

20.11.17. Pregnancy: Summary of reported congenital anomalies by HLT and PT that occurred in fetuses and neonates

Appendix 9 C – Congenital Anomalies Reported in Fetuses/Neonates, Cumulative

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Autosomal chromosomal abnormalities	Trisomy 22	4.1(b)	4 wks	unlikely	32-year-old woman vaccinated, with history of a D&C, vaccinated with Dose 1 of SPIKEVAX at 4 weeks GA, and the fetus was diagnosed with Fallot's tetralogy and Trisomy 22 and she had an 4.1(b) at 24 weeks of gestation (reason for termination: Trisomy 22). Given that the mother was vaccinated at 4 weeks GA, causality is unlikely. 4.1(b) (Parent-Child Link)
Cardiac septal defects congenital	Atrial septal defect		unknown	unassessable	Very limited information, mother used alcohol, 4.1(b) and Zoloft while pregnant, neonate born with hereditary hemolytic anemia and atrial septal defect
Cardiac septal defects congenital	Atrial septal defect		27, 31 wks	unlikely	Newborn female (maternal Spikevax immunization at 27- and 31-weeks gestation) had abnormal heart rate, atrial septal defect, ventricular septal defect and Patent ductus arteriosus diagnosed on the day of delivery at 38 weeks. The events occurred 51 days after the second dose of mRNA-1273. Limited information. Given the GA at the time of vaccination, it is unlikely that the vaccine contributed to the cardiac congenital anomalies.
Cardiac septal defects congenital	Atrial septal defect		unknown	unassessable	35-year-old woman was vaccinated at an unknown gestational age, and had fetal arrhythmia, atrial septal defect, eyelid ptosis congenital, 4.1(b) syndrome and kidney duplex diagnosed approximately 58 days after unspecified dose of SPIKEVAX. Given that the gestational age of vaccination is not reported, causality for the congenital anomalies is unassessable.
Cardiac septal defects congenital	Ventricular septal defect		Peri-conception, about 4-5 weeks	yes	29-year-old female vaccinated periconceptionally and around 4-5 weeks GA, had a fetus diagnosed with multiple congenital anomalies including exomphalos. 4.1(b). Given the GA at the time of vaccination and fetal development, causality is possible.
Cardiac septal defects congenital	Ventricular septal defect		27, 31	unlikely	Newborn female (maternal Spikevax immunization at 27- and 31-weeks gestation) had abnormal heart rate, atrial septal defect, ventricular septal defect and Patent ductus arteriosus diagnosed on the day of delivery at 38 weeks. The events occurred 51 days after the second dose of mRNA-1273. Limited information. Given the GA at the time of

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
					vaccination, it is unlikely that the vaccine contributed to the cardiac congenital anomalies.
Cardiac septal defects congenital	Ventricular septal defect	4.1(b)	paternal exposure	unlikely	regulatory case concerning a newborn female baby, with no medical history, who experienced the unexpected serious events of Ventricular septal defect and Paternal exposure before pregnancy. The event onset latency period with respect to the last dose, the dosage details and schedule of vaccination dates are not reported. Clinical details of the event ventricular septal defect is not reported.
Cerebral disorders congenital	Anencephaly	4.1(b)	6 wks GA	possible	29-year-old, female patient (primigravida), was 6 weeks gestation when she received second dose of SPIKEVAC, at 12 weeks, 6/7 days of gestation, the patient was diagnosed with Fetal Anencephaly, for what she was induced at 13 weeks gestation, as this condition is 100% lethal to the fetus. Fetal anencephaly results from failure of the neural tube closure between 25 and 27 days after conception, thus causality is possible given GA at time of vaccination.
Chromosomal abnormalities NEC	Cytogenetic abnormality	4.1(b)	unknown	unlikely	32 year-old female, with history of West Nile disease and subchorionic hemorrhage in previous pregnancy, current twin pregnancy patient had a spontaneous abortion (11 weeks GA), cytogenetic abnormality or twin-twin transfusion , with placental transfusion syndrome and subchorionic hemorrhage, 54 days after the second vaccination, and 79 days after the first vaccination. Given the time to onset, and course of events, and the alternate etiologies of genetic abnormalities, vaccine causation is unlikely.
Chromosomal abnormalities NEC	Cytogenetic abnormality	4.1(b)	8-10 weeks	unlikely	Fetal case, exposed via maternal immunization around 8-10 weeks GA, had multiple abnormalities including an increased nuchal translucency of 3.5 mm, absent nasal bone, and presence of fluid around the fetus's abdomen diagnosed 20 days after vaccination. . These abnormalities were concerning for a chromosomal/genetic abnormality. Causality is unlikely given multiple congenital abnormalities, and GA (9-10 weeks) age at time of vaccination.

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Chromosomal abnormalities NEC	Foetal chromosome abnormality	4.1(b)	peri-conception	possible	A woman of unknown age was vaccinated "three weeks before pregnancy", the fetus was diagnosed with gonadal dysgenesis (missing one X chromosome), and the fetus had no heartbeat at gestational age 18 weeks and 4 days. Given the vaccination occurred possibly around the time of conception, causality cannot be excluded.
Chromosomal abnormalities NEC	Foetal chromosome abnormality		periconception, about 4-5 weeks	unlikely	37-year-old female with two prior live births, received VAXZEVRIA, at an unknown interval was boosted with SPIKEVAX prior to pregnancy (approximately 1 week prior to LMP), reports diagnosis of congenital anomaly in the fetus that died in utero at 17 weeks GA. Although, age and previous VAXZEVRIA vaccination are confounders, and noting that vaccination was prior to LMP and conception, the congenital anomaly (Turner's syndrome) and resulting fetal death is unlikely caused to vaccination.
Congenital disorders NEC	Congenital anomaly		3-4 weeks GA	possible	Female of unknown age, with history of two previous healthy pregnancies, was vaccinated at 3-4 weeks GA, had an inconclusive prenatal ultrasound at gestational age 11 weeks 5 days, detected a high nuchal translucency and potential cystic hygroma. Given the GA at the time of vaccination, causality is possible.
Congenital disorders NEC	Conjoined twins		unknown	unassessable	31 year-old-female on oral contraceptives and became pregnant, was vaccinated at an unknown gestational age, and had conjoined twins detected at 9 weeks GA. Limited information including missing GA at time of vaccination, thus causality is unassessable.
Congenital disorders NEC	Conjoined twins		periconception	possible	31 year-old-female on oral contraceptives and became pregnant, based on EDD and vaccination, was vaccinated around the time of conception, and had conjoined twins detected at 9 weeks GA. Given GA at time of vaccination, causality is possible.
Congenital disorders NEC	Foetal malformation		unknown	unassessable	4.1(b) because of fetal malformations. Limited information about vaccination date, onset/diagnosis date and specificities of the congenital anomalies. Unable to assess.

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Congenital disorders NEC	Multiple congenital abnormalities	4.1(b)	4-5 weeks	possible	29-year-old female vaccinated periconceptionally and around 4-5 weeks GA, had a fetus diagnosed with multiple congenital anomalies including exomphalos. 4.1(b). Given the GA at the time of vaccination and fetal development, causality is possible.
Congenital disorders NEC	Multiple congenital abnormalities		8-10 weeks	unlikely, given multiple congenital abnormalities, and GA age of vx at 9-10 weeks	Fetal case, exposed via maternal immunization around 8-10 weeks GA, had multiple abnormalities including an increased nuchal translucency of 3.5 mm, absent nasal bone, and presence of fluid around the fetus's abdomen diagnosed 20 days after vaccination. These abnormalities were concerning for a chromosomal/genetic abnormality. Causality is unlikely given multiple congenital abnormalities, and GA (9-10 weeks) age at time of vaccination.
Eyelid disorders congenital	Eyelid ptosis congenital		unknown	unassessable	35-year-old woman was vaccinated at an unknown gestational age, and had fetal arrhythmia, atrial septal defect, eyelid ptosis congenital, 4.1(b) syndrome and kidney duplex diagnosed approximately 58 days after unspecified dose of SPIKEVAX. Given that the gestational age of vaccination is not reported, causality for the congenital anomalies is unassessable.
Eyelid disorders congenital	4.1(b) syndrome		unknown	unassessable	35-year-old woman was vaccinated at an unknown gestational age, and had fetal arrhythmia, atrial septal defect, eyelid ptosis congenital, 4.1(b) syndrome and kidney duplex diagnosed approximately 58 days after unspecified dose of SPIKEVAX. Given that the gestational age of vaccination is not reported, causality for the congenital anomalies is unassessable.
Gastrointestinal tract disorders congenital NEC	Exomphalos		periconception	possible	29-year-old female vaccinated periconceptionally and around 4-5 weeks GA, had a fetus diagnosed with multiple congenital anomalies including exomphalos. 4.1(b). Given the GA at the time of vaccination and fetal development, causality is possible.

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Gastrointestinal tract disorders congenital NEC	Exomphalos	4.1(b)	unknown	unassessable	Mother received Moderna dose (at perhaps 8 weeks GA?, data are unclear) and then Pfizer dose, date unknown; and it was noted that the father was vaccinated 2 days prior to conception -- an abnormal fetal ultrasound detected kyphoscoliosis and exomphalos at 18 weeks gestational age. Unassessable as GA of exposure (relative to conception and fetal development unknown). If Q21the mRNA-1273 occurred between weeks 6-10 of pregnancy, during which time the fetal intestines are developing, causality cannot be excluded; "limb-body wall complex (multiple severe congenital anomalies) was also described. There is limited and conflicting data in the report which limits assessment. No information was provided about fetal genetic tests.
Gastrointestinal tract disorders congenital NEC	Gastroschisis	4.1(b)	unknown	unassessable	Very limited information, gastroschisis reported, but unknown GA at time of vaccination, unable to assess
Great vessel disorders congenital	Transposition of the great vessels		3-4 weeks	possible	Fetal exposure via maternal vaccination at approximately 3-4 weeks GA, and fetus was diagnosed with Transposition of the Great Vessels and Tricuspid Valve Incompetence approximately 161 days later. Given the timing of vaccination, early in embryonic development, causality is possible.
Haemoglobinopathies congenital	Haemoglobinopathy		32 weeks GA	possible	Newborn, male (premature delivery), who had jaundice and hemoglobinopathy. The event Jaundice occurred within first days of life, exact onset date of haemoglobinopathy but occurred within the 1st month of life. Mother received the first dose of vaccine at 32 weeks of gestation. Causality cannot be excluded.
Laryngeal and tracheal disorders congenital	Laryngomalacia		18 weeks GA	unlikely, given background rate of	Parent case. 4.1(b) (Parent-Child Link)

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Laryngeal and tracheal disorders congenital	Laryngomalacia	4.1(b)	21 and 25 weeks GA	laryngomalacia, and lack of biological mechanism of cation	Laryngomalacia in newborn, mother vaccinated at 21- and 25-weeks GA, unlikely causality given background rate of laryngomalacia, and lack of biological mechanism of cation. Possible duplicate of 4.1(b)
Laryngeal and tracheal disorders congenital	Laryngomalacia		22 and 25 weeks GA	mechanism of cation	Laryngomalacia in newborn, mother vaccinated at 21- and 25-weeks GA, unlikely causality given background rate of laryngomalacia, and lack of biological mechanism of cation. Possible duplicate of 4.1(b)
Laryngeal and tracheal disorders congenital	Laryngomalacia		unknown	unassessable	Laryngomalacia in newborn, unknown GA at time of vaccination, unlikely causality given background rate of laryngomalacia, and lack of biological mechanism of cation 4.1(b) (Parent-Child Link).
Laryngeal and tracheal disorders congenital	Tracheo-oesophageal fistula		15-16 weeks	unlikely, given GA at vs, and polyhydramnios predated vaccination	36-year-old female vaccinated with Dose 2 of SPIKEVAX at approximately 15-16 weeks GA, had a premature delivery 101 days after vaccination. The neonate had esophageal atresia, Tracheo-oesophageal fistula. The neonate had surgery to correct both fetal anomalies one day after being born. Given the GA at the time of vaccination after embryonic and fetal development of the esophagus (approximately at 7 weeks GA), causality is unlikely, and polyhydramnios was present before vaccination.
Male reproductive tract disorders congenital	Hydrocele		13+ and 17+ weeks GA	Unlikely	Female of unknown age with history of hypertension, gestational diabetes and asthma, delivered macrosomic neonate with umbilical hernia and hydrocele and was admitted to the NICU with hypoglycemia. Confounded by the gestational diabetes and hypertension, and considering the GA of the vaccination, the background rates of these events, causality is unlikely.
Multiple cardiac abnormalities congenital	Fallot's tetralogy		4 weeks GA	possible	32-year-old woman vaccinated, with history of a D&C, vaccinated with Dose 1 of SPIKEVAX at 4 weeks GA, and the fetus was diagnosed with Fallot's tetralogy and Trisomy 22 and she had an 4.1(b) at 24 weeks of gestation (reason for termination: Trisomy 22). Given that the mother was vaccinated at 4 weeks GA, causality is possible. 4.1(b) (Parent-Child Link)

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	Cleft lip	4.1(b)	second dose periconceptional	possible, confounded	Woman taking amphetamine and dexamphetamine, which is associated with cleft palate which was diagnosed in the fetus 129 days after vaccination, received second dose around the time of conception, and thus causality cannot be excluded although amphetamines use for treatment of ADD is a strong confounding factor/alternate etiology.
Musculoskeletal and connective tissue disorders of limbs congenital	Limb malformation		8-10 weeks	unlikely, given multiple congenital abnormalities, and GA age of vx at 9-10 weeks	Fetal case, exposed via maternal immunization around 8-10 weeks GA, had multiple abnormalities including an increased nuchal translucency of 3.5 mm, absent nasal bone, and presence of fluid around the fetus's abdomen diagnosed 20 days after vaccination. . These abnormalities were concerning for a chromosomal/genetic abnormality. Causality is unlikely given multiple congenital abnormalities, and GA (9-10 weeks) age at time of vaccination.
Musculoskeletal and connective tissue disorders of skull congenital	Microcephaly		14 and 18 weeks	unlikely	Neonate exposed to maternal vaccination at 14 and 18 weeks, was found to have a genetic abnormality and microcephaly. Given the GA at vaccination, unlikely related
Nasal disorders congenital	Congenital nose malformation		8-10 weeks	unlikely	Fetal case, exposed via maternal immunization around 8-10 weeks GA, had multiple abnormalities including an increased nuchal translucency of 3.5 mm, absent nasal bone, and presence of fluid around the fetus's abdomen diagnosed 20 days after vaccination. These abnormalities were concerning for a chromosomal/genetic abnormality. Causality is unlikely given multiple congenital abnormalities, and GA (9-10 weeks) age at time of vaccination.
Ocular disorders congenital NEC	Coloboma		late 1st trimester and early second trimester	possible	A male newborn with no reported relevant medical history, whose mother received two doses of SPIKEVAX vaccines during approximately the late first trimester and early second trimester. The newborn was diagnosed with coloboma of the left iris at birth, 152 days after maternal receipt of second dose. Given temporal association, causality is possible.

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Oesophageal disorders congenital	Oesophageal atresia	4.1(b)	15-16 weeks	unlikely	36-year-old female vaccinated with Dose 2 of SPIKEVAX at approximately 15-16 weeks GA, had a premature delivery 101 days after vaccination. The neonate had esophageal atresia, Tracheo-oesophageal fistula. The neonate had surgery to correct both fetal anomalies one day after being born. Given the GA at the time of vaccination after embryonic and fetal development of the esophagus (approximately at 7 weeks GA), causality is unlikely, and polyhydramnios was present before vaccination.. causality is unlikely
Oral cavity disorders congenital NEC	Cleft uvula		unknown	unassessable	Neonate with maternal exposure at unknown gestational age, had cleft palate, cleft uvula, and cardiac dysfunction. Limited information. Unassessable.
Palate disorders congenital	Cleft palate		unknown	unassessable	Neonate with maternal exposure at unknown gestational age, had cleft palate, cleft uvula, and cardiac dysfunction. Limited information. Unassessable.
Palate disorders congenital	Cleft palate		second dose periconceptional	possible, confounded	Woman taking amphetamine and dexamphetamine, which is associated with cleft palate which was diagnosed in the fetus 129 days after vaccination, received second dose around the time of conception, and thus causality cannot be excluded although amphetamines use for treatment of ADD is a strong confounding factor/alternate etiology.
Persistent foetal circulation disorders	Patent ductus arteriosus		unknown	unassessable	Maternal history of depression and anxiety on bupropion, clonidine, and venlafaxine hydrochloride, was vaccinated at an unknown GA. The neonate was born with a patent ductus arteriosus. Confounded by the psychiatric medications. Given the unknown GA of vaccination, unassessable.
Persistent foetal circulation disorders	Patent ductus arteriosus		27 and 31 weeks GA	unlikely	Newborn female (maternal Spikevax immunization at 27- and 31-weeks gestation) had abnormal heart rate, atrial septal defect, ventricular septal defect and Patent ductus arteriosus diagnosed on the day of delivery at 38 weeks. The events occurred 51 days after the second dose of mRNA-1273. Limited information. Given the GA at the time of vaccination, it is unlikely that the vaccine contributed to the cardiac congenital anomalies.

