chest pain the same day of receiving the 3rd dose of Spikevax (first 2 doses were Comirnaty) and presented to the hospital 2 days later with suspected myocarditis. Laboratory results showed elevated Troponin I (<0.02): 0.085. ECG showed sinus bradycardia and CK-MB was within normal range (0-5): 1.3. The patient refused hospital admission and was treated at home with diclofenac and paracetamol with much improvement in symptoms. The causality assessment is considered possible for this case, as symptoms were reported on the same day as the 3rd dose of Spikevax; however, there is a lack of information concerning rule out of other potential etiologies. | [redacted] |

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| | showed Troponin I (<0.02): 0.085; Electrocardiogram: Sinus bradycardia; and CK-MB (0-5): 1.3. Symptoms improved with NSAIDs. The event was reported as resolving. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 16-Mar-2022 and was forwarded to Moderna on 16-Mar-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY DISORDER (Breathing problem), COVID-19 IMMUNISATION (2x Comirnaty and 1x Spikevax), CARDIOVASCULAR DISORDER (Cardiovascular problem), MYOCARDITIS ((peri)Myocarditis) and TROPONIN INCREASED (troponin rise) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000058A) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 prior to receiving vaccine.<br>Previously administered products included: Comirnaty on 30-Jun-2021 and Comirnaty on 31-Jul-2021.<br>Concurrent medical conditions included Asthma.<br><br>On 03-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Feb-2022, the patient experienced COVID-19 IMMUNISATION (2x Comirnaty and 1x Spikevax) (seriousness criterion hospitalization). On 04-Feb-2022, the patient experienced RESPIRATORY DISORDER (Breathing problem) (seriousness criterion hospitalization), CARDIOVASCULAR DISORDER (Cardiovascular problem) (seriousness criterion hospitalization), MYOCARDITIS ((peri)Myocarditis) (seriousness criterion hospitalization) and TROPONIN INCREASED (troponin rise) (seriousness criterion hospitalization). At the time of the report, RESPIRATORY DISORDER (Breathing problem), COVID-19 IMMUNISATION (2x Comirnaty and 1x Spikevax), CARDIOVASCULAR DISORDER (Cardiovascular problem), MYOCARDITIS ((peri)Myocarditis) and TROPONIN INCREASED (troponin rise) was resolving.<br><br>No concomitant and treatment information was provided.<br><br>Company comment. This regulatory case concerns an 18-year old, male patient with medical history of asthma and COVID-19, and past drug history of administration of two doses of Comirnaty COVID-19 vaccine, who experienced the expected, serious AESI of myocarditis, and the unexpected, serious events of respiratory disorder and cardiovascular disorder. The events, which were serious due to hospitalization, occurred one day after the administration of the dose of mRNA-1273 vaccine, considered as third dose of his COVID-19 immunization schedules. The report stated that the patient experienced respiratory and cardiovascular problems and perimyocarditis. Troponin was reported as increased. The reporter mentioned an electrocardiogram and magnetic resonance imaging of heart, although the results were not provided. Patient´s medical history of asthma could be a confounding factor for respiratory disorder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly clinical signs/symptoms, diagnostic exam results and clinical course. The patient had a prior history of COVID-19 infection which confounds this report. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Mild heart muscle inflammation) in a 39-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Dec-2021, the patient experienced MYOCARDITIS (Mild heart muscle inflammation) (seriousness criterion medically significant). On 06-Jan-2022, MYOCARDITIS (Mild heart muscle inflammation) was resolving.<br><br>No concomitant product use was provided by the reporter.<br><br>No treatment medications were reported.<br><br>The patient underwent ECG, blood count and heart ultrasound, but no results were provided.<br><br>Company Comment: This is a regulatory case concerning a 39-year-old male patient with no reported medical history, who experienced the expected, serious (medically significant) adverse event of special interest of Myocarditis (reported as Mild heart muscle inflammation), on the same day after receiving a dose of mRNA-1273 vaccine. The patient underwent ECG, Blood Count and Heart Ultrasound but the date of tests and results were not specified. Clinical course and treatment details were not provided in the case. The event Myocarditis was resolving after 28 days. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the event was assessed as per Regulatory Authority's report. | Lack of information in the case, particularly clinical signs/symptoms, diagnostic exam results and clinical course. | [redacted] |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 15-Mar-2022 and was forwarded to Moderna on 18-Mar-2022.<br>This case, initially reported to the [redacted]) by a physician, was received via the [redacted] (Ref, [redacted]. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 02-Mar-2022, the patient received the 3rd vaccination with this vaccine. On 09-Mar-2022, at 09:00, the patient experienced a severe precordial pain that tended to intensify and visited an emergency department. There was no elevation of cardiac enzymes but marked chest pain and electrocardiographic changes (ST elevation in multiple leads), and a diagnosis of acute pericarditis was made. The patient was hospitalized. On admission, the patient tested positive for COVID-19 Nucleic Acid Qualitative Tests (NEAR), but had no respiratory symptoms, pyrexia, or contact history. However, on an unspecified date around mid-Feb-2022, the patient and family members had symptoms of pharyngodynia. The nucleic acid test by PCR method was negative. On 10-Mar-2022 and later, there was an increase in cardiac enzymes. The patient was diagnosed as acute myocarditis and acute pericarditis and the natural course of the events was followed up. Both PCR and NEAR methods were negative. Detection by past COVID-19 | 18-year old male patient experienced chest pain 7 days after receiving a 3rd dose of Spikevax and subsequently hospitalized. Initial cardiac enzymes were reported to be within normal range, but increased the next day. There were ST elevations on ECG. Initial testing for COVID-19 was positive; however subsequent testing was negative. Three days after hospital admission, symptoms had resolved and the patient was discharged. Treatment information was not provided. The causality for this case is assessed as possible due to the onset of events within 7 days of receiving Spikevax; however, the patient had a positive COVID-19 diagnostic test on hospital admission and it was reported that the patient and household reported symptoms of sore throat a few weeks | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | infection (false-positive in a broad sense) was assumed. On 12-Mar-2022, the symptoms were confirmed to have resolved. The patient was discharged from the hospital. The outcome of acute myocarditis and acute pericarditis was reported as resolved. Follow-up investigation will be made. Reporter comments continuation: Other possible causes included COVID-19 infection (09-Mar-2022 Nucleic acid test positive, time of onset unknown, no history of contact). Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | prior which could provide an alternate causality for the event. | |
| [redacted] | This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 16-Mar-2022. The most recent information was received on 05-Apr-2022 and was forwarded to Moderna on 13-Apr-2022. This case was reported by a physician via the [redacted] On 05-Apr-2022, follow-up information was received from a physician. Suspected myocarditis and suspected diabetes mellitus were assessed as serious by the MAH. The vaccine recipient had a habit of drinking alcohol once a week. On an unknown date in 2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date in 2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 13-Mar-2022, the patient received the 3rd vaccination with this vaccine. After the vaccination, the patient experienced dyspnoea. On 15-Mar-2022, respiratory discomfort and chest pain developed. In the morning, the patient had a discomfort feeling when lying down. In the early evening, the patient noticed feeling of respiratory discomfort. During the night, the patient was unable to sleep. The patient sat down because she felt discomfort when lying down. Pyrexia was not noted. On 16-Mar-2022, the patient did not have respiratory discomfort so much when lying down. The patient visited a medical institution with a chief complaint of respiratory discomfort and queasy feeling. Myocarditis was suspected. BP: 127/101, BT: 36.2 degrees Celsius, Sa: 98-99%, and HR: 98-100. There was no heart murmur or lung murmur. Slight tachycardia was noted. Electrocardiogram showed sinus rhythm and HR of 89, and no abnormal findings were seen. Blood test showed no increases in cardiac troponin T, CK, and CRP. Anxiety neurosis, suspected subacute thyroiditis, and suspected diabetes mellitus were noted. For anxiety neurosis, 5 doses of 1 tablet of diazepam 2 mg were prescribed on an as-needed basis for anxiety. The patient was instructed to make an ambulance call when palpitations did not subside after oral administration of diazepam. Respiratory discomfort and chest pain resolved. The outcome of suspected myocarditis was reported as resolved. The outcome of anxiety neurosis, suspected subacute thyroiditis, and suspected diabetes mellitus was unknown. No follow-up investigation will be made. Reporter comments continuation: Since there are no judging criteria for pyrexia or blood collection, hyperventilation may have nearly developed. The treatment plan includes thyroid function examination. The patient was prescribed diazepam to calm down mentally. The patient was instructed to make an ambulance call and visit an emergency department bringing blood collection data when palpitations did not subside after oral administration of diazepam. Follow-up received on 05-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | 21-year old female with dyspnoea and chest pain 2 days after receiving a 3rd dose of Spikevax (first 2 doses were Comirnaty). On the third day following vaccination the patient was evaluated for her symptoms. All cardiac diagnostic exams were normal, including EKG, cardiac enzymes, and CRP. Anxiety neurosis, suspected subacute thyroiditis, and suspected diabetes mellitus were noted and the patient was prescribed diazepam. As myocarditis was ruled out, a causal relationship to Spikevax is unassessable. | [redacted] |

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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocardium inflammation) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No any previous allergies were reported. Information on risk factors or pre-existing conditions were not available.<br><br>On 10-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Jan-2022, the patient experienced MYOCARDITIS (myocardium inflammation) (seriousness criterion medically significant). On 29-Jan-2022, MYOCARDITIS (myocardium inflammation) had not resolved.<br><br>No relevant concomitant medications were reported.<br><br>It was reported that shortness of breath, breast pressure, general exhaustion around 2 weeks after booster vaccination. Family doctor was able to rule out serious damage, cardiologist confirmed mild heart muscle inflammation.<br><br>Treatment medication was not provided by the reporter.<br><br>Company Comment: This is a Regulatory Authority case concerning a 30-year-old male patient, with no medical history reported, who experienced the expected, serious, and AESI of Myocarditis. The event occurred 15 days after the third dose of mRNA-1273 vaccine. No information about previous doses was disclosed. Cardiologist confirmed mild heart muscle inflammation. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results and clinical course. | [redacted] |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 17-Mar-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on an unknown date.<br>This regulatory authority prospective pregnancy case was reported by a consumer and describes the occurrence of ARRHYTHMIA (Also: heart muscle inflammation, apathetic, blackouts for a few minutes, very often memory gaps (which happened 2-3 hours before, or what I wanted to do in the next moment)), APATHY (Also: heart muscle inflammation, apathetic, blackouts for a few minutes, very often memory gaps (which happened 2-3 hours before, or what I wanted to do in the next moment)), HYPOAESTHESIA (arm since vaccination completely paralyzed/numb (I can't do anything with it, drop items), numb legs, mostly at night (no more sleep), occasionally during the day (none control)), MEMORY IMPAIRMENT (very often memory gaps (which happened 2-3 hours before, or what I wanted to do in the next moment)), MONOPLEGIA (arm since vaccination completely paralyzed/numb), MYOCARDITIS (Also: heart muscle inflammation), DYSPNOEA (arm since vaccination completely paralyzed/numb (I can't do anything with it, drop items), numb legs, mostly at night (no more sleep), occasionally during the day (none control)), INSOMNIA (no more sleep) and LOSS OF CONSCIOUSNESS | 31-year old pregnant female patient reported heart muscle inflammation on the same day as receiving the 3rd dose of Spikevax, however, there are no corresponding clinical symptoms or diagnostic exam data reported. Report indicates that patient was 2 months pregnant at event onset. No additional information was provided making this report unassessable. | [redacted] |

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| | (blackouts for a few minutes) in a 31-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216046) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 18-Jan-2022, the patient experienced heart muscle inflammation, apathetic, blackouts for a few minutes, very often memory gaps (which happened 2-3 hours before, or what I wanted to do in the next moment), arm since vaccination completely paralyzed/numb (I can't do anything with it, drop items), and numb legs, mostly at night (no more sleep), occasionally during the day (none control)) (seriousness criterion hospitalization). At the time of the report, the events had not resolved.<br><br>Concomitant medications were not reported.<br><br>Treatment information was not provided.<br><br>Company comment:<br>This is a regulatory authority prospective pregnancy case concerning a 31-year-old, approximately 2 months pregnant at the time of vaccine exposure (last normal menstrual period and expected date of delivery was not reported) with no reported medical history, who experienced the unexpected serious AESI event of arrhythmia, the unexpected serious events of apathy, memory impairment, loss of consciousness, hypoaesthesia in legs, arm paralysis, dyspnea and insomnia and the expected serious AESI event of myocarditis. The events arrhythmia, apathy, memory impairment, myocarditis and loss of consciousness occurred the same day with the third dose of mRNA-1273 vaccine administration while the events hypoaesthesia in legs, arm paralysis, dyspnea and insomnia occurred 2 days after the third dose of mRNA-1273 vaccine administration. The events resulted to hospitalization. No other information surrounding the events was reported. The outcome of the events was reported as not resolved from the time of last observation. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 17-Mar-2022: Upon internal review on 24-Mar-2022, significant correction was performed. The seriousness criteria of medically significant was removed for events Arrhythmia, Monoplegia, Myocarditis and Loss of consciousness. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ANGINA PECTORIS (Slight chest pain, worse on exertion. I don't think dangerous. heart muscle inflammation?) and MYOCARDITIS (Slight chest pain, worse on exertion. I don't think dangerous. heart muscle inflammation?) in a 37-year-old male patient who received mRNA- | Lack of information in the case for evaluation, particularly diagnostic exam results and clinical course. The patient had not been medically evaluated. There is no mention of concomitant medication use, or lack thereof. | [redacted] |

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| | 1273 (Spikevax) (batch no. 000086A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for Prophylactic vaccination and TOZINAMERAN (COMIRNATY) for Prophylactic vaccination.<br><br>The patient has hay fever.<br><br>On 30-Jun-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form.<br>On 04-Aug-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form.<br>On 05-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Jan-2022, the patient experienced ANGINA PECTORIS (Slight chest pain, worse on exertion. I don't think dangerous. heart muscle inflammation?) (seriousness criterion medically significant), MYOCARDITIS (Slight chest pain, worse on exertion. I don't think dangerous. heart muscle inflammation?) (seriousness criterion medically significant) and CHEST PAIN (Slight chest pain, worse on exertion. I don't think dangerous. heart muscle inflammation?). On 12-Jan-2022, ANGINA PECTORIS (Slight chest pain, worse on exertion. I don't think dangerous. heart muscle inflammation?), MYOCARDITIS (Slight chest pain, worse on exertion. I don't think dangerous. heart muscle inflammation?) and CHEST PAIN (Slight chest pain, worse on exertion. I don't think dangerous. heart muscle inflammation?) had not resolved.<br><br>Concomitant product use was not provided by the reporter. From the next day, chest pain occurred again and again, sometimes in the middle, and sometimes slightly on the left. On effort, it was noticeably worse. The patient took some aspirin at the time of this report, but it did not seem to change anything. If it did not get better, the patient needed to see a doctor.<br><br>Company Comment: This regulatory authority case concerns a 37-year-old male patient, with no relevant medical history reported, who experienced the unexpected serious event of Angina pectoris, expected serious AESI of Myocarditis (seriousness criterion medically significant) and non-serious event of Chest pain which occurred 1 day after the third dose of mRNA-1273 vaccine. It's reported that patient had a chest pain which got worsen by exertion, he took aspirin, but it did not seem to change anything. The patient was noted to have received two doses from TOZINAMERAN (COMIRNATY) approximately 5 months prior to current vaccination with mRNA1273 (Interchange of vaccine products). The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness assessment has been retained as per Regulatory Authority reporting. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (After more than a week, I came started racing, which almost led to a panic reaction. I visited a family doctor because I was afraid of heart muscle inflammation.) in a 30- | Lack of information in the case for evaluation, particularly diagnostic exam results and clinical course. Patient reported visiting family physician due to fear of heart muscle inflammation, but did | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 27-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Jan-2022, the patient experienced FATIGUE (Fatigue). On 31-Jan-2022, the patient experienced MYALGIA (Myalgia). On 07-Feb-2022, the patient experienced MYOCARDITIS (After more than a week, I came started racing, which almost led to a panic reaction. I visited a family doctor because I was afraid of heart muscle inflammation.) (seriousness criterion medically significant), TACHYCARDIA (After more than a week, I came started racing, which almost led to a panic reaction. I visited a family doctor because I was afraid of heart muscle inflammation.) and PALPITATIONS (After more than a week, I came started racing, which almost led to a panic reaction. I visited a family doctor because I was afraid of heart muscle inflammation.). On 30-Jan-2022, FATIGUE (Fatigue) had resolved. On 03-Feb-2022, MYALGIA (Myalgia) had resolved. On 10-Feb-2022, MYOCARDITIS (After more than a week, I came started racing, which almost led to a panic reaction. I visited a family doctor because I was afraid of heart muscle inflammation.), TACHYCARDIA (After more than a week, I came started racing, which almost led to a panic reaction. I visited a family doctor because I was afraid of heart muscle inflammation.) and PALPITATIONS (After more than a week, I came started racing, which almost led to a panic reaction. I visited a family doctor because I was afraid of heart muscle inflammation.) had not resolved.<br><br>No concomitant medications reported.<br>No treatment reported.<br>Patient reported that he was told by doctor due to the heart rate that this is more common when boosting. Patient should report if the high blood pressure has not returned to normal after a week or two.<br><br>Company Comment: This regulatory authority case concerns a 30-year-old male patient, with no medical history reported, who experienced the expected serious AESI of Myocarditis (seriousness criterion medically significant) and non-serious events of Tachycardia and Palpitations which occurred 11 days after the third dose of mRNA-1273 vaccine. its reported that more than a week later, he felt heart was racing which almost led to a panic reaction and visited a family doctor as he was afraid of heart muscle inflammation. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness assessment has been retained as per Regulatory Authority reporting. | not report diagnosis or suspicion of myocarditis by healthcare practitioner. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 25-Mar-2022 and was forwarded to Moderna on 25-Mar-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and ACUTE STRESS DISORDER (Acute stress disorder) in a 34-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. | Lack of information in the case for evaluation, particularly clinical signs/symptoms, diagnostic exam results and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

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| | Previously administered products included for Prophylactic vaccination: COMIRNATY and COMIRNATY.<br><br>On 17-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and life threatening) and ACUTE STRESS DISORDER (Acute stress disorder) (seriousness criteria hospitalization and life threatening). At the time of the report, MYOCARDITIS (Myocarditis) and ACUTE STRESS DISORDER (Acute stress disorder) had not resolved.<br><br>No concomitant medications were reported.<br><br>No treatment details were provided.<br>Company comment: This regulatory case concerns a 34-year-old, male patient with no reported medical history, who experienced the unexpected, serious (Hospitalization and Life threatening) AESI of Myocarditis and unexpected, serious (Hospitalization and Life threatening) event of Acute stress disorder. The events occurred 4 days after administration of third dose of mRNA-1273. The patient was previously given 2 doses of Comirnaty, the vaccination dates were not specified. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. | | |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Mar-2022 and was forwarded to Moderna on 28-Mar-2022.<br><br>This case, initially reported to the [redacted] by a (pharmacist), was received via the [redacted] (Ref, [redacted]. Myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 10-Mar-2022, the patient received the 3rd vaccination with this vaccine. On 11-Mar-2022, myocarditis developed. Pyrexia of 39 degrees Celsius and chest pain were noted. On 13-Mar-2022, pyrexia of 39 degrees Celsius and chest pain persisted. The patient visited another hospital. CPK: 1,084. On 15-Mar-2022, the patient visited the reporting hospital. Electrocardiogram showed mild ST elevation, and echocardiogram showed a small amount of pericardial effusion with CPK of 549 and troponin T of 3,514. The outcome of myocarditis was unknown. Follow-up investigation will be made.<br><br>Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship. | 25-year old male patient experienced chest pain and pyrexia (39 degrees Celsius) 1 day after the 3rd dose of Spikevax, later diagnosed as myocarditis. Three days after vaccination, pyrexia and chest pain persisted and patient was evaluated. CPK was 1,084 and no additional information from visit was provided. Five days after vaccination, the patient was evaluated again. ECG showed mild ST elevation and echocardiogram showed small pericardial effusion. CPK was 549 and troponin T was 3,514. No additional information was provided. This case is assessed as possibly related to Spikevax due to the time to onset of 1 day following vaccination; however, there is no discussion in the report regarding investigation of alternate etiologies, nor is there mention of the patient's medical history or concomitant medications, or lack thereof. | [redacted] |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Mar-2022 and was forwarded to Moderna on 29-Mar-2022.<br><br>This case, initially reported to the [redacted] by a pharmacist, was received via the [redacted] (Ref, [redacted]. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown | 23-year old male patient experienced chest pain 2 days after the 2nd dose of a COVID-19 vaccine (unknown manufacturer), later diagnosed as myopericarditis. On the second day after vaccination, the patient was evaluated in the emergency room with the following finding: CK- | [redacted] |

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| | date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 07-Mar-2022, at 15:30, the patient received the 3rd vaccination with this vaccine. On 08-Mar-2022, in the morning, pyrexia of 38.0 degrees Celsius developed. At night, the patient took an over-the-counter antipyretic. On 09-Mar-2022, in the morning, body temperature went down to 36.0 degree Celsius. At 12:00, body temperature rose to 38.0 degrees Celsius again. At 15:00, perimyocarditis developed. The patient experienced chest discomfort in a standing position. At 19:00, the patient experienced chest tightness and palpitations when lying down. At 21:00, body temperature was 37.5 degrees Celsius, and pyrexia was prolonged. At 23:00, the patient visited an emergency outpatient department. At 23:53, blood collection, 12-lead electrocardiogram, and echocardiography were performed. CK-MB: 18 U/L, and troponin T: 0.327 ng/mL. Electrocardiogram findings showed sinus rhythm with HR of 59 times/min. ST elevations were noted in 1, 2, 3, aVF, and V2-6, PR elevation was noted in aVR, and PR declines were noted in 1 and V4-6. Echocardiographic findings showed diffuse mild hypomotility in the left ventricular wall, but no obvious abnormality in the wall motion was noted. There was no significant valvular disease or pericardial effusion. The patient was hospitalized. On 10-Mar-2022, at 00:57, blood collection was performed. CK-MB: 20 U/L, and troponin T: 0.361 ng/mL. At 07:00, blood collection and 12-lead electrocardiogram were performed. CK-MB: 22 U/L, and troponin T: 0.276 ng/mL. Electrocardiogram findings showed HR: 61 times/min with ST elevations in 2, 3, aVF, and V2-6. At 12:00, blood collection was performed. CK-MB: 32 U/L, and troponin T: 0.313 ng/mL. On 11-Mar-2022, blood collection and 12-lead electrocardiogram were performed. CK-MB: 15 U/L, and troponin T: 0.393 ng/mL. Electrocardiogram findings showed HR: 51 times/min with a trend of improvement in ST elevations of 1, 2, 3, aVF, and V2-5. On 12-Mar-2022, blood collection was performed. CK-MB: 6 U/L, and troponin T: 0.194 ng/mL. On 14-Mar-2022, blood collection was performed. CK-MB: 5 U/L, and troponin T: 0.033 ng/mL. O 15-Mar-2022, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of perimyocarditis was reported as resolving. Follow-up investigation will be made. | MB: 18 U/L, troponin T: 0.327 ng/mL, ECG showed ST elevations in multiple leads, echocardiogram showed diffuse mild hypomotility in the left ventricular wall and no significant valvular disease or pericardial effusion. The patient was hospitalized. Three days after vaccination serial CK-MB and troponin T labs were drawn, with a peack CK-MB of 32 U/L and troponin T of 0.361 ng/mL. ECG findings continued to show ST elevations in multiple leads. Four days after vaccination CK-MB was 15 U/L and troponin T was 0.393 ng/mL. ECG showed a trend of improvement in ST elevations. Five days after vaccination, CK-MB was 6 U/L and troponin T was 0.194 ng/mL. Six days after vaccination, CK-MB was 5 U/L and troponin T was 0.033 ng/mL. By the seventh day, the symptoms were resolving and the patient was discharged from the hospital. The causality assessment for case is conditional for Spikevax due to the uncertainty of COVID-19 vaccine product administered. Also, there is no discussion in the report regarding investigation of alternate etiologies, nor is there mention of the patient's medical history or concomitant medications, or lack thereof. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 29-Mar-2022 and was forwarded to Moderna on 29-Mar-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION SITE OEDEMA (Vaccination site oedema), DIZZINESS (Dizziness), MALAISE (Malaise), MYOCARDITIS (Myocarditis), HEADACHE (Headache), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), COUGH (Dry cough), CHEST PAIN (Chest pain), HEART RATE INCREASED (Heart rate increased), DYSPNOEA EXERTIONAL (Dyspnoea exertional), ARTHRALGIA (Arthralgia) and PYREXIA (Pyrexia) in a 35-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 28-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Jan-2022, the patient experienced VACCINATION SITE OEDEMA (Vaccination site oedema) (seriousness criterion hospitalization), DIZZINESS (Dizziness) | Lack of information in the case for evaluation, particularly clinical signs/symptoms, diagnostic exam results and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

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| | (seriousness criterion hospitalization), MALAISE (Malaise) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), HEADACHE (Headache) (seriousness criterion hospitalization), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization), COUGH (Dry cough) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), HEART RATE INCREASED (Heart rate increased) (seriousness criterion hospitalization), DYSPNOEA EXERTIONAL (Dyspnoea exertional) (seriousness criterion hospitalization), ARTHRALGIA (Arthralgia) (seriousness criterion hospitalization) and PYREXIA (Pyrexia) (seriousness criterion hospitalization). At the time of the report, VACCINATION SITE OEDEMA (Vaccination site oedema), DIZZINESS (Dizziness), MALAISE (Malaise), MYOCARDITIS (Myocarditis), HEADACHE (Headache), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), COUGH (Dry cough), CHEST PAIN (Chest pain), HEART RATE INCREASED (Heart rate increased), DYSPNOEA EXERTIONAL (Dyspnoea exertional), ARTHRALGIA (Arthralgia) and PYREXIA (Pyrexia) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were mentioned.<br>No treatment details were reported.<br><br>Company comment: This regulatory authority case concerns a 35-year-old female patient who experienced the serious events of vaccination site oedema, dizziness, malaise, headache, cough, chest pain, heart rate increased, dyspnoea exertional, arthralgia, pyrexia, and myocarditis. Revaccination with different COVID 19 vaccine was also reported. The events occurred approximately 3 days after the third dose of mRNA-1273. No information regarding diagnostic or laboratory findings was provided. Some of the mentioned events including malaise, chest pain, hart rate increased, dyspnoea exertional and pyrexia could be symptoms of concurrent myocarditis. The benefit-risk relationship of mRNA-1273 is not affected by this report. | | |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 24-Mar-2022 and was forwarded to Moderna on 29-Mar-2022.<br>This case, initially reported to the [redacted] by a (physician), was received via the [redacted] (Ref, [redacted]. On 14-Jul-2021, the patient received the 1st dose of this vaccine. On an unknown date, pyrexia, headache, and arthralgia developed and persisted for one week. On 11-Aug-2021, the patient received the 2nd dose of this vaccine. On an unknown date, pyrexia, headache, and arthralgia developed and persisted for one week. On 03-Mar-2022, the patient received the 3rd dose of this vaccine. On 04-Mar-2022, pyrexia, headache, and arthralgia developed. On 13-Mar-2022, pericarditis developed. Chest pain was noted. On 14-Mar-2022, the symptoms persisted. The patient visited an outpatient department for the first time. Blood test showed CRP increased to 14.74 mg/dL. Cardiac ultrasonography showed inflammation findings of the pericardium, but there was no abnormal pericardial effusion. The patient was diagnoses with pericarditis. On an unknown date, chest X-ray showed no evidence of cardiomegaly. Electrocardiography showed concave | 19-year old male patient experienced chest pain 10 days after receiving a 3rd dose of Spikevax. One day after onset, the symptoms persisted and the patient visited an outpatient medical center. Laboratory and diagnostic exams showed CRP increased to 14.74 mg/dL, cardiac ultrasonography showed inflammation of the pericardium without pericardial effusion. The patient was diagnosed with pericarditis. On an unknown date, chest X-ray showed no evidence of cardiomegaly. ECG showed concave ST elevation in the broad leads. On an unknown date, the patient was hospitalized because of the persistent symptoms. The patient was treated with colchicine and prednisolone. The | [redacted] |