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Renal and urinary tract disorders congenital NEC	Congenital hydronephrosis	4.1(b)	unknown	unassessable	Limited information, no GA at time of vaccination, no information TTO to delivery. Neonate had hyperbilirubinemia, hypoglycemia, and hypoxia. Cannot assess due to lack of information.
Renal disorders congenital	Kidney duplex		unknown	unassessable	35 year-old woman was vaccinated at an unknown gestational age, and had foetal arrhythmia, atrial septal defect, eyelid ptosis congenital, 4.1(b) syndrome and kidney duplex diagnosed approximately 58 days after unspecified dose of SPIKEVAX. Given that the gestational age of vaccination is not reported, causality for the congenital anomalies is unassessable.
Autosomal chromosomal abnormalities	Kidney malformation		unknown	unassessable	Kidney malformation and ureteric dilatation reported in fetus, maternal vaccination reported however no dates or gestational age was provided, unable to assess timing of vaccine and fetal renal development.
Renal disorders congenital	Renal aplasia		5 mos before preg	Unlikely	33-year-old, female patient with medical history of collagenous colitis, who was vaccinated before pregnancy. Five months after vaccination, bilateral renal agenesis of fetus was detected at routine 20-week anatomy scan on 8/27/2021; it was determined to be fatal for fetus, so an 4.1(b) of pregnancy occurred. Missing information on the date of vaccination and LMP. Unlikely given vaccination five months prior to pregnancy
Renal disorders congenital	Renal aplasia		before pregnancy	unlikely	Fetal patient with history of maternal exposure before pregnancy had congenital renal aplasia/anomaly detected on 20-week ultrasound so this reflects that the exposure was before pregnancy. The fetus was determined as non-viable and so, uterine dilation and evacuation was indicated and done 12 days after diagnosis. See maternal cases - 4.1(b)
Sex chromosomal abnormalities	Turner's syndrome		periconception, about 4-5 weeks	unlikely	37-year-old female with two prior live births, received VAXZEVRIA, at an unknown interval was boosted with SPIKEVAX prior to pregnancy (approximately 1 week prior to LMP), reports diagnosis of congenital anomaly in the fetus that died in utero at 17 weeks GA. Although, age and previous VAXZEVRIA vaccination are confounders, and noting that vaccination was prior to LMP and conception, the congenital anomaly (Turner's syndrome) and resulting fetal death is unlikely caused to vaccination.

HLT	PT	Case ID	GA at Vx	WHO/U MC Causality	Case summary
Skin and subcutaneous tissue disorders congenital NEC	Congenital acrochordon	4.1(b)	8 and 12	possible	Neonate born prematurely, exposed via maternal immunization at 8- and 12-weeks GA, had skin tag behind ear, unlikely given absence of biologic plausibility
Skin and subcutaneous tissue disorders congenital NEC	Congenital skin disorder		3rd trimester	unlikely	One-month old neonate, exposed during third trimester of gestation, had a congenital coin sized skin lesion (birth mark). Causality is unlikely given timing of exposure and absence of biologic plausibility.

20.11.18. Interaction with Other COVID-19 vaccines (Heterologous Vaccine Schedule): Abstract/Articles

SELECTED LITERATURE SCIENTIFIC ABSTRACTS

INTERACTION WITH OTHER VACCINES / HETEROLOGIOUS VACCINES

AM US EST)

1. Search Criteria: Search: Heterologous COVID Vaccines AND Moderna mRNA1273 OR Spikevax AND December 2021
- OR
2. Search Criteria: Heterologous COVID Vaccines AND mRNA Vaccines AND December 2021

Exact search criteria used

1. Heterologous COVID Vaccines AND Moderna mRNA1273 or Spikevax AND December 2021

(((Heterologous COVID Vaccines) AND (Moderna mRNA1273)) OR (Spikevax)) AND
(("2021/12/01"[Date - Publication] : "2021/12/31"[Date - Publication]))
2. Heterologous COVID Vaccines AND mRNA Vaccines AND December 2021

((Heterologous COVID Vaccines) AND (mRNA Vaccines)) AND (("2021/12/01"[Date - Publication] : "2021/12/31"[Date - Publication]))

PubMed NLM Search Criteria:

Search: (((Heterologous COVID Vaccines) AND (Moderna mRNA1273)) OR (Spikevax)) AND (("2021/12/01"[Date - Publication] : "2021/12/31"[Date - Publication]))

((("heterologous"[All Fields] OR "heterologously"[All Fields]) AND ("sars cov 2"[MeSH Terms] OR "sars cov 2"[All Fields] OR "covid"[All Fields] OR "covid 19"[MeSH Terms] OR "covid 19"[All Fields]) AND ("vaccin"[Supplementary Concept] OR "vaccin"[All Fields] OR "vaccination"[MeSH Terms] OR "vaccination"[All Fields] OR "vaccinable"[All Fields] OR "vaccinal"[All Fields] OR "vaccinate"[All Fields] OR "vaccinated"[All Fields] OR "vaccinates"[All Fields] OR "vaccinating"[All Fields] OR "vaccinations"[All Fields] OR "vaccination s"[All Fields] OR "vaccinator"[All Fields] OR "vaccinators"[All Fields] OR "vaccine s"[All Fields] OR "vaccined"[All Fields] OR "vaccines"[MeSH Terms] OR "vaccines"[All Fields] OR "vaccine"[All Fields] OR "vaccins"[All Fields]) AND ("Moderna"[All Fields] AND ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mrna 1273"[All Fields]) OR "2019 ncov

vaccine mrna 1273"[All Fields] OR "mrna1273"[All Fields])))) OR "Spikevax"[All Fields]) AND 2021/12/01:2021/12/31[Date - Publication]

Translations

Heterologous: "heterologous"[All Fields] OR "heterologously"[All Fields]

COVID: "sars-cov-2"[MeSH Terms] OR "sars-cov-2"[All Fields] OR "covid"[All Fields] OR "covid-19"[MeSH Terms] OR "covid-19"[All Fields]

Vaccines: "vaccin"[Supplementary Concept] OR "vaccin"[All Fields] OR "vaccination"[MeSH Terms] OR "vaccination"[All Fields] OR "vaccinable"[All Fields] OR "vaccinal"[All Fields] OR "vaccinate"[All Fields] OR "vaccinated"[All Fields] OR "vaccinates"[All Fields] OR "vaccinating"[All Fields] OR "vaccinations"[All Fields] OR "vaccination's"[All Fields] OR "vaccinator"[All Fields] OR "vaccinators"[All Fields] OR "vaccine's"[All Fields] OR "vaccined"[All Fields] OR "vaccines"[MeSH Terms] OR "vaccines"[All Fields] OR "vaccine"[All Fields] OR "vaccins"[All Fields]

mRNA1273: "2019-ncov vaccine mrna-1273"[MeSH Terms] OR ("2019-ncov"[All Fields] AND "vaccine"[All Fields] AND "mrna-1273"[All Fields]) OR "2019-ncov vaccine mrna-1273"[All Fields] OR "mrna1273"[All Fields]

URL here:

1. <https://pubmed.ncbi.nlm.nih.gov/?term=%28%28%28Heterologous+COVID+Vaccines%29+AND+%28Moderna+mRNA1273%29%29+OR+%28Spikevax%29%29+AND+%28%28%222021%2F12%2F01%22%5BDate+-+Publication%5D+%3A+%222021%2F12%2F31%22%5BDate+-+Publication%5D%29%29&sort=>
2. <https://pubmed.ncbi.nlm.nih.gov/?term=%28%28Heterologous+COVID+Vaccines%29+AND+%28mRNA+Vaccines%29%29+AND+%28%28%222021%2F12%2F01%22%5BDate+-+Publication%5D+%3A+%222021%2F12%2F31%22%5BDate+-+Publication%5D%29%29>

Findings:

Recall: Search 1: 8

Recall: Search 2: 12

Relevant to Heterologous vaccination: 5

Informative publications ONLY: 4

Literature Findings (See Below Relevant or Informative):

1. Heterologous prime-boost strategies for COVID-19 vaccines

Binaya Sapkota 1, Bhuvan Saud 2 3, Ranish Shrestha 4 5, Dhurgham Al-Fahad 6, Ranjit Sah 7, Sunil Shrestha 8, Alfonso J Rodriguez-Morales 9 10

J Travel Med. 2021 Dec 16; taab191. doi: 10.1093/jtm/taab191. Online ahead of print.

PMID: 34918097 DOI: 10.1093/jtm/taab191

<https://pubmed.ncbi.nlm.nih.gov/34918097/>

Full text article: <https://academic.oup.com/jtm/advance-article/doi/10.1093/jtm/taab191/6463576>

Abstract

Rationale for review: Heterologous prime-boost doses of COVID-19 vaccines ('mix-and-match' approach) are being studied to test for the effectiveness of Oxford (AZD1222), Pfizer (BNT162b2), Moderna (mRNA-1273) and Novavax (NVX-CoV2373) vaccines for COVID in 'Com-Cov2 trial' in UK, and that of Oxford and Pfizer vaccines in 'CombivacS trial' in Spain. Later, other heterologous combinations of CoronaVac (DB15806), Janssen (JNJ-78436735), CanSino (AD5-nCOV), and other were also being trialed to explore their effectiveness. Previously, such a strategy was deployed for HIV, Ebola virus, malaria, tuberculosis, influenza, and hepatitis B to develop the artificial acquired active immunity. The present review explores the science behind such an approach for candidate COVID-19 vaccines developed using eleven different platforms approved by the World Health Organization.

Key findings: The candidate vaccines' pharmaceutical parameters (e.g. platforms, number needed to vaccinate and intervals, adjuvanted status, excipients and preservatives added, efficacy and effectiveness, vaccine adverse events, and boosters), and clinical aspects must be analyzed for the mix-and-match approach. Heterologous prime-boost trials showed safety, effectiveness, higher systemic reactogenicity, well tolerability with improved immunogenicity, and flexibility profiles for future vaccinations, especially during acute and global shortages, compared to the homologous counterparts.

Conclusions/recommendations. Still, large controlled trials are warranted to address challenging variants of concerns including Omicron and other, and to generalize the effectiveness of the approach in regular as well as emergency use during vaccine scarcity.

Keywords: COVID-19; SARS-CoV-2; heterologous prime-boost mix-and-match; vaccine vaccination.

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2. Immunogenicity, safety, and reactogenicity of heterologous COVID-19 primary vaccination incorporating mRNA, viral-vector, and protein-adjuvant vaccines in the UK (Com-COV2): a single-blind, randomised, phase 2, non-inferiority trial.

Arabella S V Stuart 1, Robert H Shaw 1, Xinxue Liu 2, Melanie Greenland 2, Parvinder K Aley 2, Nick J Andrews 3, J C Cameron 4, Sue Charlton 5, Elizabeth A Clutterbuck 2, Andrea M Collins 6, Tom Darton 7, Tanya Dinesh 2, Christopher J A Duncan 8, Anna England 5, Saul N Faust 9, Daniela M Ferreira 6, Adam Finn 10, Anna L Goodman 11, Christopher A Green 12, Bassam Hallis 5, Paul T Heath 13, Helen Hill 6, Bryn M Horsington 2, Teresa Lambe 14, Rajeka Lazarus 15, Vincenzo Libri 16, Patrick J Lillie 17, Yama F Mujadidi 2, Ruth Payne 7, Emma L Plested 2, Samuel Provstgaard-Morys 2, Maheshi N Ramasamy 1, Mary Ramsay 18, Robert C Read 9, Hannah Robinson 2, Gavin R Screaton 19, Nisha Singh 2, David P J Turner 20, Paul J Turner 21, Iason Vichos 2, Rachel White 2, Jonathan S Nguyen-Van-Tam 22, Matthew D Snape 23, Com-COV2 Study Group.

Lancet. 2022 Jan 1;399(10319):36-49. doi: 10.1016/S0140-6736(21)02718-5. Epub 2021 Dec 6.

Lancet. 2022 1-7 January; 399(10319): 36–49. Published online 2021 Dec 6. doi: 10.1016/S0140-6736(21)02718-5. PMCID: PMC8648333. PMID: 34883053

DOI: 10.1016/S0140-6736(21)02718-5

<https://pubmed.ncbi.nlm.nih.gov/34883053/>

Full text article: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8648333/>

Abstract

Background: Given the importance of flexible use of different COVID-19 vaccines within the same schedule to facilitate rapid deployment, we studied mixed priming schedules incorporating an adenoviral-vectored vaccine (ChAdOx1 nCoV-19 [ChAd], AstraZeneca), two mRNA vaccines (BNT162b2 [BNT], Pfizer-BioNTech, and mRNA-1273 [m1273], Moderna) and a nanoparticle vaccine containing SARS-CoV-2 spike glycoprotein and Matrix-M adjuvant (NVX-CoV2373 [NVX], Novavax).

Methods: Com-COV2 is a single-blind, randomised, non-inferiority trial in which adults aged 50 years and older, previously immunised with a single dose of ChAd or BNT in the community, were randomly assigned (in random blocks of three and six) within these cohorts in a 1:1:1 ratio to receive a second dose intramuscularly (8-12 weeks after the first dose) with the homologous vaccine, m1273, or NVX. The primary endpoint was the geometric mean ratio (GMR) of serum SARS-CoV-2 anti-spike IgG concentrations measured by ELISA in heterologous versus homologous schedules at 28 days after the second dose, with a non-inferiority criterion of the GMR above 0·63 for the one-sided 98·75% CI. The primary analysis was on the per-protocol population, who were seronegative at baseline. Safety analyses were done for all participants who received a dose of study vaccine. The trial is registered with ISRCTN, number 27841311.

Findings: Between April 19 and May 14, 2021, 1072 participants were enrolled at a median of 9·4 weeks after receipt of a single dose of ChAd (n=540, 47% female) or BNT (n=532, 40%

female). In ChAd-primed participants, geometric mean concentration (GMC) 28 days after a boost of SARS-CoV-2 anti-spike IgG in recipients of ChAd/m1273 (20 114 ELISA laboratory units [ELU]/mL [95% CI 18 160 to 22 279]) and ChAd/NVX (5597 ELU/mL [4756 to 6586]) was non-inferior to that of ChAd/ChAd recipients (1971 ELU/mL [1718 to 2262]) with a GMR of 10·2 (one-sided 98·75% CI 8·4 to ∞) for ChAd/m1273 and 2·8 (2·2 to ∞) for ChAd/NVX, compared with ChAd/ChAd. In BNT-primed participants, non-inferiority was shown for BNT/m1273 (GMC 22 978 ELU/mL [95% CI 20 597 to 25 636]) but not for BNT/NVX (8874 ELU/mL [7391 to 10 654]), compared with BNT/BNT (16 929 ELU/mL [15 025 to 19 075]) with a GMR of 1·3 (one-sided 98·75% CI 1·1 to ∞) for BNT/m1273 and 0·5 (0·4 to ∞) for BNT/NVX, compared with BNT/BNT; however, NVX still induced an 18-fold rise in GMC 28 days after vaccination. There were 15 serious adverse events, none considered related to immunisation.

Interpretation: Heterologous second dosing with m1273, but not NVX, increased transient systemic reactogenicity compared with homologous schedules. Multiple vaccines are appropriate to complete primary immunisation following priming with BNT or ChAd, facilitating rapid vaccine deployment globally and supporting recognition of such schedules for vaccine certification.