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| | ST elevation in the broad leads. On an unknown date, the patient was hospitalized because of the persistent symptoms. The patient was additionally treated with colchicine and prednisolone. The outcome of pyrexia, headache, and arthralgia after the 1st and 2nd vaccinations was unknown. The outcome of pericarditis after the 3rd vaccination was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | causality for this case is assessed as possible due to the onset of events within 10 days of receiving Spikevax; however, there is no discussion in the report regarding investigation of alternate etiologies, nor is there mention of the patient's medical history or concomitant medications, or lack thereof. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 20-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination and Revaccination.<br><br>No Medical History information was reported.<br>Concomitant products included TOZINAMERAN (COMIRNATY) from 30-Jul-2021 to 20-Aug-2021 for COVID-19 vaccination.<br><br>On 18-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Feb-2022, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). On 21-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Feb-2022, Echocardiogram: Left ventricle of normal dimensions and good global systolic function, without evidence of regional alterations in contractility. Right ventricle of normal size and good systolic function. Normal right atrium. Left atrium of normal dimensions. Structurally and functionally normal valves Aortic root and AO ascend of normal dimensions. Normal size inferior vena cava and physiological respiratory variations. Normal pericardium. Full aspect intracardiac partitions with ASI (1R) with shift to AD without basal shunt through it. Doppler echocardiography: Normal left ventricular filling pattern. Color Doppler: absence of significant valve regurgitation..<br><br>No treatment information was provided.<br><br>Company comment- This regulatory case concerns a 20-year-old male patient, with no reported medical history, who experienced an expected, serious (Hospitalization) AESI event of Myocarditis 3 days after vaccination with mRNA-1273. Covid immunization (Revaccination with different COVID-19 vaccine) was also reported, since the patient had previous vaccination with 2 doses of Comirnaty. Echocardiogram result was noted. No further details regarding the hospital clinical course and treatment were given. At the time of reporting, the event is | Lack of information in the case for evaluation, particularly clinical signs/symptoms, diagnostic exam results to support diagnosis (only results provided were for a normal echocardiogram) and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

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| | resolving. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report. | | |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 27-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 28-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 01-Mar-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. Not Provided<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported.<br><br>On 1st MAR-2022, Patient had night chest pain without radiation pain. On 3rd MAR-2022, in morning chest pain again and patient went to CV clinic. ECG showed diffuse ST-T change. CPK 375 U/L, hs-Troponin 4.373 ng/ml, CK-MB 17.3 ng/ml. Under impression of suspect myocarditis, he was admitted at ward for further evaluation. On 3rd MAR-2022 at 15:13 CPK 332 U/L, hs-Troponin 4.833 ng/ml, CK-MB 17.8 ng/ml. Due to myocarditis, he was transferred to ICU for further management. On 04-MAR-2022 chest pain improved. EKG sinus rhythm, ST elevation. On 05-MAR-2022 symptom and vital sign no worsening, rechecked hs-Troponin-I: 0.714 ng/ml and EKG improving, transferred to ward care. On 06-MAR-2022, condition stable, discharged and follow up on 25-MAR-2022 the patient's mother reported that the patient had been re-examined, the symptoms had been improved without abnormality, and the patient has returned to work.<br><br>No treatment information was provided.<br><br>This is a regulatory authority case concerning a 27-year-old, male patient with no reported medical history, who experienced the expected serious (hospitalization) event of myocaditis. The events occurred 1 day after the third dose of mRNA-1273 COVID 19 Vaccine. Patients laboratory test showed Abnormal ECG results, High CPK and Troponin results. The events were reported as resolving. No treatment information was provided. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. | 27-year old male patient experienced chest pain 1 day after receiving a 3rd dose of Spikevax. Two days after initial onset, the patient experienced chest pain again and went to the clinic for evaluation. Laboratory and diagnostic exams showed ECG with diffuse ST-T change, CPK 375 U/L, hs-Troponin 4.373 ng/ml, and CK-MB 17.3 ng/ml. Under impression of suspected myocarditis, he was hospitalized for further evaluation. Repeat labs later that day showed CPK 332 U/L, hs-Troponin 4.833 ng/ml, and CK-MB 17.8 ng/ml. Three days after onset, chest pain improved. ECG showed sinus rhythm with ST elevation. Four days after symptom onset, symptoms and vital signs were stable. Lab results showed hs-Troponin-I: 0.714 ng/ml and EKG improving. Five days after symptom onset, condition was stable and he was discharged from the hospital. On follow-up examination, approximately 3 weeks later, the symptoms had improved without abnormality, and the patient had returned to work.The causality for this case is assessed as possible due to the onset of events within 1 day of receiving Spikevax; however, there is no discussion in the report regarding investigation of alternate etiologies, nor is there mention of the patient's medical history or concomitant medications, or lack thereof. | [redacted] |
| [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest distress) and CHEST PAIN (chest pain) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. | Myocarditis reported as suspected; however, patient was diagnosed with Non-ST elevation MI following evaluation. | [redacted] |

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| | No Medical History information was reported.<br><br>On 01-Mar-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-Mar-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), CHEST DISCOMFORT (Chest distress) (seriousness criterion medically significant) and CHEST PAIN (chest pain) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest distress) and CHEST PAIN (chest pain) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>The patient developed fever and limb soreness after receiving AZ-1 on 11-Sep-2021, and the symptoms were relieved in a day or so. There were no symptoms of discomfort after receiving AZ-2 on 01-Dec-2021. There was no abnormality or discomfort after the first two doses.<br><br>The patient received third dose of COVID-19 vaccine (Moderna) at a Pediatric Clinic. On 15-Mar-2022 at around 11 a.m. or afternoon, the patient visited the ER due to chills, tremors in both hands, dizziness, and delirium and myocarditis was suspected. The emergency department administered Diphenhydramine HCl inj 30mg/amp STAT. Sugar: 138 mg/dl, EKG: ST, CXR(-), LIAT(-), K: 3.2 given 0.298 percent KCL in 0.9 percent NaCl inj 500 ml/bt 1 bot STAT, Troponin-I: 206.6, cardiac catheterization was performed and Aspirin 3tab, Brillinta 2tab were given, and the patient was admitted to CCU06. The diagnosis was Non-ST elevation (NSTEMI) myocardial infarction.<br>On 15-Mar-2022 at 06:50 p.m., patient was admitted to CCU for the first time with chief complaints of chest tightness and chest pain. On 16-Mar-2022, the patient remained hospitalized for observation. Chest tightness and chest pain had improved, and some cardiac enzyme levels had decreased. His hypokalemia has since recovered. On 19-Mar-2022, the patient's medical condition had stabilized and he was discharged. No oral medication was prescribed.The patient said that he experienced mild symptoms of palpitations and shortness of breath. The patient had no blood pressure monitor at home and was instructed to seek medical attention immediately in the event of any abnormalities.<br><br>Company Comment<br>This regulatory authority case concerns a 25-year-old male patient, previously vaccinated with other COVID-19 vaccine, who experienced the serious (medically significant) expected AESI of Myocarditis and unexpected events of chest pain and chest discomfort, approximately 17 days after the third dose of mRNA-1273. The patient was hospitalized, cardiac enzyme and cardiac catheterization were performed. Hypokalemia was also reported in case narrative. The patient was discharge with no oral treatment. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |

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| [redacted] | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 28-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain and chest distress) and CHEST DISCOMFORT (Chest pain and chest distress) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>On 07-Mar-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Mar-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization), CHEST PAIN (Chest pain and chest distress) (seriousness criterion hospitalization) and CHEST DISCOMFORT (Chest pain and chest distress) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain and chest distress) and CHEST DISCOMFORT (Chest pain and chest distress) was resolving.<br><br>Patient had no past medical history. On 11 Mar 2022 the patient felt chest tightness after receiving the third dose of Moderna vaccine on March 7, so he visited the Emergency Department of the reporter's hospital and was diagnosed with myocarditis and admitted for treatment. The patient was given Acetal 500mg 1 TID and Colchicine 0.5mg 1 QD for treatment. The patient said that the chest pain had improved, and the myocardial inflammation value of the patient was still observed. On March 11 HS-Troponin was I:8530.5 and on March 14 HS-Troponin was at I:6869.10. March 14, 2022 The patient's mother said that the patient was still in hospital and in better condition, and the patient was expected to be discharged tomorrow.<br>No concomitant product use was provided by the reporter.<br><br>Company comment: This regulatory case concerns a 19-year-old male patient with no medical history reported, who experienced the unexpected serious (hospitalization) events Myocarditis (AESI), Chest pain and Chest discomfort, 7 days after the third dose of mRNA-1273. The patient experienced Myocarditis, chest pain and chest distress. The patient was hospitalized. HS-Troponin was at I:6869.10. At the time of reporting the events were resolving. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority's report. | 19-year old male patient experienced chest pain 4 days after receiving a 3rd dose of Spikevax, was diagnosed with myocarditis and hospitalized. On the day of hospital admission HS-Troponin I was 8530.5 and three days later was 6869.10. Treatment included Acetal 500mg 1 TID and Colchicine 0.5mg 1 QD. Three days after symptom onset, the patient was in better condition and was expected to be discharged the following day. The causality for this case is assessed as possible due to the onset of events within 4 days of receiving Spikevax; however, there is no discussion in the report regarding investigation of alternate etiologies. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 31-Mar-2022 and was forwarded to Moderna on 31-Mar-2022.<br><br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myopericarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 25-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concomitant products included TOZINAMERAN (COMIRNATY) from 21-Jul-2021 to 11-Aug-2021 for an unknown indication. | Lack of information in the case for evaluation, particularly clinical signs/symptoms, diagnostic exam results to support diagnosis and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