Funding: UK Vaccine Task Force, Coalition for Epidemic Preparedness Innovations (CEPI), and National Institute for Health Research. NVX vaccine was supplied for use in the trial by Novavax.

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Conflict of interest statement

Declaration of interests MDS acts on behalf of the University of Oxford as an investigator on studies funded or sponsored by vaccine manufacturers, including AstraZeneca, GlaxoSmithKline, Pfizer, Novavax, Janssen, Medimmune, and MCM. He receives no personal financial payment for this work. JSN-V-T is seconded to the Department of Health and Social Care, England. AMC and DMF are investigators on studies funded by Pfizer and Unilever. They receive no personal financial payment for this work. AF is a member of the Joint Committee on Vaccination and Immunisation and chair of the WHO European Technical Advisory Group of Experts on Immunisation. He is an investigator or provides consultative advice on clinical trials and studies of COVID-19 vaccines produced by AstraZeneca, Janssen, Valneva, Pfizer, and Sanofi, and of other vaccines from these and other manufacturers, including GlaxoSmithKline, VPI Pharmaceuticals, Takeda, and Bionet Asia. He receives no personal remuneration or benefits for any of this work. SNF acts on behalf of University Hospital Southampton NHS Foundation Trust as an investigator or provides consultative advice on clinical trials and studies of COVID-19 and other vaccines funded or sponsored by vaccine manufacturers, including Janssen, Pfizer, AstraZeneca, GlaxoSmithKline, Novavax, Seqirus, Sanofi, Medimmune, Merck, and Valneva. He receives no personal financial payment for this work. PTH acts on behalf of St George's University of London as an investigator on clinical trials of COVID-19 vaccines funded or sponsored by vaccine manufacturers, including Janssen, Pfizer, AstraZeneca, Novavax, and

Valneva. He receives no personal financial payment for this work. CAG acts on behalf of University Hospitals Birmingham NHS Foundation Trust as an investigator on clinical trials and studies of COVID-19 and other vaccines funded or sponsored by vaccine manufacturers, including Janssen, Pfizer, AstraZeneca, Novavax, CureVac, Moderna, and Valneva. He receives no personal financial payment for this work. VL acts on behalf of University College London Hospitals NHS Foundation Trust as an investigator on clinical trials of COVID-19 vaccines funded or sponsored by vaccine manufacturers including Pfizer, AstraZeneca, and Valneva. He receives no personal financial payment for this work. TL is named as an inventor on a patent application covering the ChAd vaccine and is an occasional consultant to Vaccitech, unrelated to this work. ALG is named as an inventor on a patent covering use of a particular promoter construct that is often used in ChAdOx1-vectored vaccines and is incorporated in the ChAdOx1 nCoV-19 vaccine. ALG benefits from royalty income paid to the University of Oxford from sales of this vaccine by AstraZeneca and its sublicensees under the University's revenue sharing policy. Oxford University has entered into a partnership with AstraZeneca for further development of ChAdOx1 nCoV-19. All other authors declare no competing interests.

3. Robust induction of neutralizing antibodies against the SARS-CoV-2 Delta variant after homologous Spikevax or heterologous Vaxzevria-Spikevax vaccination

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Abstract

Sera of vaccines were assessed by surrogate virus neutralization tests for their capacity to neutralize the SARS-CoV-2 Delta variant. Homologous prime-boost immunization with Moderna's Spikevax as well as heterologous immunization with AstraZeneca's Vaxzevria followed by Moderna's Spikevax were identified as highly potent vaccination regimens for the induction of Delta-neutralizing antibodies.

Additional Excerpts:

....Participants received prime injections with ChAd, MOD, or BNT. Homologous booster doses were applied 28 and 41 days after MOD and BNT primes, respectively. Following ChAd prime, participants could choose to either receive a MOD or ChAd boost approximately 12 weeks post prime (Supporting Information Fig. S1 and Table S1). These various boosting intervals

corresponded to the recommendations of the German Standing Committee on Vaccination (Ständige Impfkommission, STIKO) at that time. Sera were taken one day before boosting as well as mean 14 days and mean 28 days after boosting ...

...Data from the present study confirm that homologous vaccination with ChAd induces limited amounts of antibodies able to neutralize the Delta VoC [9]. As reported before for BNT [9], the immune response in ChAd-primed individuals could be strongly increased by a boost immunization with another mRNA-based COVID-19 vaccine, MOD. Interestingly, of all vaccination regimens tested in the present study, homologous immunization with the MOD vaccine appears to induce the highest levels of antibodies able to neutralize the Delta variant of SARS-CoV-2 and that even heterologous immunization with ChAd/MOD induces titers similar to those found after vaccination with BNT/BNT. It is currently unclear why only the median titers of the ChAd/MOD group dropped by one dilution step from day 14 to day 28. Data from additional cohorts have to show whether this heterologous vaccination approach induces less long-lived humoral immunity compared to other vaccination regimens. Although our data indicate that individuals receiving homologous ChAd immunization have lower levels of Delta-neutralizing antibodies, it is currently unclear whether these vaccinees are more prone to vaccination breakthroughs than those that developed higher titers of antibodies due to homologous or heterologous immunization with mRNA-based vaccines.

Conclusion:

In conclusion, MOD alone or in combination with Adenoviral vector vaccines provides a powerful approach to combat the Delta variant.

Cellular immunity predominates over humoral immunity after homologous and heterologous mRNA and vector-based COVID-19 vaccine regimens in solid organ transplant recipients

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Abstract

Knowledge on the immunogenicity of vector-based and mRNA-vaccines in solid organ transplant recipients is limited. Therefore, SARS-CoV-2-specific T cells and antibodies were

analyzed in 40 transplant recipients and 70 controls after homologous or heterologous vaccine-regimens. Plasmablasts and SARS-CoV-2-specific CD4 and CD8 T cells were quantified using flow cytometry. Specific antibodies were analyzed by ELISA and neutralization assay. The two vaccine types differed after the first vaccination, as IgG and neutralizing activity were more pronounced after mRNA priming ($p = .0001$ each), whereas CD4 and CD8 T cell levels were higher after vector priming ($p = .009$; $p = .0001$). All regimens were well tolerated, and SARS-CoV-2-specific antibodies and/or T cells after second vaccination were induced in 100% of controls and 70.6% of transplant recipients. Although antibody and T cell levels were lower in patients, heterologous vaccination led to the most pronounced induction of antibodies and CD4 T cells. Plasmablast numbers were significantly higher in controls and correlated with SARS-CoV-2-specific IgG- and T cell levels. While antibodies were only detected in 35.3% of patients, cellular immunity was more frequently found (64.7%) indicating that assessment of antibodies is insufficient to identify COVID-19-vaccine responders. In conclusion, heterologous vaccination seems promising in transplant recipients, and combined analysis of humoral and cellular immunity improves the identification of responders among immunocompromised individuals.

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Conflict of interest statement

The authors of this manuscript have conflicts of interest to disclose as described by the American Journal of Transplantation. H.W. has received fees for lectures and/or consultations from Actelion, Boehringer, Bayer, Biotest, GlaxoSmithKline, Janssen, MSD, Pfizer, and Roche. M.S. has received grant support from Astellas and Biotest to the organization Saarland University outside the submitted work, and honoraria for lectures from Biotest and Novartis. The other authors have no conflicts of interest to disclose.

Boosting with heterologous vaccines effectively improves protective immune responses of the inactivated SARS-CoV-2 vaccine

Jialu Zhang,* Qian He,* Chaoqiang An, Qunying Mao, Fan Gao, Lianlian Bian, Xing Wu, Qian Wang, Pei Liu, Lifang Song, Yaqian Huo, Siyuan Liu, Xujia Yan, Jinghuan Yang, Bopei Cui, Changgui Li, Junzhi Wang, Zhenglun Liang, and Miao Xu

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Full text article: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8381941/>

Abstract

Since the outbreak of COVID-19, a variety of vaccine platforms have been developed. Amongst these, inactivated vaccines have been authorized for emergency use or conditional marketing in many countries. To further enhance the protective immune responses in populations that have completed vaccination regimen, we investigated the immunogenic characteristics of different vaccine platforms and tried homologous or heterologous boost strategy post two doses of inactivated vaccines in a mouse model. Our results showed that the humoral and cellular immune responses induced by different vaccines when administered individually differ significantly. In particular, inactivated vaccines showed relatively lower level of neutralizing antibody and T cell responses, but a higher IgG2a/IgG1 ratio compared with other vaccines. Boosting with either recombinant subunit, adenovirus vectored or mRNA vaccine after two-doses of inactivated vaccine further improved both neutralizing antibody and Spike-specific Th1-type T cell responses compared to boosting with a third dose of inactivated vaccine. Our results provide new ideas for prophylactic inoculation strategy of SARS-CoV-2 vaccines.

State of the CAR-T: Risk of Infections with Chimeric Antigen Receptor T-Cell Therapy and Determinants of SARS-CoV-2 Vaccine Responses

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Journal ListElsevier Public Health Emergency CollectionPMC8473073

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Abstract

Chimeric antigen receptor T cell (CAR-T) therapy has shown unprecedented response rates in patients with relapsed/refractory (R/R) hematologic malignancies. Although CAR-T therapy gives hope to heavily pretreated patients, the rapid commercialization and cumulative immunosuppression of this therapy predispose patients to infections for a prolonged period. CAR-T therapy poses distinctive short- and long-term toxicities and infection risks among patients who receive CAR T-cells after multiple prior treatments, often including hematopoietic cell transplantation. The acute toxicities include cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome. The long-term B cell depletion, hypogammaglobulinemia, and cytopenia further predispose patients to severe infections and abrogate the remission success achieved by the living drug. These on-target-off-tumor toxicities deplete B-cells across the entire lineage and further diminish immune responses to vaccines. Early observational data suggest that patients with hematologic malignancies may not mount adequate humoral and cellular responses to SARS-CoV-2 vaccines. In this review, we summarize the immune compromising factors indigenous to CAR-T recipients. We discuss the immunogenic potential of different SARS-CoV-2 vaccines for CAR-T recipients based on the

differences in vaccine manufacturing platforms. Given the lack of data related to the safety and efficacy of SARS-CoV-2 vaccines in this distinctively immunosuppressed cohort, we summarize the infection risks associated with Food and Drug Administration-approved CAR-T constructs and the potential determinants of vaccine responses. The review further highlights the potential need for booster vaccine dosing and the promise for heterologous prime-boosting and other novel vaccine strategies in CAR-T recipients.

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Heterologous prime-boost: breaking the protective immune response bottleneck of COVID-19 vaccine candidates

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Full text article: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8009122/>

Abstract

COVID-19 vaccines emerging from different platforms differ in efficacy, duration of protection, and side effects. To maximize the benefits of vaccination, we explored the utility of employing a heterologous prime-boost strategy in which different combinations of the four types of leading COVID-19 vaccine candidates that are undergoing clinical trials in China were tested in a mouse model. Our results showed that sequential immunization with adenovirus vectored vaccine followed by inactivated/recombinant subunit/mRNA vaccine administration specifically increased levels of neutralizing antibodies and promoted the modulation of antibody responses to predominantly neutralizing antibodies. Moreover, a heterologous prime-boost regimen with an adenovirus vector vaccine also improved Th1-biased T cell responses. Our results provide new ideas for the development and application of COVID-19 vaccines to control the SARS-CoV-2 pandemic.

Keywords: COVID-19 vaccine; Heterologous prime-boost; T cell response; neutralizing antibody; th1/th2 balance.

Conflict of interest statement

No potential conflict of interest was reported by the author(s).

JAMA Intern Med

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Comparison of SARS-CoV-2 Antibody Response 4 Weeks After Homologous vs Heterologous Third Vaccine Dose in Kidney Transplant Recipients: A Randomized Clinical Trial

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Full text article: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8689434/>

Abstract

Importance: Fewer than 50% of kidney transplant recipients (KTRs) develop antibodies against the SARS-CoV-2 spike protein after 2 doses of an mRNA vaccine. Preliminary data suggest that a heterologous vaccination, combining mRNA and viral vector vaccines, may increase immunogenicity.

Objective: To assess the effectiveness of a third dose of an mRNA vs a vector vaccine in KTRs who did not have antibodies against the SARS-CoV-2 spike protein after 2 doses of an mRNA vaccine.

Design, setting, and participants: This was a single center, single-blinded, 1:1 randomized clinical trial of a third dose of vaccine against SARS-CoV-2, conducted from June 15 to August 16, 2021, in 201 KTRs who had not developed SARS-CoV-2 spike protein antibodies after 2 doses of an mRNA vaccine. Data analyses were performed from August 17 to August 31, 2021.

Interventions: mRNA (BNT162b2 or mRNA-1273) or vector (Ad26COVS1) as a third dose of a SARS-CoV-2 vaccine.

Main outcomes and measures: The primary study end point was seroconversion after 4 weeks (29-42 days) following the third vaccine dose. Secondary end points included neutralizing antibodies and T-cell response assessed by interferon- γ release assays (IGRA). In addition, the association of patient characteristics and vaccine response was assessed using logistic regression, and the reactogenicity of the vaccines was compared.

Results: Among the study population of 197 kidney transplant recipients (mean [SD] age, 61.2 [12.4] years; 82 [42%] women), 39% developed SARS-CoV-2 antibodies after the third vaccine. There was no statistically significant difference between groups, with an antibody response rate of 35% and 42% for the mRNA and vector vaccines, respectively. Only 22% of seroconverted patients had neutralizing antibodies. Similarly, T-cell response assessed by IGRA was low with only 17 patients showing a positive response after the third vaccination. Receiving nontriple immunosuppression (odds ratio [OR], 3.59; 95% CI, 1.33-10.75), longer time after kidney transplant (OR, 1.44; 95% CI, 1.15-1.83, per doubling of years), and torque teno virus plasma levels (OR, 0.92; 95% CI, 0.88-0.96, per doubling of levels) were associated with vaccine response. The third dose of an mRNA vaccine was associated with a higher frequency of local pain at the injection site compared with the vector vaccine, while systemic symptoms were comparable between groups.

Conclusions and relevance: This randomized clinical trial found that 39% of KTRs without an immune response against SARS-CoV-2 after 2 doses of an mRNA vaccine developed antibodies against the SARS-CoV-2 spike protein 4 weeks after a third dose of an mRNA or a vector vaccine. The heterologous vaccination strategy with a vector-based vaccine was well tolerated and safe but not significantly better than the homologous mRNA-based strategy.

Trial registration: EudraCT Identifier: 2021-002927-39.

Conflict of interest statement

Conflict of Interest Disclosures: Dr Heinzl reported grants from the Medical University of Vienna (Transplantation Research Platform's Start-Up Grant 2020) during the conduct of the study. Dr Böhmig reported grants from Vitaeris, Behring, and MorphoSys, and consulting fees from Hansa, outside the submitted work. No other disclosures were reported.

Vaccine effectiveness against SARS-CoV-2 infection, hospitalization, and death when combining a first dose ChAdOx1 vaccine with a subsequent mRNA vaccine in Denmark: A nationwide population-based cohort study

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Abstract

Background: The recommendations in several countries to stop using the ChAdOx1 vaccine has led to vaccine programs combining different Coronavirus Disease 2019 (COVID-19) vaccine types, which necessitates knowledge on vaccine effectiveness (VE) of heterologous vaccine schedules. The aim of this Danish nationwide population-based cohort study was therefore to estimate the VE against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection and COVID-19-related hospitalization and death following the first dose of the ChAdOx1 vaccine and the combination of the ChAdOx1/mRNA vaccines.

Methods and findings: All individuals alive in or immigrating to Denmark from 9 February 2021 to 23 June 2021 were identified in the Danish Civil Registration System. Information on exposure, outcomes, and covariates was obtained from Danish national registries. Poisson and Cox regression models were used to calculate crude and adjusted VE, respectively, along with 95% confidence intervals (CIs) against SARS-CoV-2 infection and COVID-19-related hospitalization or death comparing vaccinated versus unvaccinated individuals. The VE estimates were adjusted for calendar time as underlying time and for sex, age, comorbidity, country of origin, and hospital admission. The analyses included 5,542,079 individuals (97.6% of the total Danish population). A total of 144,360 individuals were vaccinated with the ChAdOx1 vaccine as the first dose, and of these, 136,551 individuals received an mRNA vaccine as the second dose. A total of 1,691,464 person-years and 83,034 SARS-CoV-2 infections were included. The individuals vaccinated with the first dose of the ChAdOx1 vaccine dose had a median age of 45 years. The study population was characterized by an equal distribution of males and females; 6.7% and 9.2% originated from high-income and other countries, respectively. The VE against SARS-CoV-2 infection when combining the ChAdOx1 and an mRNA vaccine was 88% (95% CI: 83; 92) 14 days after the second dose and onwards. There were no COVID-19-related hospitalizations or deaths among the individuals vaccinated with the combined vaccine schedule during the study period. Study limitations including unmeasured confounders such as risk behavior and increasing overall vaccine coverage in the general population creating herd immunity are important to take into consideration when interpreting the results.