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| | On 17-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Feb-2022, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved.<br><br>No treatment medication was provided.<br><br>Company Comment: This regulatory case concerns a 25-year-old, male patient with no medical history reported, who experienced the expected, serious (Seriousness criterion Hospitalization), AESI of Myocarditis 3 days after the third dose of mRNA-1273. Additionally COVID-19 immunisation was also reported. Patient had previously received two doses of COVID-19 VACCINE PFIZER (Interchange of vaccine products noted). No relevant lab data or details regarding clinical course and treatment received were reported. Outcome of the events was Resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 01-Apr-2022 and was forwarded to Moderna on 01-Apr-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018J21A) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Smoker, Hypertension arterial and Obesity. Concomitant products included TOZINAMERAN (COMIRNATY) from 14-Jul-2021 to 04-Aug-2021 for COVID-19 vaccination.<br><br>On 27-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 18-Feb-2022, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Feb-2022, SARS-CoV-2 test: negative Negative.<br>On 23-Feb-2022, Troponin I (0-40): 457 ng/l 457 ng/L (nanogram per litre).<br>On 24-Feb-2022, Angiocardiogram: no injuries.<br>On 25-Feb-2022, Echocardiogram: no significant alterations.<br>On 03-Mar-2022, Magnetic resonance imaging heart: Changes suggestive of myocarditis in the lower midventricular segment. | Lack of information in the case for evaluation, particularly clinical signs/symptoms, diagnostic exam results and clinical course. The causality is assessed as unlikely for this case, as the patient's concurrent medical conditions of obesity, arterial hypertension and current smoker are significant confounders. In addition, onset of 22 days following vaccination is outside of the typical range. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | No treatment information was provided.<br><br>Company comment: This regulatory authority case concerns a 37-year-old male patient, with medical history of hypertension, obesity and smoking and concomitant product of COMIRNATY COVID-19 vaccine (2 doses), who experienced the serious (hospitalization) expected AESI of myocarditis 22 days after the dose of mRNA 1273 COVID-19 vaccine (3rd in the vaccine series). Patient had increased Troponin I, Coronary Angiogram and Echocardiogram showed no abnormalities, while Magnetic resonance imaging of heart was suggestive of myocarditis in the lower midventricular segment. No treatment information was provided. Additional event of COVID-19 immunization was reported by Regulatory Authority. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. Assessment of event seriousness was based on Regulatory Authority report. | | |
| [redacted] | This case was initially received via [redacted] (Reference number [redacted] on 01-Apr-2022. The most recent information was received on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis), FATIGUE (Fatigue/unusual tiredness), PYREXIA (Fever), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), SYNCOPE (Fainting), CARDIAC DYSFUNCTION (Cardiac dysfunction), BRADYCARDIA (Bradycardia) and DIZZINESS EXERTIONAL (Dizziness exertional) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: COVID-19 VACCINE MODERNA on 18-Jun-2021 and COVID-19 VACCINE MODERNA on 09-Sep-2021; DOXYCYCLINE, MINOCYCLINE and TETRACYCLINE.<br>Concurrent medical conditions included Suspected COVID-19 since 28-Dec-2021.<br><br>On 16-Feb-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 17-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability and medically significant). 17-Feb-2022, the patient experienced PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization, disability and medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization, disability and medically significant). On 20-Feb-2022, the patient experienced BRADYCARDIA (Bradycardia) (seriousness criteria hospitalization, disability and medically significant) and DIZZINESS EXERTIONAL (Dizziness exertional) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization, disability and medically significant), PYREXIA (Fever) (seriousness criteria hospitalization, disability and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability and medically significant), SYNCOPE (Fainting) (seriousness criteria hospitalization, disability and medically significant) and CARDIAC DYSFUNCTION (Cardiac dysfunction) (seriousness criteria hospitalization, disability and medically significant). On 20-Feb-2022, BRADYCARDIA (Bradycardia) had | Clinical symptoms reported by patient, however multiple cardiac evaluations revealed no evidence of myocarditis. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | resolved. At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and FATIGUE (Fatigue/unusual tiredness), PYREXIA (Fever), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), SYNCOPE (Fainting), CARDIAC DYSFUNCTION (Cardiac dysfunction) and DIZZINESS EXERTIONAL (Dizziness exertional) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 28-Dec-2021, SARS-CoV-2 test: positive<br>On 17-Feb-2022, Heart rate: 110-120 BPM<br>On 20-Feb-2022, Heart rate: 38 BPM<br>On an unknown date, Electrocardiogram: normal heart rhythm<br>On an unknown date, Electrocardiogram ambulatory: 7-day heart monitor reasonable results<br><br>Patient experienced heavy palpitations and high heart rate (110-120bpm) on 17-Feb-2022. He noticed weakening of the cardiac muscle the following two days. Attempted exercising on 20-Feb-2022 and heart was not functioning as normal. Heart rate failed to reach normal levels during exercise, and began feeling dizzy. Upon cooling down patient's heart rate fell to approximately 38bpm for 5-10 seconds which was never been experienced by the patient.<br><br>Company comment: This regulatory authority case concerns a 29-year-old male patient with prior medical history of suspected COVID-19, who experienced the expected, serious (Hospitalization, Disabling, Medically Significant) AESI of Myocarditis and the unexpected, serious( Hospitalization, Disabling, Medically significant) events of Fatigue, Pyrexia, Dyspnoea, Palpitations, Tachycardia, Syncope, Cardiac dysfunction, Bradycardia and Dizziness exertional. The events Myocarditis, Palpitations and Tachycardia occurred 1 day after receiving the 3rd dose of mRNA 1273. Bradycardia and Dizziness exertional started 3days after the 3rd dose of mRNA 1273, however Fatigue, Pyrexia, Dyspnoea, Syncope and Cardiac dysfunction occurred at an unknown date. The patient's relevant investigations or tests conducted included multiple ECGs which had shown normal heart rhythm, 7-day heart monitor and echocardiogram showed reasonable results. Imaging such as chest X-ray and echocardiogram was also carried out for the patient. The patient's underlying medical history of suspected COVID-19 remains as a confounder in this case. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 06-Apr-2022: Significant follow up received, past drug history added, historical drug lymecycline removed, lab data added, action taken updated, concomitant medications removed, new events added, start date for the events palpitations, tachycardia added, and I-narrative updated. | | |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 01-Apr-2022 and was forwarded to Moderna on 06-Apr-2022.<br>This case, initially reported to the [redacted]) by a physician, was received via the [redacted] (Ref, [redacted]). On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown | 20-year old male patient experienced chest pain and shortness of breath 1 day after receiving the 3rd dose of Spikevax. Two days after symptom onset the patient was evaluated. Physical exam was unremarkable, troponin I was increased at 282 | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 19-Mar-2022, the patient received the 3rd dose of this vaccine. On 20-Mar-2022, acute pericarditis developed. Shortness of breath and chest pain were noted. On 22-Mar-2022, the patient visited the reporting hospital. There were no findings on physical examination that suggested pericardial effusion. Blood test showed increased troponin I 282 pg/mL and CRP 5.5 mg/dL. CK and CK-MB were not elevated. Echocardiography and chest CT showed no abnormal pericardial effusion and no evidence of pericardial inflammation. Coronary CT scan showed no coronary artery stenosis. Chest X-ray showed findings of cardiac enlargement. An electrocardiogram showed concave-up ST-segment elevation over a wide range of inductions. Acute pericarditis was diagnosed, and the patient was hospitalized. On 27-Mar-2022, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of acute pericarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship. | pg/mL and CRP was 5.5 mg/dL, CK and CK-MB were not elevated, Echocardiography and chest CT showed no pericardial effusion or evidence of pericardial inflammation, coronary CT scan showed no coronary artery stenosis, chest x-ray showed findings of cardiac enlargement, ECG showed diffuse concave-up ST-segment elevations. Acute pericarditis was diagnosed, and the patient was hospitalized. Five days after symptom onset, the symptoms were resolving, and the patient was discharged from the hospital. No additional information was provided. The causality for this case is assessed as possible due to the onset of events within 1 day of receiving Spikevax; however, there is no discussion in the report regarding investigation of alternate etiologies, nor is there mention of the patient's medical history or concomitant medications, or lack thereof. | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (myocarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>On 20-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (myocarditis). At the time of the report, MYOCARDITIS (myocarditis) outcome was unknown.<br><br>Concomitant products were not provided.<br><br>Patient reported that treatment of side effect 1: Currently observance. The patient only reported minor thoracic complaints, no rhythmogenic events.<br><br>Treatment medication were not reported.<br><br>Company Comment: This regulatory authority case concerns a 29 year old male patient with no medical history reported , who experienced Non-serious , expected , AESI event of Myocarditis which occurred three days post vaccination with the 3rd dose of mRNA-1273 vaccine. Information regarding the dose 1 and dose 2 of Covid 19 vaccine of the patient was not reported. Patient was admitted for observation and the patient only reported minor thoracic complaints, no rhythmogenic events. It was reported if the heart parameters were high, coronary angiography was to be done to rule out CHD, observation was done . Other details of | Lack of information in the case for evaluation, particularly clinical signs/symptoms, diagnostic exam results to support diagnosis and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | treatment, results of laboratories/diagnostic procedures were not reported. Outcome of the event was reported as unknown. The benefit -risk relationship of mRNA -1273 ( Moderna Covid 19 Vaccine) is not affected by this report. Event seriousness assessed as per regulatory report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of HEART RATE INCREASED (Increased heart rate at rest (average 100/minute - normal 56/minute)), PERICARDITIS (Pericarditis: 10 feb, pericarditis was diagnosed by general practitioner, leading to numerous cardiologist investigations and additional blood tests.), ARTHRALGIA (Joint Pain), PALPITATIONS (Palpitations), INJECTION SITE REACTION (Injection site response), HEADACHE (headache), PYREXIA (Fever), MYALGIA (Muscle pain), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) and CHEST PAIN (Pain in the chest area) in a 25-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000057A) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 (Covid-19 infection before vaccination.). Previously administered products included for COVID-19 immunisation: Comirnaty on 02-Jul-2021 and Comirnaty on 29-Jul-2021.<br><br>On 09-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Feb-2022, the patient experienced HEART RATE INCREASED (Increased heart rate at rest (average 100/minute - normal 56/minute)) (seriousness criterion hospitalization), ARTHRALGIA (Joint Pain) (seriousness criterion hospitalization), PALPITATIONS (Palpitations) (seriousness criterion hospitalization), INJECTION SITE REACTION (Injection site response) (seriousness criterion hospitalization), HEADACHE (headache) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness criterion hospitalization), MYALGIA (Muscle pain) (seriousness criterion hospitalization) and CHEST PAIN (Pain in the chest area) (seriousness criterion hospitalization). On 10-Feb-2022, the patient experienced PERICARDITIS (Pericarditis: 10 feb, pericarditis was diagnosed by general practitioner, leading to numerous cardiologist investigations and additional blood tests.) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). At the time of the report, HEART RATE INCREASED (Increased heart rate at rest (average 100/minute - normal 56/minute)), PERICARDITIS (Pericarditis: 10 feb, pericarditis was diagnosed by general practitioner, leading to numerous cardiologist investigations and additional blood tests.), ARTHRALGIA (Joint Pain), PALPITATIONS (Palpitations), INJECTION SITE REACTION (Injection site response), HEADACHE (headache), PYREXIA (Fever), MYALGIA (Muscle pain), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) and CHEST PAIN (Pain in the chest area) had not resolved.<br><br>No concomitant medications were mentioned. | Lack of information in the case for evaluation, particularly diagnostic exam results to support diagnosis and clinical course. History of COVID-19 infection prior to vaccination. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | On Wednesday evening 9 Feb patient started experiencing chest pain, increased resting heart rate (average 100/minute - normal 56/minute) and palpitations. On Feb. 10, pericarditis was diagnosed by a GP. It was reported that the side effects have not stopped and the heart problem may require lifelong follow-up, for a previously healthy patient. Patient was being treated with heavy anti-inflammatories and painkillers. Examinations included Blood analysis, EKG and Ultrasounds. Following up with Cardiology.<br><br>This is a regulatory case concerning a 25-year-old female patient with a medical history of COVID-19, who experienced the unexpected events of heart rate increased, pericarditis(AESI), arthralgia, palpitations, injection site reaction, headache, pyrexia, myalgia, COVID-19 immunization and chest pain. The events occurred on the same day after the third dose of mRNA – 1273 vaccine, except for the event pericarditis which was experienced a day later. All the events were reported to cause hospitalization and at the time of report all have not resolved. The reporter's assessment was not provided. The benefit-risk relationship of the vaccine is not affected by this report. A previously administered product is the Cominarty COVID-19 vaccine. | | |
| [redacted] | This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (suspected myocarditis/pericarditis) in a 26-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3005704 and 3005704) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 16-Jun-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 50 microgram.<br>On 14-Jan-2022, received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 50 microgram. On 19-Jan-2022, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (suspected myocarditis/pericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (suspected myocarditis/pericarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Cardiac murmur: Systolic murmur.<br><br>mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosing remained unchanged.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (suspected myocarditis/pericarditis) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br>The patient received COVID-19 Vaccine Moderna (Spikevax) 3rd vaccination (COVID-19 vaccine), a dosage of 50 microgram. On 19.01.2022 the patient experienced Perimyocarditis. No treatment information was provided. | Lack of information in the case for evaluation, particularly clinical signs/symptoms, diagnostic exam results to support diagnosis and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

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| | Company comment: This is a regulatory case concerning a 26 year-old, male patient with no reported medical history, who experienced the serious (due to medically important condition) expected, AESI of Myocarditis (reported as suspected myocarditis/pericarditis), approximately 5 days after the third dose of mRNA-1273 vaccine. A systolic murmur was reported. The outcome was reported as unknown. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 06-Apr-2022: Translation received on 11-Apr-2022, updated lab test. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Tabaquism (8 Year Packages).<br><br>On 17-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Jan-2022, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 24-Jan-2022, Electrocardiogram: sinus rhythm, concave ST aspect predominant in anteroapical.<br>On 24-Jan-2022, Magnetic resonance imaging heart: Inflammatory dry pericarditis without obvious signs of myocarditis..<br>On 24-Jan-2022, Troponin (<53): 72 pg/mL<br>On 24-Jan-2022, Ultrasound chest: no anomaly.<br>On 26-Jan-2022, Troponin (<53): 2075 pg/mL<br>On 27-Jan-2022, Troponin (<53): 1547 1547 pg/mL<br>On 30-Jan-2022, Electrocardiogram: without anomaly.<br>On 31-Jan-2022, Blood creatine phosphokinase: normal<br>On 31-Jan-2022, Troponin (<53): 423 pg/mL<br><br>No concomitant medications was reported.<br>Introduction of COSIMPREL<br><br>Company Comment: This regulatory case concerns a 30-year-old, male patient, with no relevant medical history reported, who experienced the expected, serious (Seriousness criterion Hospitalization), AESI of Myocarditis 7 days after the first dose of mRNA-1273. Troponin levels were elevated. Details regarding the hospitalization, treatment information were not reported. Outcome of the event was Resolving. The benefit-risk relationship of mRNA-1273 | 30-year old male patient with a reported event of myopericarditis experienced 7 days after the 3rd dose of Spikevax. ECG results showed sinus rhythm, concave ST aspect predominant in anteroapical, cardiac MRI showed inflammatory dry pericarditis without obvious signs of myocarditis, and echocardiogram was normal. Peak troponin levels were 2075 pg/mL (<53). The patient was started on treatment with Cosimprel. At follow-up approximately one week after event onset, ECG was normal and troponins were significantly decreased at 423 pg/mL. Due to the lack of clinical symptoms reported in the case and without diagnostic exam data to support, this case is unassessable for myocarditis per the Brighton Collaboration and CDC case definitions; however, according the definitions for pericarditis, this is a definitive case (level 1) per Brighton and Acute pericarditis per the CDC. The causality assessment is considered possible for this case, as there is a close temporal relationship with event onset 7 days following the 3rd dose of Spikevax. However, there is a lack of information concerning rule out of other potential etiologies and the patient is a current smoker (8 pack years), which confounds the assessment. | [redacted] |

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| | vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (At rest retroscapular pain of about an hour, associated with mild chest discomfort, not dyspnoea, neither cardiopalm, accentuated in orthostatism and with mild physical exertion (walking).) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 15-Mar-2022, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (At rest retroscapular pain of about an hour, associated with mild chest discomfort, not dyspnoea, neither cardiopalm, accentuated in orthostatism and with mild physical exertion (walking).) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (At rest retroscapular pain of about an hour, associated with mild chest discomfort, not dyspnoea, neither cardiopalm, accentuated in orthostatism and with mild physical exertion (walking).) had not resolved.<br><br>No concomitant medications were reported.<br>Patient experienced Pericarditis after about 2 months post 3rd dose of COVID-19 vaccine.<br>No treatment medications were reported.<br><br>Company Comment: This regulatory authority case concerns a 19-year-old male patient with no medical history reported, who experienced the expected serious AESI of Pericarditis (seriousness criterion medically significant) which occurred 1 month 25 days after receiving third dose of mRNA 1273 vaccine. Its reported that patient had retroscapular pain at rest associated with mild chest discomfort, which was accentuated by standing up and with mild physical exertion (walking). Electrocardiogram reported as inconclusive as on 17-Mar-2022. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report. | Lack of information in the case for evaluation, particularly diagnostic exam results to support diagnosis and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 07-Apr-2022 and was forwarded to Moderna on 07-Apr-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of TACHYCARDIA (Tachycardia), PALPITATIONS (Palpitations) and PERICARDITIS (Acute pericarditis) in a 35-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 10-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced | Lack of information in the case for evaluation, particularly diagnostic exam results to support diagnosis and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |

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| | PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion medically significant) and PALPITATIONS (Palpitations) (seriousness criterion medically significant). On 20-Mar-2022, PERICARDITIS (Acute pericarditis) had resolved. At the time of the report, TACHYCARDIA (Tachycardia) and PALPITATIONS (Palpitations) had resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications details were reported.<br>No treatment medications details were reported.<br><br>Company comment: This is a regulatory authority case concerning a 35-year-old female patient with no medical history reported, who experienced serious (medically significant) events of tachycardia, palpitations and pericarditis (AESI) which occurred 20 days after the administration of mRNA-1273 vaccine (reported as the third dose of the COVID-19 vaccination schedule). No further details regarding first and second dose, clinical course, diagnostic tests or treatment performed were disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Exudative pericarditis) in a 30-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>Patient was smoker and overweight and Denies allergies to drugs.<br><br>On 24-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 24-Jan-2022, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Exudative pericarditis) (seriousness criterion medically significant). In February 2022, PERICARDITIS (Exudative pericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 02-Feb-2022, Echocardiogram: non-hemodynamically significant pericardial effusion without alterations in myocardial tissue<br><br>No concomitant medication was provided by reporter.<br>Treatment medications included Voltaren and Colchicine.<br><br>Patient went to the hospital on 02Feb2022 for oppressive chest pain dependent breath of a piercing type since 24Jan2022. On the same day, he received the 3rd dose of vaccine booster for SARS-Cov2 Moderna. The patient went to hospital on 02Feb2022 with a suggestive clinic of acute pericarditis. On the electrocardiogram there were nonspecific changes in the repolarization. Echocardiography showed a non-hemodynamically significant pericardial | 30-year old male patient with concurrent conditions of obesity and current smoker experienced chest pain on the same day as receiving a 3rd dose of Spikevax. Nine days after symptoms started, the patient was evaluated at the hospital. Echocardiogram showed non-hemodynamically significant pericardial effusion without alterations in myocardial tissue. There was no pericardial rub or pulsus paradoxus on physical exam. Patient was treated with Voltaren and cochicine. Additional information was not provided. This caseThis causal association to Spikevax is assessed as possible for this event due to an onset of symptoms on the day of vaccination; however, the patients concurrent conditions of obesity and smoking are significant cardiac risk factors that confound the assessment. | [redacted] |