Conclusions: In this study, we observed a large reduction in the risk of SARS-CoV-2 infection when combining the ChAdOx1 and an mRNA vaccine, compared with unvaccinated individuals.

Conflict of interest statement

The authors have declared that no competing interests exist.

INFORMATIVE PUBLICATIONS ONLY FOR OTHER MEDICAL TOPICS

1. The EMA recommends the dose booster with Spikevax

Jean-Marie Manus

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8710983/>

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The Commission for Human Medical Products (CHMP) of the European Medicines Agency (EMA) has concluded that a booster dose , or booster dose , of Moderna's Covid-19 Spikevax vaccine should be considered in patients from 18 years old. This after data has concluded that this booster, administered six to eight months after the second dose of the initial regimen, makes it possible to raise the level of serum antibodies in vaccinated adults whose antibody level was decreasing.

The booster dose is half the dose given during the initial vaccination. The EMA underlines [1] that “the same data indicate that the presentation of side effects after administration of this booster are similar to those possibly observed during the second dose. The risk of heart inflammation - myocarditis - or other very rare side effects after the booster is closely monitored ”. As with all medicines, the EMA closely monitors all safety and activity data of Spikevax.

At the national level, the public health systems of European countries in conjunction with the EMA must publish recommendations on the correct use of booster doses, taking into account the local epidemiological situation, efficacy data and safety measures during the administration of the recall.

In early October, the EMA CHMP also concluded that a booster dose of the Comirnaty vaccine (BioNTech-Pfizer) should be considered at least six months after the second dose in patients from 18 years of age. . It is also recommended that this extra dose of Comirnaty and Spikevax can be given to patients with severely weakened immune systems no later than 28 days after their second dose.

The deployment of vaccination campaigns in the European Union remains the prerogative of the National Technical Advisory Groups for Immunization. They are responsible for organizing the vaccination campaigns in each member country, taking into account the local endemic conditions, the circulation of the virus, especially that of the variants of concern, the vaccine supply and the capacities of the national public health systems. .

The EMA is working closely with national health authorities and the European Center for Disease Prevention and Control to assess all data transmitted to it and disseminate recommendations to protect populations throughout the progressing pandemic.

20.11.19. Interaction with Other COVID-19 vaccines (Heterologous Vaccine Schedule): Fatal cases: Case Listings and Case Narratives

[illegible]

4.1(b)	UNITED KINGDOM	Regulatory Authority	Cardiac arrest, Cardiomegaly, Left ventricular failure, Limb discomfort, Nasopharyngitis, Pyrexia, Seizure	Serious	59.00	708.00	Male		COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA; GALPHARM IBUPROFEN; INFLUENZA VACCINE INACT SPLIT; OMEPRAZOLE; PARACETAMOL		4.1(b)
	UNITED KINGDOM	Regulatory Authority	Feeling abnormal, Sudden death	Serious	66.00	792.00	Male	Myocardial infarction(H); COVID-19 VACCINE ASTRAZENECA	ATORVASTATIN; COVID-19 VACCINE ASTRAZENECA; PARACETAMOL		8004737
	UNITED STATES	Spontaneous	Asthenia, Chills, Death, Dyspnoea, Fatigue, Loss of consciousness, Malaise	Serious	75.00	900.00	Unknown	PFIZER BIONTECH COVID-19 VACCINE; Systemic lupus erythematosus(C)			#069H21A
	UNITED KINGDOM	Regulatory Authority	Death, Dyspnoea	Serious	98.00	1176.00	Male	Macular degeneration(C); Atrial fibrillation(C); Hypothyroidism(C); Neovascular age-related macular degeneration(C); Asthenia(H); Cognitive disorder(H); Urinary tract infection(C); APIXABAN(H); CYANOCOBALAMIN(H); FERROUS FUMARATE(H); FINASTERIDE(H); OMEPRAZOLE; TAMBULOSIN	COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA; TRIMETHOPRIM		
	NETHERLANDS	Regulatory Authority	Cardiac arrest, Oedema peripheral, Parkinson's disease	Serious	91.00	1092.00	Male	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Parkinson's disease(C); Hypertension(H)	NONSPI; ANTI-PARKINSON; COLECALCIFEROL; DOPAMINE; APOMORPHINE		8005243
	KOREA, REPUBLIC OF	Spontaneous	Apallic syndrome, Myocardial infarction	Serious			Male	Rehabilitation therapy; ASTRAZENECA COVID-19 VACCINE			
	GERMANY	Regulatory Authority	Myocarditis, Sudden death	Serious	51.00	612.00	Male	COVID-19(H); COMIRNATY(H)			
	PHILIPPINES	Regulatory Authority	Chest pain, Dyspnoea, Oropharyngeal pain, Oxygen saturation decreased	Serious	34.00	408.00	Male			COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY	8055ez1a
	FRANCE	Regulatory Authority	Cardiac arrest, Intestinal obstruction, Sepsis	Serious	44.00	528.00	Female	Gene mutation(H); Lung disorder(H); Obesity(H); Intellectual disability(H)		COMIRNATY, COMIRNATY, COMIRNATY	
	GERMANY	Regulatory Authority	Aortic aneurysm rupture	Serious	52.00	624.00	Male	COVID-19 VACCINE JANSSEN			
	FRANCE	Regulatory Authority	Cardiac failure, Ischaemic stroke	Serious	92.00	1104.00	Male	COMIRNATY; COMIRNATY; Myocardial ischaemia(H); Myocardial infarction(H); Dyslipidaemia(H); Osteoarthritis(H); Carotid endarterectomy; Carotid endarterectomy; Prostatic operation	BISOPROLOL; CLOPIDOGREL; ATORVASTATIN; COVERAM; FUROSEMIDE; ZYMAD; SILODOSINE; PARACETAMOL		8214031
	KOREA, REPUBLIC OF	Spontaneous	Cardiac arrest	Serious	62.00	744.00	Male			JANSSEN COVID-19 VACCINE	
	UNITED KINGDOM	Regulatory Authority	Cardiac arrest, Death, Dyspnoea, Headache, Influenza like illness, Oxygen saturation decreased	Serious	39.00	468.00	Male	COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2			8005686
	SWEDEN	Regulatory Authority	Pulmonary embolism	Serious	67.00	804.00	Female	Breast cancer(H); Vascular dementia(C); Psychotic disorder(C)	FLUZONE [INFLUENZA VACCINE]	COMIRNATY	8023F21A
	GERMANY	Regulatory Authority	Acute myocardial infarction	Serious	50.00	600.00	Male	Hypertension(H); COMIRNATY; COMIRNATY			8004233
	ITALY	Regulatory Authority	Acute myocardial infarction, Cough, Haemoptysis, Pulmonary embolism	Serious	79.00	948.00	Male	COMIRNATY(H); COMIRNATY(H)			8005887
	GERMANY	Regulatory Authority	Sudden death	Serious	39.00	468.00	Male	Mental impairment(H); COMIRNATY(H); COMIRNATY(H)			8092F21A

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
4.1(b)	4.1(b)	This case was received via United States FDA VAERS (Reference number: 4.1(b) on 27-Apr-2021 and was forwarded to Moderna on 27-Apr-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of DEATH (death), ANAEMIA (Anaemia), GASTROINTESTINAL HAEMORRHAGE (Gastrointestinal haemorrhage) and SPINAL COMPRESSION FRACTURE (Jefferson fracture) in an 87-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. EN6199) for COVID-19 vaccination. Co-suspect product included non-company product COVID-19 VACCINE for COVID-19 vaccination. Concurrent medical conditions included Chronic kidney disease and Jefferson's fracture. On 11-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Mar-2021, the patient received first dose of COVID-19 VACCINE (Intramuscular) 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, the patient experienced ANAEMIA (Anaemia) (seriousness criterion hospitalization prolonged), GASTROINTESTINAL HAEMORRHAGE (Gastrointestinal haemorrhage) (seriousness criterion hospitalization prolonged) and SPINAL COMPRESSION FRACTURE (Jefferson fracture) (seriousness criterion hospitalization prolonged). The patient died on 11-Apr-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, ANAEMIA (Anaemia), GASTROINTESTINAL HAEMORRHAGE (Gastrointestinal haemorrhage) and SPINAL COMPRESSION FRACTURE (Jefferson fracture) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Apr-2021, Blood lactic acid: high increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment information was provided.	
4.1(b)	4.1(b)	This case was received via United States FDA VAERS (Reference number: 4.1(b) on 27-Apr-2021 and was forwarded to Moderna on 27-Apr-2021.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of GENERAL PHYSICAL HEALTH DETERIORATION (Rapidly deteriorated), CONDITION AGGRAVATED (Congestive heart failure rapidly worsened and previously stable leukemia flared up), LIVER DISORDER (Hepatic disease) and RENAL FAILURE (Renal failure) in an 84-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: COVID-19. Concurrent medical conditions included Leukemia and Congestive heart failure. On 25-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 2 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In February 2021, the patient experienced LIVER DISORDER (Hepatic disease) (seriousness criterion hospitalization) and RENAL FAILURE (Renal failure) (seriousness criteria hospitalization and medically significant). On 25-Feb-2021, the patient experienced CONDITION AGGRAVATED (Congestive heart failure rapidly worsened and previously stable leukemia flared up) (seriousness criterion medically significant). On 01-Mar-2021, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (Rapidly deteriorated) (seriousness criterion death). The patient was hospitalized from sometime in February 2021 to 19-Feb-2021 due to LIVER DISORDER and RENAL FAILURE. The patient was treated with Hospice care for Condition aggravated; Hospice care for Liver disorder and Hospice care for Renal failure. The patient died on 01-Mar-2021. The reported cause of death was rapidly deteriorated. It is unknown if an autopsy was performed. At the time of death, CONDITION AGGRAVATED (Congestive heart failure rapidly worsened and previously stable leukemia flared up), LIVER DISORDER (Hepatic disease) and RENAL FAILURE (Renal failure) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In December 2020, COVID-19: fully recovered Fully recovered. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The patient was fully recovered from natural SARS-COV-2 infection in early December 2020. The patient was doing quite well between mid December and mid January. Patient was hospitalized with congestive heart failure in late January 2021. The patient received first dose of Moderna COVID19 vaccine shortly before being discharged around February 1 (not sure of exact date). The patient was feeling well at that time. The patient became quite ill within 24 hours of Moderna COVID19 vaccine. Patient steadily worsened during Feb-2021. The patient was hospitalized in mid February (unsure of date) and diagnosed with kidney failure and liver disease. Congestive heart failure rapidly worsened and previously stable leukemia flared up. The patient was discharged from hospital February 19 and was placed in quarantine at care center. The patient was considered terminal and was to go into hospice care. The patient was administered second COVID19 vaccine on February 25, rapidly deteriorated, and died on March 1. Action taken with mRNA-1273 in response to the event was not applicable. The concomitant medications were not provided. Company comment: This is an 84-year-old female patient who received mRNA-1273 vaccine (batch no. unk) experienced GENERAL PHYSICAL HEALTH DETERIORATION and died 5 days after receiving second dose of vaccine. Medical conditions include Leukemia and Congestive heart failure and Hx of COVID 19 Infection. No conmeds were provided. The patient has been suffering from kidney failure and liver disease. Very limited information has been reported at this time. No further information is expected.	
4.1(b)	4.1(b)	This case was received via United States FDA VAERS (Reference number: 4.1(b) on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) and CARDIAC FAILURE CONGESTIVE (Cardiac failure congestive) in a 91-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Congestive heart failure. On 20-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Feb-2021, the patient experienced CARDIAC FAILURE	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		CONGESTIVE (Cardiac failure congestive) (seriousness criterion medically significant), CONDITION AGGRAVATED (Condition aggravated) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). The patient died on 05-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, CARDIAC FAILURE CONGESTIVE (Cardiac failure congestive), CONDITION AGGRAVATED (Condition aggravated) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient received Pfizer vaccine lot number EL9265 IM left deltoid on 01Feb2021 and then received Moderna vaccine. Patient has not had any reactions initial reactions with the vaccine. patient was on hospice due to Congestive Heart Failure and died on 05Mar2021. Concomitant and treatment information not provided. Very limited information regarding this events has been provided at this time. However, the underlying medical condition in this advanced age remains a confounder. Further information can't be requested.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 07-Jun-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death), VIRAL MYOCARDITIS (Viral myocarditis) and PNEUMONIA VIRAL (Pneumonia viral) in a 58-year-old female patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Bechterew's disease and Arthritis rheumatoid. Previously administered products included for Product used for unknown indication: COVID-19 vaccine on 18-Jan-2021. Past adverse reactions to the above products included Drug intolerance NOS with COVID-19 vaccine. On 15-Feb-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On an unknown date, the patient	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		experienced VIRAL MYOCARDITIS (Viral myocarditis) (seriousness criterion death), PNEUMONIA VIRAL (Pneumonia viral) (seriousness criterion death) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). The patient died on an unknown date. An autopsy was performed. The autopsy-determined cause of death was Viral myocarditis and Pneumonia viral. At the time of death, INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. The concomitant medications were not reported. The treatment information was not provided. In the biopsies of the heart muscle and lung tissue, the DNA of the Parvovirus B-19 was detected. Company Comment: Very Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Follow-up information was received and had significant information. Updated the start date and stop date for the events which was missed from the previous version. On 25-Aug-2021: Translation received it contains no new information.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 15-Jun-2021. The most recent information was received on 15-Jun-2021 and was forwarded to Moderna on 28-Jun-2021. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Tod in zeitlichem Zusammenhang mit Corona-Impfung (3 Tage zw. Impfung und Versterben) Todesursache: Verdacht auf akuten Herzinfarkt bei Herzmuskelhypertrophie) in a 54-year-old male patient who received mRNA-1273 (Moderna Covid-19 Vaccine) for COVID-19 vaccination. Previously administered products included for Prophylactic vaccination: VaxzevriaCOVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca; for an unreported indication: COVID-19 VACCINE ASTRAZENECA. Concurrent medical conditions included Aortic valve stenosis, Infarct myocardial since 2020, Aneurysm of aorta and Asthma.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 05-May-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. An autopsy was performed. No concomitant medication was reported. No treatment information was reported. Company comment: This is a case of sudden death in a patient who was found dead at home 3 days after second vaccination. Very limited information of this event has been provided at this time. In autopsy suspected myocardial infarction, myocarditis cannot be excluded. The patient's concurrent medical conditions of Aortic valve stenosis, Infarct myocardial, Aneurysm of aorta and Asthma remains as confounders. Previously administered AstraZeneca vaccine also remains as confounder. Most recent FOLLOW-UP information incorporated above includes: On 15-Jun-2021: Translation added. In autopsy suspected myocardial infarction, myocarditis cannot be excluded. On 25-Aug-2021: Follow up received contained No new information	
4.1(b)	4.1(b)	This case was received via United States FDA VAERS (Reference number: 4.1(b) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), CEREBROVASCULAR ACCIDENT (Cerebrovascular accident), HAEMORRHAGE (Haemorrhage), THROMBOCYTOPENIA (Thrombocytopenia), TRANSIENT ISCHAEMIC ATTACK (Transient ischaemic attack), PETECHIAE (Petechiae) and INJURY (Injury) in a 51-year-old patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect products included non-company products TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for COVID-19 vaccination and COVID-19 VACCINE NRVV AD26 for COVID-19 vaccination. No Medical History information was reported.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 01-Apr-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form, dose of TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) (unknown route) 1 dosage form and dose of COVID-19 VACCINE NRVV AD26 (unknown route) 1 dosage form. On 01-Apr-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death, hospitalization prolonged, disability, medically significant and life threatening), CEREBROVASCULAR ACCIDENT (Cerebrovascular accident) (seriousness criteria death, hospitalization prolonged, disability, medically significant and life threatening), HAEMORRHAGE (Haemorrhage) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criteria death, hospitalization prolonged, disability, medically significant and life threatening), TRANSIENT ISCHAEMIC ATTACK (Transient ischaemic attack) (seriousness criteria death, hospitalization prolonged, disability, medically significant and life threatening), PETECHIAE (Petechiae) (seriousness criteria death, hospitalization prolonged, disability and life threatening) and INJURY (Injury) (seriousness criteria death, hospitalization prolonged, disability and life threatening). The patient died on 28-May-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported Treatment medications were not reported Very limited information regarding this event/s has been provided at this time. Further information is not expected Discrepancy on death date exists in the SD Regulatory Authority. Co- suspect medication: includes COVID-19 JANSSEN and COVID-19 PFIZER- BIONTECH	
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of INTRACRANIAL MASS (Brain mass) in a 58-year-old female patient who received mRNA-1273 (Moderna Covid-19 Vaccine) (batch no. 521458) for COVID-19 vaccination. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 vaccination. No Medical History information was reported.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 21-Jan-2001, the patient received first dose of mRNA-1273 (Moderna Covid-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Dec-2010, the patient started COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form. On 10-Sep-2001, the patient experienced INTRACRANIAL MASS (Brain mass) (seriousness criterion death). The patient died on 17-Mar-2007. The reported cause of death was Brain mass. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative COVID-19 test. Company comment Very limited information regarding this event has been provided at this time. No further follow-up information is expected.	
4.1(b)	4.1(b)	This case was received via another Manufacturer (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. The license partner had received the report from United States FDA VAERS (Reference number: 4.1(b) This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) and COVID-19 (COVID-19) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for an unknown indication. The patient's past medical history included Quadruple vessel bypass graft (Quadruple heart bypass) in 2004. Concurrent medical conditions included Chronic lymphocytic leukemia (had blood infusions last summer, last one was on July07), Heart disorder (Chronic), Chronic kidney disease and Blood pressure high (High blood pressure). On 04-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form and second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 08-May-2021, the patient experienced COVID-19 (COVID-19) (seriousness criteria death and hospitalization). The patient died on 08-May-2021. The reported cause of death was covid-19 illness. It is unknown if an autopsy was performed.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Apr-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route), the reporter did not provide any causality assessments. No concomitant medication was provided. No treatment medication was provided.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Aug-2021 and was forwarded to Moderna on 04-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Unknown cause of death) in a 72-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Smoker, Lipid metabolism disorder NOS and LDL increased. Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant]) COVID-19 Vaccine AstraZeneca suspension for injection COVID-19 Vaccine AstraZeneca; for an unreported indication: COVID-19 VACCINE ASTRAZENECA. On 11-Jul-2021, the patient received dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. Death occurred on 14-Jul-2021. The patient died on 14-Jul-2021. The cause of death was not reported. An autopsy was not performed. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant information was not provided. Treatment information was not provided. Company Comment: This is a case of death of an unknown cause in a 72-year-old female subject with hx of smoking and lipid metabolism disorder who died 3 days after receiving mRNA-1273. An autopsy was not performed. Very limited information has been provided at this time. Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Non-significant Follow up appended	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 06-Aug-2021. The most recent information was received on 09-Aug-2021 and was forwarded to Moderna on 09-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (V.a. nicht natürlichen Tod in Zusammenhang mit Impfung) in a 74-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) for Prophylactic vaccination. Concurrent medical conditions included Hypertension. Concomitant products included PHENPROCUMON (MARCUMAR) for an unknown indication. On 26-Apr-2021, the patient started COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (unknown route) 1 dosage form. On 19-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product). The patient died on 29-Jul-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product) outcome was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This case concerns an 74-year old male with medical history of Hypertension who died after receiving mRNA-1273. The cause of death was not reported. It is unknown if an autopsy was performed. Very limited information regarding this event has been provided at this time. Further information (translation) is expected. Most recent FOLLOW-UP information incorporated above includes: On 09-Aug-2021: Follow-up document attached on 9-AUG-2021 contain concomitant drug and medical history was updated On 25-Aug-2021: Follow-up document received include no new information On 25-Aug-2021: Follow-up document received, included no new information	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
4.1(b)	4.1(b)	This spontaneous case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Pulmonary thromboembolism) and CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest / respiratory deterioration) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TREPROSTINIL SODIUM for Pulmonary hypertension. The patient's past medical history included Resuscitation on 14-Aug-2021. Previously administered products included for COVID-19 immunisation: Sputnik V in May 2021. Concurrent medical conditions included Pulmonary hypertension, Pulmonary fibrosis, Interstitial lung disease and Interstitial pneumonia. Concomitant products included SILDENAFIL CITRATE for an unknown indication. On 11-Feb-2021, the patient started TREPROSTINIL SODIUM (Nasal) at an unspecified dose. On 13-Aug-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Aug-2021, the patient experienced PULMONARY EMBOLISM (Pulmonary thromboembolism) (seriousness criteria death and medically significant) and CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest / respiratory deterioration) (seriousness criteria death and medically significant). On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (First dose Sputnik V and second dose of Moderna vaccine). The patient died on an unknown date. The reported cause of death was Pulmonary thromboembolism. It is unknown if an autopsy was performed. At the time of death, INTERCHANGE OF VACCINE PRODUCTS (First dose Sputnik V and second dose of Moderna vaccine) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was mentioned by reporter No treatment medication information was mentioned by reporter	