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| | effusion without alterations in myocardial tissue. They frame the clinic as from acute exudative pericarditis for which they set up anti-inflammatory therapy (Voltaren and Colchicine) and arrange a check next week. At the 09Feb2022 visit marked improvement in symptoms remains only slight pain when lying on his left side. There were no significant changes in the clinical evaluation, there were no hypotension, paradox pulse or pericardial rubbing. Blood tests in the normal. We continue the therapy already set up. Further course not known.<br><br>Company comment: This is a regulatory case concerning a 30 year-old, male patient with no relevant medical, who experienced the serious (due to medically important condition) expected, AESI of Pericarditis (reported as Exudative pericarditis), the same day after the mRNA-1273 vaccine, received as the booster dose of COVID-19 vaccination schedule. Patient went to the hospital for oppressive chest pain. An electrocardiogram showed nonspecific changes in repolarization. Echocardiography show a non-hemodynamically significant pericardial effusion without alterations in myocardium. Blood tests were reported as normal. Treatment with diclofenac and Colchicine. The outcome was reported as recovering. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number [redacted] on 04-Apr-2022 and was forwarded to Moderna on 08-Apr-2022.<br>This case, initially reported to the [redacted]) by a physician, was received via the [redacted] (Ref, [redacted]. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 18-Mar-2022, the patient received the 3rd vaccination with this vaccine. On 19-Mar-2022, swelling and pain at the vaccination site and pyrexia developed. On 20-Mar-2022, at 17:00, perimyocarditis developed. Anterior chest pain was noted, and it persisted thereafter. On 21-Mar-2022, at 05:00, the patient visited the emergency room of the reporting hospital. There were no physical findings suggestive of accumulation of pericardial effusion. There was no change in the electrocardiogram. Chest X-ray showed no findings of cardiac enlargement. Blood samples showed elevations in high-sensitivity troponin I of 925.6 pg/mL and CRP of 8.15 mg/dL. Echocardiography showed no abnormal findings. The patient was hospitalized with a diagnosis of perimyocarditis. Thereafter, electrocardiogram showed PR depressions in II, III, aVF, and V2-5. On 22-Mar-2022, electrocardiogram showed ST elevations in II, III, aVF, and V4-6. Echocardiography and chest CT scan showed no abnormal pericardial effusion and no evidence of pericardial inflammation. On 23-Mar-2022, electrocardiography was performed. The symptoms were resolving, and the patient was discharged from the hospital. The outcome of swelling and pain at the vaccination site was unknown. The outcome of perimyocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | 30-year old male patient experienced chest pain 2 days after receiving a 3rd dose of Spikevax (first 2 doses of COVID-19 vaccine with unknown manufacturer). One day after symptoms started, the patient was evaluated in the emergency room. Physical exam, ECG, chest x-ray, and echocardiogram were all normal. Blood samples showed elevations in high-sensitivity troponin I of 925.6 pg/mL and CRP of 8.15 mg/dL. The patient was hospitalized with a diagnosis of perimyocarditis. Thereafter, ECG showed PR depressions in multiple leads. Two days after symptom onset, ECG showed ST elevations in multiple leads, Echocardiography and chest CT scan showed no abnormal pericardial effusion and no evidence of pericardial inflammation. Three days after symptom onset, symptoms were resolving and the patient was discharged from the hospital. Additional information was not provided. This causal association to Spikevax is assessed as possible for this event due to an onset of symptoms within 2 days of vaccination; however, there is no discussion in the report regarding investigation of alternate etiologies, nor is there mention of the patient's medical history or concomitant medications, or lack thereof. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 01-Apr-2022 and was forwarded to Moderna on 08-Apr-2022.<br>This case, initially reported to the [redacted] by a physician, was received via the [redacted] (Ref, [redacted] Suspected myocarditis and suspected pericarditis were assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 18-Mar-2022, the patient received the 3rd dose of this vaccine. On 28-Mar-2022, in the afternoon, the patient suddenly experienced pain with oppressive feeling in the left chest. Myocarditis or pericarditis was suspected. On an unknown date, the patient visited the reporting hospital. Since then, the symptom had been intermittent with fluctuation of severity to the present. Myocarditis or pericarditis due to this vaccine was suspected, and the patient was referred to another hospital. The outcome of suspected myocarditis and suspected pericarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | Lack of information in the case for evaluation, particularly diagnostic exam results to support diagnosis and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | [redacted] |
| | This case was received via European Medicines Agency (Reference number: [redacted] on 08-Apr-2022 and was forwarded to Moderna on 08-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocarditis) in a 35-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 30-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Jan-2022, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (myocarditis) was resolving.<br><br>No concomitant medications were mentioned.<br>No treatment details were reported.<br><br>Company comment-This regulatory authority case concerns a male patient aged 35 years with no medical history reported, who experienced the expected serious (medically significant) event of Myocarditis (AESI) 2 days after third dose of mRNA-1273 vaccine administration. No further details on clinical course, lab test results and treatment given were reported. Outcome of the event was resolving at the time of report. Benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. | Lack of information in the case for evaluation, particularly clinical signs/symptoms, diagnostic exam results to support diagnosis and clinical course. There is no mention of medical history or concomitant medication use, or lack thereof. | |
| | This case, initially reported to the [redacted] by a physician, was received via the [redacted] (Ref, [redacted]. The vaccine recipient was taking oral contraceptives. On 02-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 24-Jun-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 35.2 degrees Celsius. On 24-Feb-2022, at 18:00, the patient received the 3rd vaccination with this vaccine. On 01- | Lack of information in the case for evaluation, particularly diagnostic exam results to support diagnosis and clinical course. There is no mention of medical history, or lack thereof. | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Mar-2022, left chest pain and respiratory discomfort were noted. The patient was examined in another hospital, and there were no abnormalities. On 03-Mar-2022, the patient visited the reporting hospital. Myocarditis was suspected. Blood collection showed elevations in CK-MB and others. In the early evening, respiratory discomfort was such that the patient was unable to stand up. Therefore, the patient was referred to a hospital. The patient was diagnosed with myocarditis and hospitalized. On 07-Mar-2022, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 14-Apr-2022 and was forwarded to Moderna on 14-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of INJECTION SITE PAIN (Injection site pain), INFLUENZA (Flu symptoms) and MYOCARDITIS (myocarditis) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 05-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced INJECTION SITE PAIN (Injection site pain). On 06-Jan-2022, the patient experienced INFLUENZA (Flu symptoms). On 07-Jan-2022, the patient experienced MYOCARDITIS (myocarditis). On 07-Jan-2022, INJECTION SITE PAIN (Injection site pain) had resolved, INFLUENZA (Flu symptoms) was resolving. At the time of the report, MYOCARDITIS (myocarditis) had not resolved.<br><br>No relevant concomitant medications were reported.<br>Treatment information was unknown.<br><br>Company Comment: This is a Regulatory Authority case concerning a 30-year-old male patient, with no medical history reported, who experienced the expected, non-serious and AESI of Myocarditis. The event occurred 2 days after the third dose of mRNA-1273 vaccine, and at the time of the report it had not resolved. Seriousness assessed by the Regulatory Authority. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly clinical signs/symptoms and diagnostic exam results. There was no mention of patient's medical history or concomitant medications, or lack thereof. | [redacted] |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 17-Apr-2022. The most recent information was received on 20-Apr-2022 and was forwarded to Moderna on 20-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and PAIN (Generalised aching) in a 31-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Previously administered products included for COVID-19 vaccination: COVID-19 MRNA VACCINE BIONTECH on 15-May-2021 and COVID-19 MRNA VACCINE BIONTECH on 26-Jun-2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 MRNA VACCINE BIONTECH and COVID-19 MRNA VACCINE BIONTECH.<br><br>On 11-Apr-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 12-Apr-2022, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant) and PAIN (Generalised aching) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had resolved with sequelae, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations) and PAIN (Generalised aching) had resolved and DYSPNOEA (Shortness of breath) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 15-Apr-2022, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.<br><br>Patient has not had symptoms associated with COVID-19.<br>Concomitant Medication use information was not provided by reporter.<br>Day following booster vaccination, patient was experiencing fatigue, shortness of breath, full body aches, sharp stabbing pain in chest sometimes after taking deep breathes or lying down in bed. Recovered from most symptoms, still experiencing shortness of breath 4 days on.<br>The laboratory exam was done that includes Covid-19 rapid antigen test (RAT) displaying a negative test.<br>Symptoms was not lead to a hospital stay. Diagnosis was not made by a medical professional.<br>Patient was not had symptoms associated with COVID-19. Patient was not tested positive for COVID-19 since the vaccine. Patient was not enrolled in clinical trial.<br>The report was related to possible myocarditis or pericarditis.There were no any blood tests, such as for certain proteins (called troponin) that signal heart muscle damage taken.<br>Treatment Medication use information was not provided by reporter.<br><br>Company comment:<br>This regulatory authority case concerns a 31-year-old, male patient, with no medical history reported, who experienced the expected serious (Medically significant) AESI event of Pericarditis along with other unexpected serious (Medically significant) events of fatigue, chest | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | pain, Dyspnoea, palpitations and pain (generalised aching) which all occurred 1 day after the third dose of mRNA-1273. The patient was experiencing fatigue, shortness of breath, full body aches, sharp stabbing pain in chest a day after the third dose of vaccination. All events were resolved except Dyspnoea. Patient completed the primary doses with Pfizer vaccine at an interval of 41 days, about 10 months back, with no adverse events reported. Interchange of vaccine products was noted. Covid-19 rapid antigen test (RAT) was done which was negative. Patient was not hospitalized. It was reported that the diagnosis was not made by a medical professional. The benefit-risk relationship<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Apr-2022: Follow up received that contains significant information that includes Updated case seriousness criteria as Medically significant, Updated past drug information, Updated suspect product dose no and Action taken, Updated Event start date and Outcome, Added Event Generalized Aching, Updated Narrative. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 19-Apr-2022 and was forwarded to Moderna on 19-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ARRHYTHMIA (Diagnosed pericarditis) and PERICARDITIS (Diagnosed pericarditis) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216044) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 07-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Dec-2021, the patient experienced MYALGIA (Myalgia). On 09-Dec-2021, the patient experienced ARRHYTHMIA (Diagnosed pericarditis) (seriousness criterion medically significant) and PERICARDITIS (Diagnosed pericarditis) (seriousness criterion medically significant). On 09-Dec-2021, MYALGIA (Myalgia) had resolved. On 13-Dec-2021, ARRHYTHMIA (Diagnosed pericarditis) and PERICARDITIS (Diagnosed pericarditis) had not resolved.<br><br>No concomitant medication were provided.<br>From 9 to the present day 12/13 Stronger pain in the heart area with radiance to the throat.<br>Today, diagnosis pericitis. Probably lasting a few days<br>No treatment information were given.<br><br>Company Comment: This regulatory authority case concerns a 32-year-old male patient with no reported medical history, who experienced the unexpected serious (medically significant) adverse events of special interest Arrhythmia and Pericarditis, that occurred 2 days after receiving the third dose of mRNA- 1273 Vaccine. Patient experienced pain in the heart area with radiation to the throat that lasted a few days. Both events were reported with dates of end of reaction on 13 Dec 2021 (4 days from onset of events) but outcome of events was reported as not resolved. The male gender could be considered as a predisposing factor for Pericarditis. The | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report. | | |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 19-Apr-2022 and was forwarded to Moderna on 21-Apr-2022.<br>This case, initially reported to the [redacted] by a (physician), was received via the [redacted] (Ref, [redacted]. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 08-Apr-2022, the patient received the 3rd vaccination with this vaccine. On 09-Apr-2022, pyrexia of 38-39 degrees Celsius was noted. The patient took acetaminophen in hand on an as-needed basis and was followed up. On 11-Apr-2022, at 18:00, myocarditis developed. The patient was aware of chest pain and shortness of breath. On 12-Apr-2022, at 06:00, as the symptoms did not improve, an emergency call was made, and the patient was raced to the reporting hospital. High values of high-sensitivity myocardial markers were observed. Twelve-lead electrocardiogram showed nonspecific ST elevation, and echocardiography showed no pericardial effusion or ventricular wall oedema. Left ventricular ejection fraction was 63%. Chest CT showed no abnormal findings. The patient was determined to have a relatively mild case of myocarditis and was hospitalized for follow-up. On an unspecified date in Apr-2021, it was confirmed that troponin peaked out. On 15-Apr-2022, the patient was discharged home. On 18-Apr-2022, the patient was followed up. Although mild symptoms remained, troponin I became negative, and electrocardiographic and echocardiographic findings were unremarkable. The symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship. | 28 year old male with unknown medical history who developed fever the next day after the 3rd dose of Spikevax and two days later chest pain and shortness of breath. The next day he was admitted and found to have elevated troponin, abnormal EKG, abnormal Echo, and was diagnosed with mild myocarditis. Ten days later follow up showed improvement of symptoms with normal troponin and unremarkable EKG and Echo findings. The causality assessment is considered possible for this case, as there is a close temporal relationship with event onset 3 days following the 3rd dose of Spikevax. However, there is a lack of information concerning other potential etiologies | [redacted] |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 21-Apr-2022. The most recent information was received on 10-May-2022 and was forwarded to Moderna on 10-May-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (unconscious), HEADACHE (headache), MYOCARDITIS (Myocarditis), FATIGUE (Fatigue/unusual tiredness), PYREXIA (Fever), DYSPNOEA (Shortness of breath), TACHYCARDIA (Racing heart (tachycardia)), SYNCOPE (Fainting), THROMBOSIS (Clot blood), POLYURIA (Polyuria) and DIARRHOEA (Diarrhoea) in a 40-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000075A) for COVID-19 vaccination.<br><br>Patient was registered as vulnerable because of the medication he had been prescribed. Patient had no symptoms associated with COVID-19.<br>Results of tests and procedures for investigation of the patient- Double what it should had been.<br>Previously administered products included for COVID-19 vaccination: COVID-19 VACCINE ASTRAZENECA on 13-Feb-2021, COVID-19 VACCINE ASTRAZENECA on 02-May-2021 and COVID-19 MRNA VACCINE BIONTECH on 23-Oct-2021; for Product used for unknown indication: INFLUENZA VIRUS in September 2021. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Past adverse reactions to the above products included No adverse event with COVID-19 MRNA VACCINE BIONTECH, COVID-19 VACCINE ASTRAZENECA, COVID-19 VACCINE ASTRAZENECA and INFLUENZA VIRUS.<br>Family history included Deep vein thrombosis and Myocardial infarction.<br>Concurrent medical conditions included Complex regional pain syndrome (Sulphasalazine-Complex regional pain syndrome Type II.) and Epilepsy.<br>Concomitant products included SULFASALAZINE (SULPHASALAZINE) from 2017 to an unknown date for Complex regional pain syndrome Type II, VALPROATE SODIUM, VALPROIC ACID (EPILIM CHRONO) from 1988 to an unknown date and ETHOSUXIMIDE from 1990 to an unknown date for Epilepsy.<br><br>On 10-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 11-Apr-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (unconscious) (seriousness criterion medically significant), HEADACHE (headache) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), PYREXIA (Fever) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant) and SYNCOPE (Fainting) (seriousness criterion medically significant). an unknown date, the patient experienced THROMBOSIS (Clot blood) (seriousness criterion medically significant), POLYURIA (Polyuria) (seriousness criterion medically significant) and DIARRHOEA (Diarrhoea) (seriousness criterion medically significant). At the time of the report, LOSS OF CONSCIOUSNESS (unconscious), HEADACHE (headache), MYOCARDITIS (Myocarditis), FATIGUE (Fatigue/unusual tiredness), PYREXIA (Fever), DYSPNOEA (Shortness of breath), TACHYCARDIA (Racing heart (tachycardia)), SYNCOPE (Fainting), THROMBOSIS (Clot blood), POLYURIA (Polyuria) and DIARRHOEA (Diarrhoea) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 28-Dec-2021, SARS-CoV-2 test: positive (Positive) Yes - Positive COVID-19 test.<br>On 14-Apr-2022, Fibrin D dimer: results not reported Results not reported.<br>On an unknown date, Blood test: positive for blood clots (Positive) Positive for blood clots..<br>On an unknown date, Echocardiogram: results not reported Results not reported.<br>On an unknown date, Electrocardiogram: results not reported Results not reported.<br>On an unknown date, Heart rate: 160* double what it should have been..<br><br>It was reported that patient had Headache, high temperature, unconscious, looked as though he was going to stop breathing. Patient went to hospital where blood tests came back showing positive for blood clots, Told to arrange a further D-Dimer blood test for two days later, these were done on Thursday 14 April at our general practitioner but results yet received due to bank holiday. | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| | Patient had complex regional pain syndrome (CRPS), sulphasalazine, for which he was supposed to had regular blood tests. Up until this last vaccination he had no problem. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. Report were related to possible myocarditis or pericarditis and diagnosis made by a medical professional- Hospital doctor.<br>No treatment was given because of symptoms, blood tests such as for certain proteins (called troponin) that signal heart muscle damage taken was unknown. There were no other recent or ongoing illness reported.<br>Follow up received on 6-May-2022 which stated Patient had no pains in his legs and he had never been diagnosed with bad circulation. His father had a deep vein thrombosis years ago, He also had a heart attack in July 2020, had 2 stents fitted at the Hospital. His maternal grandmother lived to 94 but had 2 heart attacks one when she was 39 and one when she was 63. His maternal Grandfather died at the age of 75 from a Myocardial infarction.<br>It was reported that neither patient nor his mother, father and brother smoke. Patient had no recent surgery or any accidents.<br>Patient suffered from Complex regional pain syndrome which was completely misdiagnosed by his GP. This started after a knock whilst playing Hockey. He was now registered as disabled. Patient took regular medication for epilepsy and the CRPS. while patient were taken to hospital he had high temperature and as patient was unconscious and his breathing was very faint he was unable to respond to medical staff.<br><br>Company comment: This regulatory case concerns a 40-year-old male patient with relevant medical history of COVID 19, who experienced the expected serious (medically significant) AESI of Myocarditis 1 day after, along with unexpected serious (medically significant) events of Loss of consciousness, Headache, Fatigue, Pyrexia, Dyspnoea, Tachycardia, Syncope, Thrombosis (AESI), Polyuria and Diarrhoea, unknown days after receiving the 4th dose of mRNA-1273 vaccine in the covid 19 vaccination series. Electrocardiogram was performed and showed heart rate of 160 beats per minute. Blood tests conducted in the hospital were suggestive of blood clots. Echocardiogram and Fibrin D dimer were performed (results not available). Medical history of COVID 19, and concomitant medication sulfasalazine remain confounding factors for the event myocarditis. Patient previously received 1 dose of Tozinameran vaccine, and 2 doses of CHADOX1 NCOV-19 COVID 19 vaccine about 6 months, 11 months, and 14 months ago respectively from the last dose. Interchange of vaccine products noted. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the events retained as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 10-May-2022: Significant information received- Event has been added, Past Drug History updated. | | |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 22-Apr-2022. The most recent information was received on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022. | 26-year-old male patient, with no medical history reported, who experienced 8 days after the second dose of mRNA-1273 vaccine fever, headache and dizziness, a magnetic resonance imaging performed 2 weeks after vaccination showed | [redacted] |

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| | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000063A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Feb-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 26-Feb-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 24-Feb-2022, SARS-CoV-2 test: negative (Negative) Negative.<br>On 03-Mar-2022, Magnetic resonance imaging: undilated left ventricle, with slightly depressed Undilated left ventricle with slightly depressed overall systolic function (LVEF 48%).<br>Undilated right ventricle with slightly depressed global systolic function (LVEF 49%)<br>.Myocardial hypersignal on T2 and late subepicardial enhancement at the level of the basal segments of the lower and inferolateral LV walls. Cardiac MRI findings suggestive of acute myocarditis with mild biventricular systolic dysfunction..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>No concomitant medication information was provided.<br>No treatment medication were provided.<br>It was reported that after patient received moderna 2nd dose he had fever of 38-39 degree C, right frontotemporal headache and dizziness on 22-Feb. Patient was febrile (40 degree C) on admission. Myocardial hypersignal on T2 and subepicardial delayed enhancement at the level of the basal segments of the inferior and inferolateral walls of the left ventricle. Cardiac MRI findings suggestive of acute myocarditis with mild biventricular systolic dysfunction.<br><br>Company comment: This regulatory case concerns a 26-year-old male patient, with no medical history reported, who experienced the serious expected (due to hospitalization) AESI of Myocarditis, 8 days after the second dose of mRNA-1273 vaccine. Details of previous doses were not provided. He was febrile on admission for suspected post-COVID-19 vaccine myocarditis, having had headache and dizziness. A SARS-CoV-2 test negative was performed and a magnetic resonance imaging performed 2 weeks after vaccination showed findings suggestive of acute myocarditis with mild biventricular systolic dysfunction. The benefit-risk relationship of the mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report.<br><br>Most recent FOLLOW-UP information incorporated above includes: | findings suggestive of acute myocarditis with mild biventricular systolic dysfunction. The causality assessment is considered possible for this case, as there is a close temporal relationship with event onset 8 days following the 2nd dose of Spikevax. However, there is a lack of information concerning other potential etiologies | |

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| | On 22-Apr-2022: Significant Follow Up Appended :Event outcome updated.<br>On 22-Apr-2022: Translation document received: Event verbatim translated.<br><br>Company comment:<br>This is a regulatory authority case concerning a 26-year-old, male patient with no known medical history, who experienced the expected serious (hospitalization according to regulatory authority) AESI event of myocarditis. The event occurred approximately 8 days after the second dose of mRNA-1273 vaccine administration. Allegedly the event was described as, patient received second dose of mRNA-1273 vaccine, patient experienced fever 38-39 ºC, right fronto-temporal headache and dizziness approximately 4 days after the second dose of mRNA-1273 vaccine administration. Patient tested negative for Covid-19 PCR test approximately 6 days after the second dose of mRNA-1273 vaccine administration. On unknown date, patient was subsequently admitted to ICU and was febrile (40 ºC) on admission for suspected post-vaccine myocarditis. Approximately 13 days after the second dose of mRNA-1273 vaccine, the patient underwent nuclear magnetic resonance (NMR) with the following results: 1. Undilated left ventricle with slightly depressed overall systolic function (LVEF 48%). 2. Undilated right ventricle with slightly depressed global systolic function (LVEF 49%). 3. Myocardial hypersignal on T2 and late subepicardial enhancement at the level of the basal segments of the lower and inferolateral LV walls. It was reported that the Cardiac MRI findings suggestive of acute myocarditis with mild biventricular systolic dysfunction. No other information surrounding the event was reported. The outcome of the event was reported as unknown. The patient's age and gender remain confounders for the event myocarditis. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (First modern vaccine dose to a 12-year-old child made in December.After the second dose of ever-modern vaccine made on 18 January on January 20, he was hospitalized for acute myocarditis.) in a 12-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000033A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Jan-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (First modern vaccine dose to a 12-year-old child made in December.After the second dose of ever-modern vaccine made on 18 January on January 20, he was hospitalized for acute myocarditis.) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (First modern vaccine dose to a 12-year-old child made in December.After the second dose of ever-modern vaccine made on 18 January on January 20, he was hospitalized for acute myocarditis.) had not resolved. | 12 year old male patient, with no reported medical history, who experienced myocarditis 2 days after receiving a second dose of mRNA-1273. Clinical course, concomitant medications, and hospitalization details including labs and treatment information were not reported. | [redacted] |

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| | The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.<br><br>Concomitant medication was not provided.<br><br>Treatment information was not provided.<br><br>Company Comment: This regulatory authority case concerns a 12 year old male patient, with no reported medical history, who experienced expected, serious (hospitalization) AESI myocarditis 2 days after receiving a second dose of mRNA-1273. Clinical course, concomitant medications, and hospitalization details including labs and treatment information were not reported. The outcome of the event was not recovered. The benefit risk relationship of mRNA-1273 is not affected by this report. Event seriousness is assessed as per regulatory authority's report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Jun-2022: Follow-up received is NNI. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 25-Apr-2022 and was forwarded to Moderna on 25-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (PERICARDITIS 20 days after the second dose of MODERNA (covid vaccine)) in a 30-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000063A scad 6-5-22) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 15-Mar-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Apr-2022, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (PERICARDITIS 20 days after the second dose of MODERNA (covid vaccine)) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (PERICARDITIS 20 days after the second dose of MODERNA (covid vaccine)) outcome was unknown.<br><br>Treatment information was not provided.<br>List of concomitant medication were not given.<br><br>Company comment: This is a regulatory case concerning a 30 year-old, male patient with no reported medical history, who experienced the serious (due to hospitalization) expected, AESI of pericarditis, approximately 21 days after the second dose of mRNA-1273 vaccine. The outcome was reported as unknown. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Most recent FOLLOW-UP information incorporated above includes:<br>On 04-May-2022: Non Significant Follow Up includes no new information. | | |
| [redacted] | This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 22-Apr-2022 and was forwarded to Moderna on 26-Apr-2022.<br>This case, initially reported to the [redacted] ([redacted]) by a pharmacist, was received via the [redacted] (Ref, [redacted]. On an unspecified date around Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unspecified date around Jun-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 02-Apr-2022, at 17:30, the patient received the 3rd vaccination with this vaccine. On 03-Apr-2022, generalised aching developed. On 05-Apr-2022, at 06:30, low-grade fever, precordial pain, and chest discomfort developed. The patient visited a previous physician. COVID-19 was confirmed negative. On 06-Apr-2022, the patient visited the previous physician due to persistent precordial pain. Since there was also ST-segment elevation in the lower wall lead, the patient was referred to the reporting hospital for the possibility of myocarditis. Blood collection showed elevated levels of troponin I and CK/CK-MB, leading to a diagnosis of myocarditis, and the patient was hospitalized for rest and follow-up. On 07-Apr-2022 to 08-Apr-2022, troponin I and CK/CK-MB blood samples were collected, and the patient was followed up. Each value showed a decrease. On 09-Apr-2022, chest symptoms almost completely resolved, and the patient was discharged from the hospital. The outcome of generalised aching was unknown. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. | 19 year old male with unknown medical history who 3 days after the 3rd dose of Spikevax developed fever, precordial pain and chest discomfort. The next day he was admitted and found to have elevated troponin, abnormal EKG, abnormal Echo, and was diagnosed with mild myocarditis. The causality assessment is considered possible for this case, as there is a close temporal relationship with event onset 3 days following the 3rd dose of Spikevax. However, there is a lack of information concerning other potential etiologies | [redacted] |
| [redacted] | This case was initially received via European Medicines Agency (Reference number: [redacted] on 26-Apr-2022. The most recent information was received on 04-May-2022 and was forwarded to Moderna on 04-May-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (24.01.22 thoracic pressure Dyspnoea on exertion when walking, tachycardia, up to 120/min. -> suspected myocarditis) and PULMONARY EMBOLISM (peripheral pulmonary embolism left) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005241) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: Comirnaty and Comirnaty.<br>Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.<br><br>On 19-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Jan-2022, the patient experienced MYOCARDITIS (24.01.22 thoracic pressure Dyspnoea on exertion when walking, tachycardia, up to 120/min. -> suspected myocarditis) (seriousness criterion hospitalization) and PULMONARY EMBOLISM (peripheral pulmonary embolism left) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (24.01.22 thoracic pressure Dyspnoea on exertion when walking, | 31 year old male with unknown medical history who 36 days (long TTO) after the 3rd dose of Spikevax was diagnosed with pulmonary embolism and myocarditis. No other information was provided. | [redacted] |