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		Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, history of pulmonary hypertension, pulmonary fibrosis, and interstitial lung disease may have contributed to the events and the fatal outcome.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number 4.1(b)) on 07-Sep-2021 and was forwarded to Moderna on 07-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of PNEUMONIA (Klínísk merki um lagnabólgu) and PYREXIA (Fever) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004730) for COVID-19 immunisation. The patient's past medical history included Alzheimer's disease (advanced alzheimer's disease). Previously administered products included for an unreported indication: COMIRNATY. Concomitant products included FISH OIL, XANTOXYL, ZEAXANTHIN (ACTAVISIO), LOSARTAN POTASSIUM (LOSATRIX), PARACETAMOL (PARATABS), ACETYLSALICYLIC ACID (HJARTAMAGNYL), SIMVASTATIN (SIMVASTATIN +PHARMA), MEMANTINE HYDROCHLORIDE (ZALATINE), SOTALOL, BUPRENORPHINE and CEFUROXIME (FURIX [CEFUROXIME]) for an unknown indication. On 17-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Aug-2021, the patient experienced PNEUMONIA (Klínísk merki um lagnabólgu) (seriousness criteria death and medically significant). On an unknown date, the patient experienced PYREXIA (Fever) (seriousness criterion death). The patient died on 19-Aug-2021. The reported cause of death was most likely cause is bacterial pneumonia. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Aug-2021, Body temperature: 38.2 (normal) 38.2 degree celcius. On an unknown date, Breath sounds abnormal: abnormal (abnormal) abnormal. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment medication provided.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The case concerns a 79 -year-old male patient with past medical history of Alzheimer's disease, presented with unexpected events of Pneumonia and pyrexia 1 day after booster dose of vaccine. Patient died 2 days after booster dose, cause of death was most likely Bacterial Pneumonia. The benefit risk relationship of vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via United States FDA VAERS (Reference number: 4.1(b) on 14-Sep-2021 and was forwarded to Moderna on 14-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of LYMPHOMA (Lymphoma), GASTROESOPHAGEAL REFLUX DISEASE (Gastroesophageal reflux disease), VICTIM OF ABUSE (Victim of abuse), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), ACCIDENTAL OVERDOSE (Accidental overdose) and DEATH (death) in a 57-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. Concurrent medical conditions included HIV disease. On 15-May-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) at an unspecified dose. On 16-May-2021, the patient experienced LYMPHOMA (Lymphoma) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), GASTROESOPHAGEAL REFLUX DISEASE (Gastroesophageal reflux disease) (seriousness criteria death, hospitalization, disability and life threatening), VICTIM OF ABUSE (Victim of abuse) (seriousness criteria death, hospitalization, disability and life threatening), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criteria death, hospitalization, disability and life threatening) and ACCIDENTAL OVERDOSE (Accidental overdose) (seriousness criteria death, hospitalization, disability and life threatening). The patient died on 18-Aug-2021. The reported cause of death was Accidental overdose, Lymphoma, Gastroesophageal reflux disease, Interchange of vaccine products and Victim of abuse. It is unknown if an autopsy was performed.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product included hiv medications. Treatment information was not provided. It was reported that doctor gave patient two different types and he was scheduling a third patient side affects were ignored and told it was normal due to injection he soon after was hospitalized having lymph nodes cancer and all the tests ran by doctor were not found abbott said well never looked at imaging and we were sure it was acid reflex .Another doctor a specialist said he should not have given him that type of vaccine with his medical history and allergies. Patient died and the hospital staff said either vaccine caused this or overdose when shift change happened because he was given too many pain medicines and three kinds. Company comment: This case concerns a death of 57-year-old, male patient with relevant medical history of HIV disease, who experienced the unexpected events of lymphoma, gastrointestinal reflux disease, victim of abuse, accidental overdose and interchange of vaccine products. The events occurred approximately 1 day after the third dose of Moderna COVID-19 Vaccine. It was reported that both Pfizer and Moderna vaccine were administered on the same day. The patient was hospitalized having lymph nodes cancer. The patient died approximately three months after the third dose of vaccine and the reporter stated that either vaccine caused this or overdose when shift change happened because he was given too many pain medicines. The rechallenge was not applicable. Patient's medical history of HIV remains a confounder. Causality for event of victim of abuse is assessed as unlikely due to nature of event. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.	
4.1(b)	4.1(b)	This case was received via United States FDA VAERS (Reference number: 4.1(b) on 14-Sep-2021 and was forwarded to Moderna on 14-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE KIDNEY INJURY (Acute kidney injury), ACUTE RESPIRATORY FAILURE (Acute respiratory failure), COVID-19 (COVID-19), CANDIDA INFECTION (Candida infection), CARDIOGENIC SHOCK (Cardiogenic shock), COAGULOPATHY (Coagulopathy), PNEUMONIA STAPHYLOCOCCAL (Pneumonia staphylococcal), PYREXIA (Pyrexia) and RENAL IMPAIRMENT (Renal impairment) in a 58-year-old female patient who received mRNA-1273 (Moderna COVID-19	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Vaccine) (batch no. 048B21A) for COVID-19 vaccination. The patient's past medical history included Catheter placement (The patient continued to decline over the next 48 hours with worsening hemodynamics and renal function and therefore a dialysis catheter was placed and pt was started on renal replacement therapy) on 31-Jul-2021. Previously administered products included for COVID-19 vaccination: Pfizer Vaccines (Pfizer Vaccines) on 21-Apr-2021. Concurrent medical conditions included Allergy (Codeine Hallucinations), Allergy (Morphine (Hallucinations)), Congestive heart failure, Diabetes mellitus and Hypertension. Concomitant products included APIXABAN, CARVEDILOL, DULOXETINE, GLIPIZIDE, HYDRALAZINE, ISOSORBIDE DINITRATE, INSULIN ASPART, INSULIN ASPART PROTAMINE (CRYSTALLINE) (INSULIN ASPART 30), PIOGLITAZONE, POTASSIUM CHLORIDE and SPIRONOLACTONE for an unknown indication. On 18-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 31-Jul-2021, the patient experienced ACUTE KIDNEY INJURY (Acute kidney injury) (seriousness criteria death, hospitalization and medically significant), ACUTE RESPIRATORY FAILURE (Acute respiratory failure) (seriousness criteria death, hospitalization and medically significant), COVID-19 (COVID-19) (seriousness criteria death and hospitalization), CANDIDA INFECTION (Candida infection) (seriousness criteria death and hospitalization), CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death, hospitalization and medically significant), COAGULOPATHY (Coagulopathy) (seriousness criteria death and hospitalization), PNEUMONIA STAPHYLOCOCCAL (Pneumonia staphylococcal) (seriousness criteria death, hospitalization and medically significant) and RENAL IMPAIRMENT (Renal impairment) (seriousness criteria death, hospitalization and medically significant). On 11-Aug-2021, the patient experienced PYREXIA (Pyrexia) (seriousness criteria death and hospitalization). The patient was hospitalized on 31-Jul-2021 due to ACUTE KIDNEY INJURY, ACUTE RESPIRATORY FAILURE and CARDIOGENIC SHOCK. The patient was treated with DOBUTAMINE for Cardiogenic shock, at an unspecified dose and frequency; NOREPINEPHRINE BITARTRATE (LEVOPHED) on 16-Aug-2021 for Product used for unknown indication, at an unspecified dose and frequency; VASOPRESSIN on 16-Aug-2021 at an unspecified dose and frequency; Surgery (Intra-aortic balloon	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		placement) for Cardiogenic shock and Surgery (dialysis catheter was placed, renal replacement therapy) for Renal impairment. The patient died on 18-Aug-2021. The reported cause of death was Acute kidney injury, Acute respiratory failure, covid-19, Candida infection, Cardiogenic shock, Coagulopathy, Pneumonia staphylococcal, Pyrexia and Renal impairment. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Jul-2021, SARS-CoV-2 test: positive (Positive) POSITIVE. On 16-Aug-2021, SARS-CoV-2 antibody test: positive (Positive) had positive IgM COVID antibodies and it was suspected that developed a new COVID infection. On 17-Aug-2021, Culture urine: candida albicans (Positive) candida albicans. On an unknown date, Polymerase chain reaction: mrsa (abnormal) MRSA in pneumonia PCR. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Moderna COVID-19 Vaccine EUA: COVID-19 case resulting in Hospitalization / Death. Patient received Pfizer Vaccines on 4/21/2021 and 5/18/2021. Patient admitted on 7/31/2021 for cardiogenic shock complicated by acute renal failure, coagulopathy and acute respiratory failure. To assist in management of the cardiogenic shock pt was placed on axillary IABP and dobutamine for inotropic support. Pt was decongested with combination of aquadex and diuretics with improvement in filling conditions. Unfortunately, patient developed persistent fever on 8/11 and was placed on broad spectrum antibiotics, ID was consulted and underwent extensive infectious evaluation. She did have MRSA in pneumonia PCR and candida albicans has grown in urine culture. On 8/16/21 morning pt decompensated hemodynamically requiring levophed and vasopressin and continued evaluation revealed that pt had positive IgM COVID antibodies and it was suspected that pt developed a new COVID infection. She continued to decline over the next 48 hours with worsening hemodynamics and renal function and therefore a dialysis catheter was placed and pt was started on renal replacement therapy. Family was kept up to date about the patient's clinical status and at this point decided to transition focus of care to comfort. Pt then expired the morning of 8/18/21. Company comment: This case concerns a 58 year old female with a medical history of Congestive heart failure, Diabetes and Hypertension who experienced the serious unexpected events leading	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		to death of COVID-19, Acute Kidney injury, Acute respiratory failure, Cardiogenic shock, Coagulopathy and Pneumonia along with other non-serious events including Vaccine failure/Drug ineffective approximately 6 to 8 weeks after the second dose of Moderna COVID-19 vaccine. There is no re-challenge as the patient expired. The medical history of concurrent diseases of CHF, Diabetes and Hypertension are confounders. The benefit-risk relationship of Moderna COVID-19 vaccine is not a	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021. The most recent information was received on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL THROMBOSIS (Major cerebral infarction occurred on 15/08/2021 approximately between 12:00 am and 2:00 am), HEMIPARESIS (Hospitalized on 15 August because of hemiplegia symptoms) and CEREBRAL THROMBOSIS (There was a small clot in the brain during the night of 14-15 Aug at 3:00 pm, for which direct blood thinners were given) in a 45-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003659) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Motor cycling accident (hospitalised in Kassel, Germany) in 2016 and Artificial coma (for a few days after motor cycle accident) in 2016. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty)COVID-19 VACCIN PFIZER INJVLST 0 and3ML on 27-Jun-2021. Past adverse reactions to the above products included No adverse event with BioNTech/Pfizer vaccin (Comirnaty)COVID-19 VACCIN PFIZER INJVLST 0 and3ML. Concurrent medical conditions included Hypertension and Diplopia (2015 is an estimate for "years" . Patient states that in recent years has regularly seen double (binocular, no double image from monocular vision), ophthalmologist could give no explanation) since 2015. On 02-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Aug-2021, the patient experienced MALAISE (Feeling unwell), FATIGUE (Fatigue), HEADACHE (Headache) and PYREXIA (Fever). On 15-Aug-2021, the patient experienced HEMIPARESIS (Hospitalized on 15 August	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		because of hemiplegia symptoms) (seriousness criteria hospitalization and medically significant) and CEREBRAL THROMBOSIS (There was a small clot in the brain during the night of 14-15 Aug at 3:00 pm, for which direct blood thinners were given) (seriousness criteria hospitalization prolonged and medically significant). On 16-Aug-2021, the patient experienced CEREBRAL THROMBOSIS (Major cerebral infarction occurred on 15/08/2021 approximately between 12:00 am and 2:00 am) (seriousness criteria death, hospitalization and medically significant). On 07-Aug-2021, MALAISE (Feeling unwell), HEADACHE (Headache) and PYREXIA (Fever) had resolved. The patient died on 16-Aug-2021. The reported cause of death was Cerebral thrombosis. It is unknown if an autopsy was performed. At the time of death, HEMIPARESIS (Hospitalized on 15 August because of hemiplegia symptoms), CEREBRAL THROMBOSIS (There was a small clot in the brain during the night of 14-15 Aug at 3:00 pm, for which direct blood thinners were given) and FATIGUE (Fatigue) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Aug-2021, Computerised tomogram head: abnormal (abnormal) substantially widened blood vessels found behind the eyes. and abnormal (abnormal) abnormal. On 15-Aug-2021, Electrocardiogram: normal (normal) sinusritme 83/min. On 15-Aug-2021, Laboratory test: abnormal (abnormal) Hemoglobine: 10.5 mmol/L (8.5-11.0). Hematocriet. 0.49 LL (0.41-0.51), Erytrocyten 5.7 $10^{12}/L$ (4.4-5.8), MCV; 86 fL (80-100), Trombocyten 314 $10^9/L$ (150-400), Leukocyten. $5.4 \times 10^9/L$ (4.0-10.0) Neutrofielen. $3.2 \times 10^9/L$ (1.5-9.0), Lymfocyten. $1.4 \times 10^9/L$ (1.0-4.0) PT (sec): 10.9 seconden (9.5-12.0), INR. 1.0 NR (0.9-1.1) Glucose (H) 8.3 mmol/L (4.0-7.8), CRP. 4 mg/L (<5), Ureum: 4.7 mmol/L (1.8-6.4), Kreatinine. 72 $\mu\text{mol}/L$ (65-105), eGFR (CKD-EPI) 106 mL./mi/1.73m² (>-60), Natrium 139 mmol/L (135-145). Kalium: 3.9 mmol/L (3.5-5.0), Calcium. 2.27 mmol/L (2.20-2.65), ASAT 34 U/L, Uitslag minder betrouwbaar ivm hemolytisch materiaal (0-40), ALAT (H) 50 U/L (0-45), Alkalische fosfatase 106 U/L (40-130), GGT 51 U/L (<55), LDH. 163 U/L, Gecorrigeerde uitslag ivm hemolytisch materiaal (50-250), Totaal eiwit 72 g/L (60-80), Triglyceriden (H): 2.4 mmol/L (0.6-2.2), Cholesterol (H) 6.5 mmol/L (3.5-4.9), HDL- cholesterol 1.1 mmol/L (0.9-1.7), LDL-cholesterol (H) 4.3 mmol/L (<3.9). On 15-Aug-2021, Vital signs measurement: abnormal (abnormal) abnormal and abnormal (abnormal) abnormal. On 16-Aug-2021, Computerised tomogram head: abnormal (abnormal) abnormal. On 16-Aug-2021, Laboratory test: abnormal (abnormal) Hemoglobine: 10.3 mmol/L (8.5-11.0).	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Hematocrit. 0.48 L/L (0.41-0.51), Erythrocyten 5.6 $10^{12}/L$ (4.4-5.8), MCV: 86 fL (80-100), Trombocyten 337 $10^9/L$ (150-400), Leukocyten. 14.6 $\times 10^9/L$ (4.0-10.0) PT (sec): 10.9 seconden (9.5-12.0), aPTT 26, (20-30) Glucose (H) 8.4 mmol/l (4.0-7.8), CRP. 4 mg/L (<5), Ureum: 4.0 mmol/l (1.8-6.4), Kreatinine. 84 $\mu\text{mol}/L$ (65-105), eGFR (CKD-EPI 96 mL./mi/1.73m² (>-60), Natrium 139 mmol/L (135-145). Kalium: 3.9 mmol/L (3.5-5.0), Chloride 104 mmol/l (2.20-2.65), ASAT 25U/L (0-40), ALAT 42 U/L (0-45), Alkalische fosfatase 97 U/L (40-130), GGT 47 U/L (<55), LDH. 221 U/L, (50-250), Albumine 44 (35-55), Lipase 24 (0-60), Bilirubine 12 (<17). Concomitant medications were not provided by the reporter however mentioned use of non-specified blood pressure medicine with unknown route of administration and batch number. It was reported that the patient experienced a small clot in his brain during the night of 14-Aug-2021/15-Aug-2021 at 3:00 pm, for which direct blood thinners were received. It was further reported that a major cerebral infarction developed on 15-Aug-2021, approximately between 12:00 am and 2:00 pm. Company comment -This case concerns a 45-year-old, male patient with past medical history of hypertension and artificial coma (for a few days after motor cycle accident), who experienced the fatal events of hemiparesis and cerebral thrombosis. The events developed approximately 13 days after the first dose of Spikevax and fatal outcome occurred the following day. Causality for the fatal events were not provided by the reporter. The benefit-risk relationship of Spikevax is not affected by this report. Thrombosis is an adverse event of special interest and assessed as serious due to hospitalization and fatal outcome per regulatory reporting. Most recent FOLLOW-UP information incorporated above includes: On 02-Nov-2021: Follow up received added lab test and medical history. On 02-Nov-2021: Translation received for FU 3 on 5 Nov 2021, with translated Medical history comments, event verbatim and lab results	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 08-Oct-2021. The most recent information was received on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021.	Thank you for your report of a suspected adverse reaction following vaccination. Thank you for your report of a suspected adverse reaction. We have received a duplicate report about the same event from another healthcare staff member. We have collated all the