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| | tachycardia, up to 120/min. -> suspected myocarditis) and PULMONARY EMBOLISM (peripheral pulmonary embolism left) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 27-Jan-2022, Computerised tomogram thorax: in comparison, slightly lower caliber and worse co In comparison, slightly lower caliber and worse contrasting lower lobes pulmonary arteries left mostly antero- and laterobasally, differential diagnostic, subacute pulmonary emboliein is considered. No pleural effusions..<br>On 27-Jan-2022, Electrocardiogram: sinus rhythm, hf 92/min, steep type, sl q3 type. sinus rhythm, HF 92/min, steep type, Sl Q3 type, increased ST output in Vl until V3, T-negativation in III and aVF.<br>On 27-Jan-2022, Fibrin D dimer: 1091 1091 pg/ml.<br>On 27-Jan-2022, Troponin increased: 341 341 pg/ml.<br>On 16-Feb-2022, Angiocardiogram: no indication of coronary artery calcification. No indication of coronary artery calcification. Agatston Score 0. No evidence of relevant coronary artery stenosis.<br>On 07-Mar-2022, Magnetic resonance imaging heart: image as in expired myocarditis with very discreet Image as in expired myocarditis with very discreet subepicardial and intramyocardial fibrosis basal postero-basal. No indication of active lnflammatlon. Global good left and right ventricle function. No vitamin..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (24.01.22 thoracic pressure Dyspnoea on exertion when walking, tachycardia, up to 120/min. -> suspected myocarditis) and PULMONARY EMBOLISM (peripheral pulmonary embolism left) to be probably related.<br><br>No concomitant medications were provided.<br><br>No treatment information was provided.<br><br>Company Comment: This regulatory case concerns a 31-year-old, male patient with no relevant medical history reported, who experienced the unexpected, serious (hospitalization) AESI of pulmonary embolism (peripheral pulmonary embolism, left) and the expected, serious (hospitalization) AESI of myocarditis which occurred approximately 1 month after receiving the third dose of the mRNA-1273 vaccine in the covid 19 vaccination series. Patient had received two previous doses of Pfizer vaccines at an unknown date and interval between the doses, with no adverse events reported., Interchange of vaccine products was noted. Patient experienced thoracic pressure, dyspnea on exertion and tachycardia. Three days after the event onset, CT Thorax was suggestive of Subacute pulmonary embolism, ECG showed sinus rhythm, HF 92/min, steep type, Sl Q3 type, increased ST output in Vl until V3, T-waves negative in III and aVF, Fibrin D dimer was 1091 pg/ml, Troponin was increased: 341 pg/ml. Angiocardiogram: No indication of coronary artery calcification and coronary artery stenosis. MRI heart: Image as in expired myocarditis subjects with very discreet subepicardial and | | |

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| | intramyocardial fibrosis, basal postero-basal. No indication of active lnflammatlon. Global good left and right ventricle function. Treatment information was also not provided. The events had resolved. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-May-2022: Follow up received contains outcome of events myocarditis and pulmonary embolism from not recovered to recovered updated and laboratory tests added (angiocardiogram, computerised tomogram thorax, electrocardiogram, fibrin d dimer, magnetic resonance imaging heart, troponin hs). | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 26-Apr-2022. The most recent information was received on 29-Apr-2022 and was forwarded to Moderna on 29-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of AUTONOMIC NERVOUS SYSTEM IMBALANCE (Dysautonomia), CARDITIS (Inflammed heart), DYSPNOEA (Shortness of breath and breathing difficulties), THROAT TIGHTNESS (Throat tightening and throat spasms), FEELING ABNORMAL (Brain pains, brain pressure and brain fog), SPINAL PAIN (Spinal cord pains), NECK PAIN (Neck pains), PRESYNCOPE (Light headed, pre-syncope, close to backout / fainting, dizzy), COGNITIVE DISORDER (Cognitive impairment), HEADACHE (Brain pains, brain pressure and brain fog), HEAD DISCOMFORT (Brain pains, brain pressure and brain fog), GAIT DISTURBANCE (Difficulty in walking), CHILLS (Rigors), PERIPHERAL COLDNESS (Cold extremities), CHEST DISCOMFORT (Chest tightness), SNEEZING (Sneezing), MUSCULAR WEAKNESS (Weakness of arms), ERYTHEMA (Redness of external ear), THIRST (Thirst), NAUSEA (Nausea), PAIN IN EXTREMITY (Leg pain), INNER EAR INFLAMMATION (Inner ear inflammation), TREMOR (Shaking), PALLOR (Pallor), DIZZINESS (Dizziness), PALPITATIONS (Palpitations), BACK PAIN (Back pain), LYMPHADENOPATHY (Gland in neck), ABDOMINAL PAIN UPPER (Stomach cramps), CHEST PAIN (Chest pain), ANGINA PECTORIS (Cardiac pain) and ABDOMINAL DISCOMFORT (Gastrointestinal upset) in a 31-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005287) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 in March 2020.<br>Concurrent medical conditions included Dysautonomia (Post covid Dysautonomia (from covid in March 2020) which had largely resolved prior to Moderna boost).<br>Concomitant products included COLECALCIFEROL (VITAMIN D3) for Disorder bone (NOS), Muscle disorder NOS and Disorder immune system (NOS), ALLIUM SATIVUM (GARLIC ODOURLESS) for Prophylaxis urinary tract infection.<br><br>On 14-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 19-Dec-2021, the patient experienced AUTONOMIC NERVOUS SYSTEM IMBALANCE (Dysautonomia) (seriousness criteria disability and medically significant), CARDITIS (Inflammed heart) (seriousness criteria disability and medically significant), DYSPNOEA (Shortness of breath and breathing difficulties) | Not a case of myocarditis | [redacted] |

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| | (seriousness criteria disability and medically significant), SPINAL PAIN (Spinal cord pains) (seriousness criteria disability and medically significant), NECK PAIN (Neck pains) (seriousness criteria disability and medically significant), GAIT DISTURBANCE (Difficulty in walking) (seriousness criteria disability and medically significant) and CHEST DISCOMFORT (Chest tightness) (seriousness criteria disability and medically significant). On 20-Dec-2021, the patient experienced CHILLS (Rigors) (seriousness criteria disability and medically significant), PERIPHERAL COLDNESS (Cold extremities) (seriousness criteria disability and medically significant), TREMOR (Shaking) (seriousness criteria disability and medically significant) and PALLOR (Pallor) (seriousness criteria disability and medically significant). On 23-Dec-2021, the patient experienced PRESYNCOPE (Light headed, pre-syncope, close to backout / fainting, dizzy) (seriousness criteria disability and medically significant)and DIZZINESS (Dizziness) (seriousness criteria disability and medically significant). On 26-Dec-2021, the patient experienced PALPITATIONS (Palpitations) (seriousness criteria disability and medically significant). On 28-Dec-2021, the patient experienced SNEEZING (Sneezing) (seriousness criteria disability and medically significant). On 29-Dec-2021, the patient experienced MUSCULAR WEAKNESS (Weakness of arms) (seriousness criteria disability and medically significant) and ERYTHEMA (Redness of external ear) (seriousness criteria disability and medically significant). On 30-Dec-2021, the patient experienced FEELING ABNORMAL (Brain pains, brain pressure and brain fog) (seriousness criteria disability and medically significant), HEADACHE (Brain pains, brain pressure and brain fog) (seriousness criteria disability and medically significant), HEAD DISCOMFORT (Brain pains, brain pressure and brain fog) (seriousness criteria disability and medically significant) and BACK PAIN (Back pain) (seriousness criteria disability and medically significant). On 31-Dec-2021, the patient experienced LYMPHADENOPATHY (Gland in neck) (seriousness criteria disability and medically significant). On 01-Jan-2022, the patient experienced THIRST (Thirst) (seriousness criteria disability and medically significant), NAUSEA (Nausea) (seriousness criteria disability and medically significant), ABDOMINAL PAIN UPPER (Stomach cramps) (seriousness criteria disability and medically significant), CHEST PAIN (Chest pain) (seriousness criteria disability and medically significant) and ANGINA PECTORIS (Cardiac pain) (seriousness criteria disability and medically significant). On 02-Jan-2022, the patient experienced THROAT TIGHTNESS (Throat tightening and throat spasms) (seriousness criteria disability and medically significant). On 05-Jan-2022, the patient experienced PAIN IN EXTREMITY (Leg pain) (seriousness criteria disability and medically significant). On 15-Jan-2022, the patient experienced COGNITIVE DISORDER (Cognitive impairment) (seriousness criteria disability and medically significant). On 16-Jan-2022, the patient experienced INNER EAR INFLAMMATION (Inner ear inflammation) (seriousness criteria disability and medically significant). On an unknown date, the patient experienced ABDOMINAL DISCOMFORT (Gastrointestinal upset) (seriousness criteria disability and medically significant). The patient was treated with OMEPRAZOLE ongoing from 15-Jan-2022 for Upset stomach, at a dose of 20 milligram once a day. At the time of the report, AUTONOMIC NERVOUS SYSTEM IMBALANCE (Dysautonomia), DYSPNOEA (Shortness of breath and breathing difficulties), THROAT TIGHTNESS (Throat tightening and throat spasms), FEELING ABNORMAL (Brain pains, brain pressure and brain fog), SPINAL PAIN (Spinal cord pains), NECK PAIN (Neck pains), PRESYNCOPE (Light headed, pre-syncope, close to backout / fainting, dizzy), | | |

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| | COGNITIVE DISORDER (Cognitive impairment), HEADACHE (Brain pains, brain pressure and brain fog) and HEAD DISCOMFORT (Brain pains, brain pressure and brain fog) had not resolved, CARDITIS (Inflammed heart) had resolved with sequelae and GAIT DISTURBANCE (Difficulty in walking), CHILLS (Rigors), PERIPHERAL COLDNESS (Cold extremities), CHEST DISCOMFORT (Chest tightness), SNEEZING (Sneezing), MUSCULAR WEAKNESS (Weakness of arms), ERYTHEMA (Redness of external ear), THIRST (Thirst), NAUSEA (Nausea), PAIN IN EXTREMITY (Leg pain), INNER EAR INFLAMMATION (Inner ear inflammation), TREMOR (Shaking), PALLOR (Pallor), DIZZINESS (Dizziness), PALPITATIONS (Palpitations), BACK PAIN (Back pain), LYMPHADENOPATHY (Gland in neck), ABDOMINAL PAIN UPPER (Stomach cramps), CHEST PAIN (Chest pain), ANGINA PECTORIS (Cardiac pain) and ABDOMINAL DISCOMFORT (Gastrointestinal upset) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 30-Dec-2021, SARS-CoV-2 test: negative (Negative) Test Result: Negative.<br>On 31-Dec-2021, SARS-CoV-2 test: negative (Negative) Test Result: Negative.<br>On 04-Jan-2022, Electrocardiogram: normal (normal) Test Result: Normal.<br>On 19-Jan-2022, SARS-CoV-2 test: negative (Negative) Test Result: Negative.<br>On 21-Jan-2022, SARS-CoV-2 test: negative (Negative) Test Result: Negative.<br><br>Company Comment: This is a regulatory case concerning a 31-year-old male patient with relevant medical history of Post-COVID Dysautonomia, bone disorder and muscle disorder, who experienced the unexpected serious (disability, medically significant) events of Autonomic nervous system imbalance, Carditis, Dyspnoea, Throat tightness, Feeling abnormal, Spinal pain, Neck pain, Presyncope, Cognitive disorder, Headache, Head discomfort, Gait disturbance, Chills (reported as chills and | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 26-Apr-2022 and was forwarded to Moderna on 26-Apr-2022.<br><br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Acute unspecified pericarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018J21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 25-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 30-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Acute unspecified pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Acute unspecified pericarditis) was resolving.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 25-Jan-2022.<br><br>No concomitant medications were reported.<br>The patient received third dose of mRNA-1273 (Spikevax) on left arm. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | No treatment medications were reported.<br><br>Company comment: This regulatory case concerns a 34-year-old, male patient with no medical history reported, who experienced the expected, serious medically significant AESI of pericarditis. The event occurred 5 days after the administration of a booster dose of mRNA-1273 vaccine, reported as third dose of his COVID-19 immunization schedules. The report stated that the patient experienced acute unspecified pericarditis. No further details such as electrocardiogram, myocardial biomarkers, or imaging study diagnosis tests were provided for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022.<br>This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDITIS (Vaccine-induced Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214012) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Product used for unknown indication: Comirnaty on 22-May-2021 and Comirnaty on 03-Jul-2021.<br>Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.<br><br>On 02-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Jan-2022, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 24-Jan-2022, the patient experienced MYOCARDITIS (Vaccine-induced Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Vaccine-induced Myocarditis) was resolving and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 24-Jan-2022, Blood creatine phosphokinase MB: 1,7 1,7 ng/ml.<br>On 24-Jan-2022, Chest X-ray normal: unaffected unaffected.<br>On 24-Jan-2022, Echocardiogram: unaffected unaffected.<br>On 24-Jan-2022, Fibrin D dimer: < 0,19 < 0,19 mg/l.<br>On 24-Jan-2022, N-terminal prohormone brain natriuretic peptide: <35 <35 ng/l.<br>On 24-Jan-2022, Troponin I: 69,4 69,4 ng/l.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br>Treatment medication was not provided by the reporter. | Not a case of myocarditis. All values except troponing were within normal levels. EKG was "unaffected" | [redacted] |

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| | Company Comment: This is a Regulatory Authority case concerning a 23-year-old male patient, with no medical history reported, who experienced the expected, serious (due to hospitalization) and AESI of Myocarditis. The event occurred 22 days after the third dose of mRNA-1273 vaccine, and at the time of the report it was resolving. Various tests were performed: blood creatine phosphokinase MB: 1,7ng/ml, chest x-ray normal, echocardiogram unaffected, fibrin D dimer less than 0,19, troponin I: 69,4ng/l. Primary vaccination completed with Pfizer vaccine; hence, Revaccination with different COVID-19 vaccine was also reported, and remains as a confounding factor for Myocarditis. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Apr-2022: Translation document received on 29-Apr-2022 with no new significant medical information. | | |
| [redacted] | This case was initially received via [redacted] (Reference number: [redacted] on 28-Apr-2022. The most recent information was received on 29-Apr-2022 and was forwarded to Moderna on 29-Apr-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of ABDOMINAL PAIN UPPER (epigastric pain), DIZZINESS (dizziness), MYOPERICARDITIS (Perimyocarditis), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea) and PALPITATIONS (Palpitations) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>Patient has not had symptoms associated with COVID-19.<br>Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination.<br><br>On 26-Apr-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 27-Apr-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOPERICARDITIS (Perimyocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced ABDOMINAL PAIN UPPER (epigastric pain) (seriousness criterion medically significant), DIZZINESS (dizziness) (seriousness criterion medically significant), CHEST PAIN (Chest Pain) (seriousness criterion medically significant), DYSPNOEA (Dyspnoea) (seriousness criterion medically significant) and PALPITATIONS (Palpitations) (seriousness criterion medically significant). At the time of the report, ABDOMINAL PAIN UPPER (epigastric pain), DIZZINESS (dizziness), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea) and PALPITATIONS (Palpitations) outcome was unknown and MYOPERICARDITIS (Perimyocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 27-Apr-2022, Troponin: not provided not provided.<br>On an unknown date, Electrocardiogram: sinus rhythm Sinus rhythm. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | On an unknown date, SARS-CoV-2 test: no- negative covid-19 test (Negative) No- Negative COVID-19 test.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient had Moderna covid vaccine booster on the 26-Apr-2022. Presented to the ED (emergency department) with central and epigastric pain with associated shortness of breath, palpitations and dizziness.<br><br>Unsure if patient was enrolled in clinical trial.<br><br>The report did not relate to possible blood clots or low platelet counts. The report relate to possible myocarditis or pericarditis: Myocarditis and pericarditis. The patient was not admitted to the hospital. The patient was not seen by a cardiologist.<br><br>A chest X-ray was not performed. An echocardiogram was not carried out. A chest computed tomography was not carried out. A cardiac MRI was not carried out. A cardiac biopsy was not performed. A coronary angiography was not carried out.<br><br>There was no presence of pericardial rub, or changes in heart sounds. The patient was not asymptomatic. There were no signs of a systemic disease that may be responsible for the presentation.<br><br>Company Comment:<br>This regulatory case concerns a 29-year-old, male patient with no reported medical history, who experienced the unexpected, serious (Medically significant) events of Abdominal pain upper, Dizziness, Chest pain, Dyspnoea and Palpitations and expected, serious (Medically significant) event of Myopericarditis. The event Myopericarditis occurred 1 day after administration of third dose of mRNA-1273. The date of onset of the events Abdominal pain upper, Dizziness, Chest pain, Dyspnoea and Palpitations was not specified in respect to the administration of third dose of mRNA-1273, hence latency could not be assessed. The patient was previously administered with Pfizer, the dose and date of administration was not specified. Patient was brought to the emergency room due to chest pain, dizziness, shortness of breath and abdominal pain. Troponin was done with unknown result, Electrocardiogram was done with result of sinus rhythm and SARS-CoV-2 test was done with negative result. The benefit-risk relationship of mRNA-1273 is not<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Apr-2022: Follow-up information appended: Seriousness updated for the events, concomitant drug indication updated and Suspect drug's action taken was updated from unknown to not applicable. Event pericardial rub and shortness of breath was deleted. | | |

| Case ID | Narrative | MAH Comment | WW Identifier |
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| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of INFLUENZA LIKE ILLNESS (heart muscle inflammation, dizziness, fever, chills, hot flashes, headache, muscle pain), CHILLS (Chills), FATIGUE (Fatigue), MYALGIA (Myalgia), ARRHYTHMIA (heart muscle inflammation, dizziness, fever, chills, hot flashes, headache, muscle pain), FEELING HOT (Feeling hot), TACHYCARDIA (Tachycardia), MYOCARDITIS (myocardium inflammation) and PARAESTHESIA (Paresthesia) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214015 and 000077A) for COVID-19 vaccination.<br><br>Co-suspect product included non-company product COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (COVID-19 VACCINE JANSSEN) for Prophylactic vaccination.<br><br>Concurrent medical conditions included Pollen allergy (Various pollen allergies such as Rye, Wheat, birch etc. known and confirmed since birth since the age of 16. be tested annually - status MAR-2022), Asthma and Depression.<br>Concomitant products included CORTISONE for Allergy, PAROXETINE for Depression, PANTOPRAZOLE for an unknown indication.<br><br>On 16-Jul-2021, the patient received dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (COVID-19 VACCINE JANSSEN) (unknown route) 1 dosage form.<br>On 04-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 28-Feb-2022, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 16-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYALGIA (Myalgia) (seriousness criterion hospitalization). On 17-Jul-2021, the patient experienced CHILLS (Chills) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization) and FEELING HOT (Feeling hot) (seriousness criterion hospitalization). On 05-Dec-2021, the patient experienced INFLUENZA LIKE ILLNESS (heart muscle inflammation, dizziness, fever, chills, hot flashes, headache, muscle pain) (seriousness criterion hospitalization), ARRHYTHMIA (heart muscle inflammation, dizziness, fever, chills, hot flashes, headache, muscle pain) (seriousness criterion hospitalization) and TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization). On 07-Mar-2022, the patient experienced MYOCARDITIS (myocardium inflammation) (seriousness criterion hospitalization) and PARAESTHESIA (Paresthesia) (seriousness criterion hospitalization). At the time of the report, INFLUENZA LIKE ILLNESS (heart muscle inflammation, dizziness, fever, chills, hot flashes, headache, muscle pain), FATIGUE (Fatigue), ARRHYTHMIA (heart muscle inflammation, dizziness, fever, chills, hot flashes, headache, muscle pain), FEELING HOT (Feeling hot) and TACHYCARDIA (Tachycardia) had resolved with sequelae and CHILLS (Chills), MYALGIA (Myalgia), MYOCARDITIS (myocardium inflammation) and PARAESTHESIA (Paresthesia) outcome was unknown. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Other concomitant medication included VianiForte (daily intake of two strokes VianiForte 25ug/ 250ug) for Asthma.<br><br>After appearance of Side effects with First vaccination patient consulted physician and it was reported that vaccination side effect according to physician were possible. Second vaccination after which the side effects occurred and physician was consulted, vaccination side effect according to physician were likely. Massive side effects occurred after Third vaccination and physician was consulted, vaccination side effect clearly confirmed by the physician including heart muscle inflammation, further complaints are no longer ruled out and permanent medical treatment was required.<br>No treatment information was provided by the reporter.<br>Company comment: This Regulatory Authority case concerns a 34-year-old, male patient, with no relevant medical history, who experienced the unexpected, serious (hospitalization) events of Influenza like illness, tachycardia and AESI of arrhythmia one day after receiving a dose, considered as the second dose of his COVID-19 vaccination schedule, as he previously received a dose of Janssen's COVID-19 vaccine and experienced in that context the events of chills, fatigue and feeling hot, that apparently led to hospitalization as well. After receiving a dose of mRNA-1273 vaccine, considered as the third dose of his vaccination schedule, he developed unexpected, serious (Hospitalization) event of paraesthesia and expected, serious (Hospitalization) AESI of Myocarditis 7 days. No further clinical information was provided for medical reviewing. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness criteria of hospitalization was captured for all reported events according to Regulatory Authority assessment, however; there was no information provided on hospitalization dates, clinical course and/or discharge summary. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (pericarditis - pericarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 10-Jun-2021 and Comirnaty BNT162b2 on 22-Jul-2021.<br>Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.<br><br>On 16-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (pericarditis - pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (pericarditis - pericarditis) had not resolved.<br><br>No information on risk factors or pre-existing conditions No severe chest pain and increased heartbeat occurrence. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | Concomitant medications details were not reported by the reporter.<br>Third day after third vaccination. Pain persists until this day.<br>Treatment details was not reported by the reporter.<br><br>Company Comment:<br>This regulatory authority case concerns a 24-year-old male patient, with previous vaccinations of Comirnaty BNT162b2, who experienced the expected serious (medically significant) AESI of Pericarditis. The event occurred approximately 4 days after receiving the third dose of mRNA-1273 Vaccine (Primary doses - Comirnaty). No information on risk factors or pre-existing conditions and no severe chest pain and increased heartbeat occurrence were reported. The concomitant and treatment medications were not provided. The outcome of the event was reported as not resolved. The patient's medical history of previous vaccinations of Comirnaty BNT162b2, remain as confounders for the occurrence of the events. Event seriousness assessed as per Regulatory Authority report. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (myocardium inflammation) in a 33-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 17-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jun-2021, the patient experienced MYOCARDITIS (myocardium inflammation) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (myocardium inflammation) outcome was unknown.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information provided.<br><br>Company Comment: This is a regulatory case concerning a 33-year-old male patient with no reported medical history, who was hospitalized due to the expected serious adverse event of special interest of Myocarditis, 4 days after receiving a dose of mRNA-1273 vaccine. Clinical course, diagnostics tests and treatment details were not provided in the case. The outcome of the event was unknown at the time of the report. It should be noted that the dose was reported as second dose of COVID-19 vaccine however, there was no information regarding the first dose of COVID-19 vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event retained as serious as per Regulatory Authority. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. | Lack of information in the case, particularly diagnostic exam results. | [redacted] |

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| | This regulatory authority case was reported by a consumer and describes the occurrence of MALAISE (Faintness), DYSPNOEA (Problem breathing during physical exertion), NAUSEA (Nausea), SKIN DISORDER (Skin Problem), CHILLS (Chills), INJECTION SITE REACTION (Reaction at the injection site), PALPITATIONS (Heart palpitations), PYREXIA (Fever), HEADACHE (Headache), ARTHRALGIA (Joint pain), COVID-19 IMMUNISATION (Covid revaccination with a different vaccine), MYOCARDITIS (Myocardite), MYALGIA (Muscle pain), EXTENSIVE SWELLING OF VACCINATED LIMB (Extensive swelling of the arm), AXILLARY MASS (Appearance of a huge node under the arm), VOMITING (Vomiting) and FATIGUE (Fatigue) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000057A) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 immunisation: COMIRNATY on 21-Sep-2021 and Comirnaty on 12-Oct-2021.<br>Past adverse reactions to the above products included No adverse event with COMIRNATY and Comirnaty.<br><br>On 04-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Feb-2022, the patient experienced MALAISE (Faintness) (seriousness criterion life threatening), DYSPNOEA (Problem breathing during physical exertion) (seriousness criterion life threatening), NAUSEA (Nausea) (seriousness criterion life threatening), SKIN DISORDER (Skin Problem) (seriousness criterion life threatening), CHILLS (Chills) (seriousness criterion life threatening), INJECTION SITE REACTION (Reaction at the injection site) (seriousness criterion life threatening), PALPITATIONS (Heart palpitations) (seriousness criterion life threatening), PYREXIA (Fever) (seriousness criterion life threatening), HEADACHE (Headache) (seriousness criterion life threatening), ARTHRALGIA (Joint pain) (seriousness criterion life threatening), COVID-19 IMMUNISATION (Covid revaccination with a different vaccine) (seriousness criterion life threatening), MYOCARDITIS (Myocardite) (seriousness criterion life threatening), MYALGIA (Muscle pain) (seriousness criterion life threatening), EXTENSIVE SWELLING OF VACCINATED LIMB (Extensive swelling of the arm) (seriousness criterion life threatening), AXILLARY MASS (Appearance of a huge node under the arm) (seriousness criterion life threatening), VOMITING (Vomiting) (seriousness criterion life threatening) and FATIGUE (Fatigue) (seriousness criterion life threatening). On 04-Mar-2022, MALAISE (Faintness), DYSPNOEA (Problem breathing during physical exertion), NAUSEA (Nausea), SKIN DISORDER (Skin Problem), CHILLS (Chills), INJECTION SITE REACTION (Reaction at the injection site), PALPITATIONS (Heart palpitations), PYREXIA (Fever), HEADACHE (Headache), ARTHRALGIA (Joint pain), COVID-19 IMMUNISATION (Covid revaccination with a different vaccine), MYOCARDITIS (Myocardite), MYALGIA (Muscle pain), EXTENSIVE SWELLING OF VACCINATED LIMB (Extensive swelling of the arm), AXILLARY MASS (Appearance of a huge node under the arm), VOMITING (Vomiting) and FATIGUE (Fatigue) had resolved with sequelae.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): | | |

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| | In February 2022, Specialist consultation: not reported Not reported.<br><br>Patient had treated with Analgesics and Antibiotics (not specified).<br>It was reported as choice of incorrect vaccine Other include too many doses examination.<br>Patient also had epicarditis.<br>Concomitant medications were not reported.<br>Company comment<br>This regulatory authority case concerns a 34-year-old male patient, with no reported relevant medical history, who experienced the unexpected serious (life threatening) AESI of MYOCARDITIS, and the unexpected serious (life threatening) events of MALAISE, DYSPNOEA, NAUSEA, SKIN DISORDER, CHILLS, INJECTION SITE REACTION, PALPITATIONS, PYREXIA, HEADACHE, ARTHRALGIA, MYALGIA, EXTENSIVE SWELLING OF VACCINATED LIMB, AXILLARY MASS , VOMITING and FATIGUE, which occurred on the same day after receiving a dose of mRNA-1273 vaccine, considered as the third dose for COVID19 vaccination (Received Comirnaty as doses 1 and 2, Covid revaccination with a different vaccine). Patient also had epicarditis. Patient was treated with Analgesics and Antibiotics (not specified). Approximately 1 month later, events had resolved with sequelae. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Apr-2022: Follow-up information included Updated event verbatim from Malaise to Faintness, from Palpitations cardiaques to heart palpitations. | | |
| [redacted] | This case was received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (KH: Myocarditis detected), CHEST DISCOMFORT (slight pressure on chest left KH -not tightened, got better but continued to slack, without energy) and CHEST PAIN (significantly worse persistent pain left chest) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214012) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for COVID-19 vaccination: Comirnaty in 2021 and Comirnaty in 2021.<br>Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.<br><br>On 02-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Jan-2022, the patient experienced FATIGUE (slight pressure on chest left KH -not tightened, got better but continued to slack, without energy) and CHEST DISCOMFORT (slight pressure on chest left KH -not tightened, got better but continued to slack, without energy) (seriousness criterion hospitalization). On 20-Jan-2022, the patient | Lack of information in the case, particularly diagnostic exam results. | [redacted] |