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		This regulatory authority case was reported by an other health care professional and describes the occurrence of SEPSIS (Sepsis), GENERAL PHYSICAL HEALTH DETERIORATION (Reduced general condition), RESPIRATORY FAILURE (Respiratory failure type 1), ELECTROLYTE IMBALANCE (Electrolyte disturbance) and PYREXIA (Fever) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty (Dose no. in series: 2 Vaccination site: Unknown . Batch :EK9788) on 03-Feb-2021. Past adverse reactions to the above products included No adverse reaction with Comirnaty. Concomitant products included PARACETAMOL from an unknown date to 27-Sep-2021 for Back pain, ACETYLSALICYLIC ACID (ACETYLSALISYLSYRE ACTAVIS) from an unknown date to 27-Sep-2021 for Cardiac disorder prophylaxis, RINGER-ACETAT from 20-Sep-2021 to 27-Sep-2021 for Dehydration, MEMANTINE HYDROCHLORIDE (EBIXA) from 30-Mar-2021 to 27-Sep-2021 for Dementia, CARBOMER (VISCOTEARs) from 13-Feb-2020 to 27-Sep-2021 and HYPROMELLOSE (HYPROSAN) from an unknown date to 27-Sep-2021 for Dry eyes, METOPROLOL SUCCINATE (METOPROLOL SANDOZ [METOPROLOL SUCCINATE]) from 16-Mar-2021 to 27-Sep-2021 for Hypertension, POTASSIUM CHLORIDE (KALEORID) from 16-Mar-2021 to 27-Sep-2021 for Hypokalemia, CEFOTAXIME SODIUM (CEFOTAXIM MIP) from 26-Sep-2021 to 27-Sep-2021 for Infection, CALCIUM CARBONATE, COLECALCIFEROL (CALCIGRAN FORTE) from 23-Aug-2021 to 27-Sep-2021 for Osteoporosis, MORPHINE SULFATE (MORFIN [MORPHINE SULFATE]) and FENTANYL (FENTANYL SANDOZ [FENTANYL]) for Pain, PREDNISOLONE from 06-Jul-2020 to 27-Sep-2021 for Rheumatic disorder, QUETIAPINE FUMARATE (SEROQUEL) from 19-Jan-2021 to 27-Sep-2021 for Sleep disorder, CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE (TRIOBE [CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE]) from 24-Aug-2020 to 27-Sep-2021 for Vitamin B12 deficiency, METHOTREXATE from an unknown date to 27-Sep-2021 and PROPRANOLOL HYDROCHLORIDE (PRANOLOL) from 16-Mar-2021 to 27-Sep-2021 for an unknown indication. On 22-Sep-2021 at 10:45 AM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Sep-2021, the patient experienced GENERAL PHYSICAL	information into one report with reference number U15epj. Report with reference number Uq8jnx has been deleted. Assessment is based on collated information from both reports. It is stated in the report that the patient received Spikevax dose three on 22 September 2021, but this information does not correspond with the dose number registered in the SYSVAK [Norwegian Immunisation Registry]. In SYSVAK this vaccination is registered as dose number two. For corona vaccination, reporting must be made immediately after vaccination. The vaccinator has a duty to report to SYSVAK and is responsible for ensuring the accuracy of the information. Missing or incorrectly registered vaccination information for corona vaccines must be corrected by the vaccination centre responsible. If information about the vaccination centre responsible has been recorded in the patient's records, we would appreciate it if the vaccinator pointed this out to us so that the information is registered as quickly as possible. Since the vaccine is new, it is subject to special monitoring in order to identify new safety information as quickly as possible. It is particularly important that serious and/or unusual adverse reactions are reported. Your report is therefore important for increasing knowledge about adverse reactions that have not been identified in the studies, and it is an important contribution to the international cooperation aimed at maintaining safe vaccination worldwide. Reports after coronavirus vaccination in the Adverse Reaction Registry are processed by the Norwegian Institute of Public Health in cooperation with the Regional Medicines Information and Pharmacovigilance Centres (RELIS). We currently do not have the capacity to send individual assessments of adverse reaction reports. The Norwegian Medicines Agency publishes weekly summaries of reports of suspected adverse reactions following vaccination: https://legemiddelverket.no/godkjenning/koronavaksine-r-mistenkte-bivirkninger-av-koronavaksiner Causal links are assessed in accordance with international criteria (1). If you have any further information concerning the event such as information about outcome, copies of case notes/discharge notes/laboratory results and/or other

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		HEALTH DETERIORATION (Reduced general condition) (seriousness criterion death) and PYREXIA (Fever) (seriousness criterion death). On 25-Sep-2021, the patient experienced SEPSIS (Sepsis) (seriousness criteria death and medically significant). On 26-Sep-2021, the patient experienced RESPIRATORY FAILURE (Respiratory failure type 1) (seriousness criteria death and medically significant) and ELECTROLYTE IMBALANCE (Electrolyte disturbance) (seriousness criterion death). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). The patient died on 27-Sep-2021. The reported cause of death was Fever, Reduced general condition, Sepsis and Electrolyte disturbance. It is unknown if an autopsy was performed. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Sep-2021, C-reactive protein: 34 (abnormal) 34 milligram per litre. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered SEPSIS (Sepsis), GENERAL PHYSICAL HEALTH DETERIORATION (Reduced general condition), RESPIRATORY FAILURE (Respiratory failure type 1), ELECTROLYTE IMBALANCE (Electrolyte disturbance), PYREXIA (Fever) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) to be possibly related. The condition got worse, and the patient developed sepsis after three days. The patient was hospitalized due to rapidly progressive disease and died on 27 Sep 2021, five days after vaccination. No treatment medications were reported. Reporters qualification: Nurse Company Comment: This case concerns a 78 year-old female patient with no reported medical history, who experienced the unexpected serious fatal events of Respiratory failure, Sepsis, Pyrexia, General physical health deterioration, and Electrolyte imbalance. The events occurred 1-4 days after the most recent dose of mRNA-1273 vaccine, and the patient died (unknown cause) 5 days after the last dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event coding and seriousness criteria maintained for consistency in RA report, however there is also mention of hospitalization in the source document. * Fever and severe reduced general condition * The condition got worse, and the patient developed sepsis after three days.	investigations, this can be sent in reply to this message. The information is processed securely, and this dialogue is automatically deleted after 4 months. The processing and storage of personal data take place in accordance with the Norwegian Personal Health Data Filing System Act. For updated information and advice about use of the vaccines and precautionary measures, please see the Vaccination Guide (2): https://www.fhi.no/nettpub/vaksinasjonsveilederen-forhelsepersonell/vaksiner-mot-d

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		* Treated with antibiotics at the nursing home. * The patient was hospitalized due to rapidly progressive disease. * Completely deranged,had respiratory failure type 1 and electrolyte disturbance and died 27/Sep/2021, five days after vaccination. 30/Sep/2021 RELIS: additional information received by phone. The following fields have been updated: product. Reporters qualification: Nurse 13/10/2021, NoMA: Information received as duplicate report. All information kept in 4.1(b) (this report). Report 4.1(b) has been nullified. 20/10/2021 RELIS: additional information received as a duplicate report. The following fields have been updated: event, event description. Most recent FOLLOW-UP information incorporated above includes: On 27-Oct-2021: Significant Follow-up appended. Two events (RESPIRATORY FAILURE TYPE 1 & ELECTROLYTE DISTURBANCE) were added. On 27-Oct-2021: Translated document received on 29-oct-21- contain no new information.	
4.1(b)	4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b) on 08-Oct-2021. The most recent information was received on 04-Nov-2021 and was forwarded to Moderna on 04-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of LUNG NEOPLASM MALIGNANT (Lung cancer), LOWER RESPIRATORY TRACT INFECTION (Lower respiratory tract infection), CHEST PAIN (Chest pain) and DYSPNOEA (Dyspnoea) in a 69-year-old male patient who received mRNA-1273 (Moderna Covid-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Steroid therapy (Taking regular steroid treatment (e.g. orally or rectally)). Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS and SARS-COV-2 VIRUS . Past adverse reactions to the above products included No adverse drug reaction with SARS-COV-2 VIRUS ; and No adverse event with SARS-COV-2 VIRUS. Concurrent medical conditions included Neoplasm (Recently had treatment for cancer, leukaemia or lymphoma (radiotherapy or chemotherapy)), Learning disability and Lung cancer (Terminal). Concomitant products included MORPHINE SULFATE (MST CONTINUS) for Pain, CLOPIDOGREL, CYCLIZINE, PREDNISONE, RAMIPRIL and ZOPICLONE for an unknown indication.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 02-Oct-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced LUNG NEOPLASM MALIGNANT (Lung cancer) (seriousness criteria death and medically significant), LOWER RESPIRATORY TRACT INFECTION (Lower respiratory tract infection) (seriousness criterion death), CHEST PAIN (Chest pain) (seriousness criterion medically significant) and DYSPNOEA (Dyspnoea) (seriousness criterion medically significant). The patient died on 03-Oct-2021. The reported cause of death was Lung cancer, Lower respiratory tract infection and Lung adenocarcinoma. It is unknown if an autopsy was performed. At the time of death, CHEST PAIN (Chest pain) and DYSPNOEA (Dyspnoea) outcome was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient had no symptoms associated with COVID-19 and not had a COVID-19 test. Patient was not enrolled in clinical trial. Patient had terminal lung cancer. Patient received vaccine day prior to death. The patient received a booster dose and not had any reaction to 1st and 2nd vaccine. Patient took vaccine not in hospital but from a different location. Hence was not able to find the batch number. Patient had shortness of breath and chest pain and it was presumed this related to his lung cancer. COVID 19 status was unknown. Company Comment: This case concerns a 69-year-old male patient, with medical history of terminal lung cancer, who experienced the unexpected serious fatal event s of Lung neoplasm malignant and Lower respiratory tract infection. The patient received the booster dose of Moderna COVID-19 Vaccine on the day prior to death. The patient's medical history of terminal lung cancer remains a confounder as a cause of death and recent treatment for cancer on unspecified date may have increased the risk of infection. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Nov-2021: Follow up document received contains, additional cause of death, medical history, events and I narrative was updated	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
	4.1(b)	MYOCARDIAL INFARCTION (Heart attack), RETINAL TEAR (Retinal tear), RETINAL DETACHMENT (Retinal detachment), MENTAL DISORDER (All DSM 5), DYSLEXIA (Dyslexia), NEOPLASM MALIGNANT (Cancer), RETINAL DEGENERATION (Retinal thinning), INTELLECTUAL DISABILITY (Retardation) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) in a 29-year-old male patient who received mRNA-1273 (Moderna Covid-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product BNT162B2 for COVID-19 immunisation. The patient's past medical history included Meningococcal meningitis (Hospitalisation prolonged: Yes, No treatment received) in May 2018, Mental disorder NOS and Electroconvulsive therapy (Hospitalised for 4 days and hospitalization prolonged, Treatment received :unknown) on 10-Mar-2021. On 01-May-2021, the patient received second dose of BNT162B2 (unknown route) 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna Covid-19 Vaccine) (unknown route) 1 dosage form. On 01-May-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant). On an unknown date, the patient experienced MYOCARDIAL INFARCTION (Heart attack) (seriousness criteria death, hospitalization and medically significant), RETINAL TEAR (Retinal tear) (seriousness criterion medically significant), RETINAL DETACHMENT (Retinal detachment) (seriousness criterion medically significant), MENTAL DISORDER (All DSM 5) (seriousness criterion medically significant), DYSLEXIA (Dyslexia) (seriousness criterion medically significant), NEOPLASM MALIGNANT (Cancer) (seriousness criterion medically significant), RETINAL DEGENERATION (Retinal thinning) (seriousness criterion medically significant) and INTELLECTUAL DISABILITY (Retardation) (seriousness criterion medically significant). The patient died on 10-Aug-2021. The reported cause of death was Heart attack. It is unknown if an autopsy was performed. At the time of death, RETINAL TEAR (Retinal tear), RETINAL DETACHMENT (Retinal detachment), MENTAL DISORDER (All DSM 5), DYSLEXIA (Dyslexia), NEOPLASM MALIGNANT (Cancer), RETINAL DEGENERATION (Retinal thinning), INTELLECTUAL DISABILITY (Retardation) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. Not Provided	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		No relevant concomitant and treatment medications were reported. Company comment This is a case of Interchange of vaccine products for this 29-year-old, male patient with no relevant medical history, who experienced the serious unexpected events of Myocardial infarction with a fatal outcome, Retinal tear, Retinal detachment, Mental disorder, Dyslexia, Neoplasm malignant, Retinal degeneration, and Intellectual disability. The events occurred on an unknown day after receiving the most recent COVID vaccine BNT162B2 (Pfizer vaccine) with date of administration 01 May 2021. However, mRNA-1273 was also administered prior to the patient receiving the BNT162B2 for COVID-19 immunization. (Date of administration of Moderna product is in question per source document). The benefit-risk relationship of mRNA-1273 is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 11-Nov-2021 and was forwarded to Moderna on 11-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of CORONAVIRUS TEST POSITIVE (Coronavirus test positive), SOMNOLENCE (Sleepy), SKIN HAEMORRHAGE (Skin bleeding) and ASTHENIA (Weakness) in an 82-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005290) for Prophylactic vaccination. Previously administered products included for COVID-19 vaccination: ComirnatyBNT162b2 (Strength- 0.3 milliliter) on 16-Jan-2021 and ComirnatyBNT162b2 (Strength- 0.3 milliliter) on 06-Feb-2021. Past adverse reactions to the above products included No adverse drug reaction with ComirnatyBNT162b2; and No adverse event with ComirnatyBNT162b2. On 04-Oct-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Oct-2021, the patient experienced CORONAVIRUS TEST POSITIVE (Coronavirus test positive) (seriousness criterion death). On 24-Oct-2021, the patient experienced SOMNOLENCE (Sleepy) (seriousness criterion death), SKIN HAEMORRHAGE (Skin bleeding) (seriousness criterion death) and ASTHENIA (Weakness) (seriousness criterion death). The patient died on 26-Oct-2021. The reported cause of death was Coronavirus test positive, Weakness, Sleepy and Skin bleeding. It is unknown if an autopsy was performed.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. No treatment information was provided by the reporter. Company Comment - This case concerns an 82 year-old male patient with reported history of 2 previous doses of Comirnaty vaccine (16Jan2021 and 06Feb2021), who experienced the unexpected serious events of Death (unknown cause), Coronavirus test positive, Asthenia, Somnolence, and Skin haemorrhage. The death occurred 23 days after the most recent dose of mRNA-1273 vaccine and 7 days after a positive COVID test that occurred 19 days after the dose of mRNA-1273. Event coding and seriousness criteria of Death were maintained for all events for consistency with RA report. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 11-Nov-2021: Translation document received on 15-Nov-2021, does not contain any new information (NNI)	
4.1(b)	4.1(b)	This case was received via Zuellig Pharma (Reference number: 4.1(b)) on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death), LOSS OF CONSCIOUSNESS (Unconscious), CHEST DISCOMFORT (Chest Tightness) and DYSPNOEA (Short of breath) in a 26-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. No Medical History information was reported. On 23-Nov-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 23-Nov-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Mixed vaccination between Sinovac and Moderna). On 24-Nov-2021, the patient experienced DEATH (Death) (seriousness criteria death and medically significant), LOSS OF CONSCIOUSNESS (Unconscious) (seriousness criteria death and medically significant), CHEST DISCOMFORT (Chest Tightness) (seriousness criterion death) and DYSPNOEA (Short of breath) (seriousness criterion death). On 23-Nov-2021, INTERCHANGE	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		OF VACCINE PRODUCTS (Mixed vaccination between Sinovac and Moderna) had resolved. The patient died on 24-Nov-2021. The reported cause of death was Unconscious, Chest tightness and Short of breath. An autopsy was performed, but no results were provided. The patient received the first dose of Sinovac vaccine in the beginning of Sep-2021. He reserved the Moderna vaccine with the hospital and went to receive the Moderna vaccine as the second dose in the afternoon of 23-Nov-2021 which was the mixed vaccination between Sinovac and Moderna. After receiving the second dose, his condition was normal until the middle of the night. While he was using on the phone, he experienced chest tightness and short of breath. Patient was carried unconscious from the second floor to lie down on the ground floor. Then the paramedics arrived and pumped the patient's heart and used a defibrillator to save his life. But the paramedics could not save the patient's life. The patient died without wound or any injuries. No concomitant medications were reported. No treatment medications were reported. Company Comment: This case concerns a death of a 26-year-old male patient with no medical history, who experienced the unexpected events of loss of consciousness, chest discomfort and dyspnoea. The events occurred approximately 1 day after the second dose of mRNA-1273. As reported, the patient received the first dose of Sinovac vaccine as first dose and Moderna vaccine as the second dose approximately one month later. After receiving the second dose, his condition was normal until the middle of the night. While the patient was using on the phone, he experienced chest tightness and shortness of breath and passed away. Patient was carried unconscious from the second floor to lie down on the ground floor. The paramedics arrived and pumped the patient's heart and used a defibrillator to save his life but the patient died. Patient's body to the hospital for autopsy. Results were not yet provided. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Nov-2021: Follow up received on 25-NOV-2021 contains no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number 4.1(b)) on 26-Nov-2021 and was forwarded to Moderna on 26-Nov-2021.	THE ATTENDING PHYSICIAN BELIEVES SUSPECTED ACUTE HEART FAILURE (ISCHEMIC)

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (VACCINATED AT 12 PM ON 18/11. WORSENING OF PRE-EXISTING DYSPNEA TOWARDS EVENING. EMERGENCY SERVICES CALLED ATAROUND 3:00 AM THE FOLLOWING MORNING DUE TO WOSENING OF CLINICAL PICTURE. DECEASED SHORTLY AFTERWARD) in an 80-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005244) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: COMIRNATY - 0,45 ML - CONCENTRATO PER DISPERSIONE INIETTABILE - VIA INTRAMUSCOLARE - FLAONCINO (VE (0.45 ML CONCENTRATE FOR INJECTABLE DISPERSION - INTRAMUSCULAR ROUTE - VIAL) on 23-Mar-2021, COMIRNATY - 0 and 45 ML - CONCENTRATO PER DISPERSIONE INIETTABILE - VIA INTRAMUSCOLARE - FLAONCINO (VE (0.45 ML CONCENTRATE FOR INJECTABLE DISPERSION - INTRAMUSCULAR ROUTE - VIAL) on 13-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY - 0,45 ML - CONCENTRATO PER DISPERSIONE INIETTABILE - VIA INTRAMUSCOLARE - FLAONCINO (VE, COMIRNATY - 0 and 45 ML - CONCENTRATO PER DISPERSIONE INIETTABILE - VIA INTRAMUSCOLARE - FLAONCINO (VE. Concomitant products included PANTOPRAZOLE, INSULIN LISPRO (HUMALOG), INSULIN DEGLUDEC (TRESIBA PENFILL), TAFLUPROST (SAFLUTAN) and ACETYLSALICYLATE LYISINE (CARDIRENE) for an unknown indication. On 18-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) .25 milliliter. On 18-Nov-2021, the patient experienced DYSPNOEA (VACCINATED AT 12 PM ON 18/11. WORSENING OF PRE-EXISTING DYSPNEA TOWARDS EVENING. EMERGENCY SERVICES CALLED ATAROUND 3:00 AM THE FOLLOWING MORNING DUE TO WOSENING OF CLINICAL PICTURE. DECEASED SHORTLY AFTERWARD) (seriousness criterion death). The patient died on 19-Nov-2021. The reported cause of death was vaccinated at 12 pm on 18/11. worsening of pre-existing dyspnea towards evening. emergency services called at around 3:00 am the following morning due to worsening of clinical picture. deceased shortly afterward. It is unknown if an autopsy was performed.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided by the reporter. The patient was given a half dose of moderna (0.25 instead of 0.5). The previous doses were both of COMIRNATY. Company Comment: This RA case concerns a 80 year old female with no reported medical history , vaccinated with Comirnaty Vaccine (Pfizer Covid 19 vaccine for dose 1 and dose 2) , who experienced Serious (Fatal) , unexpected event of Dyspnea which occurred 1 day after vaccination with an unknown dose number of mRNA -1273 vaccine (Moderna Covid 19 Vaccine) . The patient's dyspnea worsened , emergency service called , condition deteriorated and later on died. It is unknown if an autopsy was done. Reporting physician suspected Acute Heart failure likely . The re-challenge for this case is not applicable since no additional doses will be given and the nature of the event. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. THE REPORTING PHYSICIAN BELIEVES THAT SUSPECTED ACUTE (ISCHEMIC) HEART FAILURE IS LIKELY Most recent FOLLOW-UP information incorporated above includes: On 26-Nov-2021: Translation received on 30-NOV-21 for initial SD: Event verbatim translated. Patient medical historical drug added, concomitants added, senders comment added On 30-Nov-2021: Follow up received is NNI. On 14-Dec-2021: non-significant follow up received	
4.1(b)	4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 15-Dec-2021. The most recent information was received on 22-Dec-2021 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest), CARDIOMEGALY (Heart enlarged), PYREXIA (Fever), LIMB DISCOMFORT (Arm discomfort), NASOPHARYNGITIS (Cold symptoms), SEIZURE (Seizure) and LEFT VENTRICULAR FAILURE (Left ventricular failure) in a 59-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concomitant products included OMEPRAZOLE for Acid indigestion, COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 19-Mar-2021 to an unknown date, COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA)	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		from 04-Jun-2021 to an unknown date, IBUPROFEN (GALPHARM IBUPROFEN), INFLUENZA VACCINE INACT SPLIT and PARACETAMOL for an unknown indication. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 09-Dec-2021, the patient experienced LIMB DISCOMFORT (Arm discomfort) (seriousness criteria hospitalization and life threatening) and NASOPHARYNGITIS (Cold symptoms) (seriousness criteria hospitalization and life threatening). On 10-Dec-2021, the patient experienced CARDIOMEGALY (Heart enlarged) (seriousness criteria hospitalization and life threatening) and LEFT VENTRICULAR FAILURE (Left ventricular failure) (seriousness criteria hospitalization and life threatening). On 11-Dec-2021, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria death, hospitalization and life threatening) and SEIZURE (Seizure) (seriousness criteria hospitalization and life threatening). On an unknown date, the patient experienced PYREXIA (Fever) (seriousness criteria hospitalization and life threatening). The patient died on an unknown date. The reported cause of death was Cardiac arrest. It is unknown if an autopsy was performed. At the time of death, CARDIOMEGALY (Heart enlarged), SEIZURE (Seizure) and LEFT VENTRICULAR FAILURE (Left ventricular failure) had not resolved and PYREXIA (Fever), LIMB DISCOMFORT (Arm discomfort) and NASOPHARYNGITIS (Cold symptoms) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Dec-2021, SARS-CoV-2 test: negative (Negative) Negative. No medical history information was provided. Concomitant product reported as MILPHARM OMEPRAZOLE GASTRO-RESISTANT (Omeprazole). The patient had booster on 8-Dec-2021 he felt a little under the weather of a cold, sore arm. On Friday he felt a little worse than the day before like a heavier cold. At 4am he woke had a seizure whilst laying face down. Reporter called emergency, Patient was put into an induced coma. Where over the last week they have carried out numerous tests out on his brain as he has had continuous seizures which then gave him no brain activity which has led to his death. He experienced cardiac arrest. His heart was enlarged which led to severe impairment of the left ventricle.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		No increase of alcohol intake. No recreational drug use. No use of steroids/hormonal drugs. Never had a reaction to a vaccine. Did not have or has not been diagnosed with COVID-19 during the pandemic. From the first AZ vaccines he was okay, experienced the standard vaccine side affects, the second never had any side effects. Company comment: This regulatory authority case concerns a 59-year-old male patient, with no relevant medical history reported, who experienced the unexpected fatal event of CARDIAC ARREST and the serious unexpected events of CARDIOMEGALY(AESI), PYREXIA, LIMB DISCOMFORT, NASOPHARYNGITIS, SEIZURE (AESI) and LEFT VENTRICULAR FAILURE (AESI) after the third dose of mRNA-1273 (reported as booster dose). The next day after vaccination the patient experienced nasopharyngitis and limb discomfort. 4 days later the patient had a seizure and was hospitalized, complementary studies were not reported. It was reported that the patient had continuous seizures and then, experienced a cardiac arrest The cause of death was reported as Cardiac arrest. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 23-Dec-2021: Non significant follow up appended On 24-Dec-2021: Follow-up received included significant information. Historical condition of Acid reflux (oesophageal) was removed. Concomitant details were updated. Previously reported co-suspected COVID-19 VACCINE ASTRAZENECA was changed to concomitant. Myocarditis event was deleted. I-Narrative updated. Additional event cardiac arrest was reported with fatal outcome. Cause of death - cardiac arrest. Added events Arm discomfort, Cold symptoms, Seizure, Left ventricular failure.	
4.1(b)	4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 15-Dec-2021. The most recent information was received on 22-Dec-2021 and was forwarded to Moderna on 22-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (Sudden death) in a 66-year-old male patient who received mRNA-1273 (Moderna Covid-19 Vaccine) (batch no. 3004737) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Heart attack (Heart attack around seven years ago).	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Previously administered products included for Drug use for unknown indication: COVID-19 VACCINE ASTRAZENECA. Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE ASTRAZENECA. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 15-May-2021 to an unknown date for COVID-19 vaccination, ATORVASTATIN from 14-Dec-2014 to an unknown date for Heart attack and Heart attack, PARACETAMOL from 12-Dec-2021 to 12-Dec-2021 for an unknown indication. On 12-Dec-2021, the patient received third dose of mRNA-1273 (Moderna Covid-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced FEELING ABNORMAL (Feeling strange). The patient died on 13-Dec-2021. The reported cause of death was Sudden death unexplained. An autopsy was performed, but no results were provided. At the time of death, FEELING ABNORMAL (Feeling strange) outcome was unknown. Patient dead hours after covid booster. Patient had not been reporting any other recent illness The post mortem was scheduled for 22 Dec 2021. Patient had a heart attack about seven years ago and was taking daily statins. He also had regular health check ups and the most recent was only a few weeks ago. There was nothing of major concern. Patient saw a friend who said after the vaccine he felt strange and had a funny turn but he didn't elaborate. A similar think has also happened to cousins husband, who took injection on Sunday 21 November and died suddenly hours later on Monday 22 November. They had not yet submitted a yellow card report and my auntie was asking how they reported patient death to you. Company Comment -This case concerns a 66-year-old male patient with medical history of heart attack, who experienced the serious (death) unexpected event of sudden death. The event occurred 1 day after the third dose of mRNA-1273 vaccine. The reported cause of death was sudden death. Patient's medical history of heart attack remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Interchange of vaccine products (two doses was with COVID-19 VACCINE ASTRAZENECA, 6 months 27 days before current vaccination) is also noted in this case.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 22-Dec-2021: Follow-up received on 22 Dec 2021: Relevant history updated, added cause of death, added batch number, dosage text, indication, updated action taken for suspect product, concomitant drugs added and events updated.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of MALAISE (several hours(2-4) later went to bed not feeling well), ASTHENIA (weak), CHILLS (Chills), FATIGUE (Fatigue), DYSPNOEA (Labored Breathing), LOSS OF CONSCIOUSNESS (shortly lost consciousness) and DEATH (Died) in a 75-year-old patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. #069H21A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Pfizer. Past adverse reactions to the above products included No adverse event with Pfizer. Concurrent medical conditions included Lupus syndrome (lupus). On 15-Dec-2021 at 4:40 PM, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced MALAISE (several hours(2-4) later went to bed not feeling well) (seriousness criterion death), ASTHENIA (weak) (seriousness criterion death), CHILLS (Chills) (seriousness criterion death), FATIGUE (Fatigue) (seriousness criterion death), DYSPNOEA (Labored Breathing) (seriousness criterion death), LOSS OF CONSCIOUSNESS (shortly lost consciousness) (seriousness criteria death and medically significant) and DEATH (Died) (seriousness criteria death and medically significant). The patient died on 15-Dec-2021. The reported cause of death was several hours (2-4) later went to bed not feeling well, weak, Chills, Fatigue, Labored breathing and shortly lost consciousness. It is unknown if an autopsy was performed. No concomitant medication was provided by reporter. Patient shortly lost consciousness Paramedics called, Husband and Daughter applied CPR in the interim could not Resuscitate. No treatment drug was provided by reporter.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 04-Jan-2022: Follow up document received that contains no new information.	
4.1(b)	4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 17-Dec-2021. The most recent information was received on 23-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death) and DYSPNOEA (Breathlessness) in a 98-year-old male patient who received mRNA-1273 (Moderna Covid-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Frailty and Cognitive impairment. Previously administered products included for Drug use for unknown indication: APIXABAN, CYANOCOBALAMIN, TAMSULOSIN, FINASTERIDE, OMEPRAZOLE and FERROUS FUMARATE. Past adverse reactions to the above products included No adverse event with APIXABAN, CYANOCOBALAMIN, FERROUS FUMARATE, FINASTERIDE, OMEPRAZOLE and TAMSULOSIN. Concurrent medical conditions included Macular degeneration, Atrial fibrillation, Hypothyroidism, Wet macular degeneration and Urinary tract infection (Prone to Urinary Tract infections). Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 vaccination, TRIMETHOPRIM for Urinary tract infection. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna Covid-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (Death) (seriousness criteria death and medically significant) and DYSPNOEA (Breathlessness) (seriousness criterion death). The patient died on 08-Dec-2021. The reported cause of death was Valvular heart disease NOS. It is unknown if an autopsy was performed. Patient has not had symptoms associated with COVID-19. Not had a COVID-19 test The patient was administered the Moderna Covid - 19 vaccination on the afternoon of the 8 Dec 2021 He was 98 years old and already suffering with	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Atrial Fibrillation, Hypothyroidism, Macular degeneration, and general physical frailty with some cognitive impairment. At the time of him being given the vaccination, he was still experiencing a urine infection, being treated with anti biotics. The paramedics had already attended the same afternoon as patient's son had arrived at his home on a visit and was concerned that Dad was breathless. The nurse administering the vaccine arrived as the paramedics were there and administered the vaccine, without checking on the medical history of the patient and his up to date health. The following day, the patient was found lying on the floor dead in his lounge by his neighbour. It was thought he had been dead since late the night before. It just seems too coincidental that his death occurred only a few hours following administration of the vaccination. The patient had been housebound for two years since the pandemic began. The matter was currently with the Coroners and were awaiting contact from him/her. Treatment medication was not provided. Company Comment - This case concerns a 98 year old female patient with medical history past medical history of atrial fibrillation, frailty and hypothyroidism, who experienced the serious (death) unexpected events of death and dyspnoea. The events occurred on an unknown date after the third dose of mRNA-1273 vaccine, with death occurring the same day after receiving the third dose of mRNA-1273 vaccine. A concomitant product in this case is the Covid-19 AstraZeneca vaccine. The rechallenge was not applicable as there are no plans for future dosing. Patient's past medical history of atrial fibrillation remains a confounder. The reported cause of death was valvular heart disease NOS and it is unknown if an a Most recent FOLLOW-UP information incorporated above includes: On 23-Dec-2021: Significant Follow Up- Historical drug updated, cause of death updated.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 20-Dec-2021. The most recent information was received on 03-Jan-2022 and was forwarded to Moderna on 03-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Cardiac arrest) and PARKINSON'S DISEASE (Increase of symptoms of Parkinson's disease) in a 91-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005243) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The patient's past medical history included Hypotension. Previously administered products included for Product used for unknown indication: PFIZER BIONTECH COVID-19 VACCINE on 30-Jan-2021 and PFIZER BIONTECH COVID-19 VACCINE on 07-Mar-2021. Past adverse reactions to the above products included No adverse event with PFIZER BIONTECH COVID-19 VACCINE and PFIZER BIONTECH COVID-19 VACCINE. Concurrent medical conditions included Parkinson's disease since 2014. Concomitant products included PINDOLOL (NONSPI), CARBIDOPA (ANTI-PARKINSON), COLECALCIFEROL, DOPAMINE and APOMORPHINE for an unknown indication. On 22-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Nov-2021, the patient experienced PARKINSON'S DISEASE (Increase of symptoms of Parkinson's disease) (seriousness criteria death, disability and medically significant). On 01-Dec-2021, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criterion death). On an unknown date, the patient experienced OEDEMA PERIPHERAL (The doctor also diagnosed increasing fluid retention in legs,). The patient died on 01-Dec-2021. The reported cause of death was the doctor has diagnosed a cardiac arrest. and increased symptoms of parkinson's disease. An autopsy was not performed. At the time of death, OEDEMA PERIPHERAL (The doctor also diagnosed increasing fluid retention in legs,) outcome was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This case concerns a 91-year-old male patient, with medical history of hypotension and Parkinson's disease, and in treatment with polypharmacy, who experienced the unexpected events of Cardiac arrest and Parkinson's disease. The event of Parkinson's disease occurred 1 day after the third dose of mRNA-1273 vaccine. The event of Cardiac arrest occurred 9 days after the third dose of mRNA-1273 vaccine. Both events had a fatal outcome, with death occurring. The reported cause of death was cardiac arrest and increased symptoms of Parkinson's disease. An autopsy was not performed. Previous doses of COVID-19 vaccine administered with Pfizer Biontech COVID-19 vaccine. Patient's advanced age, as well as medical history and polypharmacy, remain	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Jan-2022: Follow-up received included: Updated patient cause of death, Updated patient autopsy details, Added concomitant medications, Added event (cardiac arrest). On 03-Jan-2022: Translation received on 06-Jan-2022 as live follow up, updated event verbatim	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Heart attack) and APALLIC SYNDROME (vegetative state) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Rehabilitation therapy (long term alcohol rehabilitation). Previously administered products included for Product used for unknown indication: Astrazeneca. Past adverse reactions to the above products included No adverse event with Astrazeneca. On 13-Dec-2021 at 3:00 PM, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Dec-2021 at 11:00 AM, the patient experienced MYOCARDIAL INFARCTION (Heart attack) (seriousness criteria death, hospitalization and medically significant). In December 2021, the patient experienced APALLIC SYNDROME (vegetative state) (seriousness criteria hospitalization and medically significant). The patient died on 18-Dec-2021. The reported cause of death was Heart attack. It is unknown if an autopsy was performed. At the time of death, APALLIC SYNDROME (vegetative state) outcome was unknown. At 11 am on 14-Dec2021, the patient was transferred hospital immediately and was hospitalized in intensive care unit. The hospital reported that it was difficult to conclude that the vaccine may have caused a heart attack. No concomitant medication details were provided by reporter. No treatment medication details were provided by reporter. Company comment: This spontaneous case concerns a male patient of unknown age, with medical history of alcohol	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		problem, who experienced the unexpected, serious (fatal/hospitalization/medically significant) event of myocardial infarction and unexpected, serious (hospitalization/medically significant) event of apallic syndrome. The patient developed myocardial infarction after 1 day of receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient's COVID-19 vaccination schedule. He was admitted to the hospital in the intensive care unit, however he was diagnosed with vegetative state and he died 5 days after vaccination. Autopsy report is not available. The patient received as first and second dose of his COVID-19 vaccination schedule two doses AstraZeneca's COVID-19 vaccine. The hospital reported that it is difficult to conclude that the vaccine may have caused the myocardial infarction. The rechallenge is not applicable, considering the outcome. The medical history of alcohol problem remains as a confounder. The benefit -risk relationship of mRNA -1273 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 22-Dec-2021. The most recent information was received on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) and MYOCARDITIS (Myocarditis) in a 51-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included SARS-CoV-2 infection. Previously administered products included for COVID-19 vaccination: COMIRNATY. Past adverse reactions to the above products included No adverse event with COMIRNATY. On 04-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Dec-2021, the patient experienced SUDDEN DEATH (Sudden death unexplained) (seriousness criterion death) and MYOCARDITIS (Myocarditis) (seriousness criterion death). The patient died on 07-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication provided. No treatment information mentioned. According autopsy report: Dilative cardiomyopathy. Death is not related to vaccination	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Company Comment: This is a regulatory case concerning a 51-year-old, male patient with medical history of SARS-CoV-2 infection, who experienced the unexpected fatal events of Sudden death and myocarditis (AESI). The events occurred 3 days after the administration of third/booster dose of mRNA-1273 vaccine. Patient's medical history of SARS-CoV-2 infection could be a confounder factor for the event myocarditis. The cause of death was reported as unknown. Autopsy reported Dilative cardiomyopathy. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 27-Dec-2021: Significant FU. autopsy report and onset age is updated.	
4.1(b)	4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), OROPHARYNGEAL PAIN (Sore throat), DYSPNOEA (DOB) and OXYGEN SATURATION DECREASED (Oxygen saturation low) in a 34-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 055ez1a) for an unknown indication. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. No Medical History information was reported. On 17-Aug-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 27-Sep-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) at an unspecified dose. On 11-Dec-2021 at 5:00 PM, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion death), OROPHARYNGEAL PAIN (Sore throat) (seriousness criterion death), DYSPNOEA (DOB) (seriousness criterion death) and OXYGEN SATURATION DECREASED (Oxygen saturation low) (seriousness criterion death). The reported cause of death was Chest pain, Sore throat, dob and Oxygen saturation low. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications was reported. Treatment information was not provided. It was reported that Patient referred for sudden onset of chest pain accompanied by DOB and	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Desaturation. Chief Complaint prior to detection: Cough for 3 days and Sore throat with DOB Company Comment: This regulatory case concerns a 34-year-old, male patient with history of co-administration of the Comirnaty (tozinameran) COVID-19 vaccine, who experienced the unexpected, serious events of chest pain, oropharyngeal pain, dyspnoea and oxygen saturation decreased. The events, which resulted in a fatal outcome, occurred 3 months, 24 days after administration of the first dose of the Moderna mRNA-1273 vaccine. The patient initially experienced cough for 3 days and sore throat with difficulty of breathing (DOB). He was then referred due to sudden onset of chest pain accompanied by DOB and desaturation. No further details were provided. The history of co-administration of the Comirnaty (tozinameran) COVID-19 vaccine remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 24-Dec-2021 and was forwarded to Moderna on 24-Dec-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of INTESTINAL OBSTRUCTION (Bowel obstruction), SEPSIS (Septicaemia) and CARDIAC ARREST (Arrest cardiac) in a 44-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. The patient's past medical history included Gene mutation, Pneumopathy, Obesity and Retardation mental. On 01-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 29-Mar-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 25-Nov-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 27-Nov-2021, the patient experienced INTESTINAL OBSTRUCTION (Bowel obstruction) (seriousness criterion death), SEPSIS (Septicaemia) (seriousness criterion death) and CARDIAC ARREST (Arrest cardiac) (seriousness criterion death). The reported cause of death was Bowel obstruction, Septicaemia and Arrest cardiac. It is unknown if an autopsy was performed.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company comment: This regulatory authority case concerns a 44-year-old female patient with a relevant medical history of Obesity, who experienced the unexpected fatal events of Intestinal obstruction, Sepsis and Cardiac arrest after mRNA- 1273 Moderna vaccine. The patient received initial schedule of vaccination with mRNA-1273 Moderna vaccine and after 7 months and 27 days, third dose of Tozinameran /Comirnaty was administered. The onset of the events occurred approximately 7 months and 29 days after the second dose of mRNA- 1273 vaccine, 2 days after the dose of Tozinameran /Comirnaty and had a fatal outcome (date of death was not reported). Very limited information is available regarding clinical course and circumstances leading to death. Cause of death was not further specified. It is unknown if an autopsy was performed. Underlying obesity and co-suspect administration of Tozinameran /Comirnaty Vaccine remain a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of AORTIC ANEURYSM RUPTURE (burst belly aneurysm) in a 52-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Previously administered products included for Prophylactic vaccination: COVID-19 VACCINE JANSSEN on 27-May-2021. Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE JANSSEN. On 26-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Dec-2021, the patient experienced AORTIC ANEURYSM RUPTURE (burst belly aneurysm) (seriousness criteria death and medically significant). The patient died on 01-Dec-2021. The reported cause of death was Abdominal aneurysm, ruptured. It is unknown if an autopsy was performed. No Concomitant drugs were reported.	No Information on pre-existing conditions The aneurysm was not known. He thought he was healthy. Date of birth 23.08.1969 When working from home, the person became nauseous, dizzy and he was lying down. Shortly thereafter, breathing stopped. It was reanimated and the ambulance was called. It continued to be animated to the hospital, but after about an hour he died. In retrospect, a burst aneurysm in the abdomen was detected. It's my best friend husband. He leaves a wife and two children behind.

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		No Treatment information were reported. It was reported, that No Information on risk factors or pre-existing conditions The aneurysm was not known. He thought he was healthy. Date of birth 23.08.1969 When working at work from home, the person became nauseous and dizzy and he was lying down. Shortly thereafter, breathing stopped. It was reanimated and the ambulance was called. It continued to be animated to the hospital, but after about an hour he died. In retrospect, a burst aneurysm in the abdomen was detected.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of ISCHAEMIC STROKE (Ischemic stroke) and CARDIAC FAILURE (Heart Decompensation) in a 92-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214031) for COVID-19 vaccination. The patient's past medical history included Ischemic heart disease (Severe ischemic heart disease with tri-truncular lesions Preserved FEVf), Myocardial infarction (Myocardial Infarction (unspecified)), Dyslipidemia, Gonarthrosis (Right internal tibial femoral gonarthrosis), Carotid endarterectomy (Right (juillet 2014)) in July 2014, Carotid endarterectomy (left (november 2020)) in November 2020 and Prostatic operation (Prostatic adenomectomy). Previously administered products included for Product used for unknown indication: COMIRNATY (Dose 1: Pfizer/Biontech Vaccine, Left Arm, Intramuscular Injection, Lot #: EK9788) on 01-Feb-2021, COMIRNATY (Dose 2: Pfizer/Biontech Vaccine, Left Arm, Intramuscular Injection and Lot #: EP9598) on 22-Feb-2021. Past adverse reactions to the above products included No adverse effect with COMIRNATY and COMIRNATY. Concomitant products included BISOPROLOL, CLOPIDOGREL, ATORVASTATIN, AMLODIPINE BESILATE, PERINDOPRIL ARGININE (COVERAM), FUROSEMIDE, COLECALCIFEROL (ZYMAD), SILODOSINE and PARACETAMOL for an unknown indication. On 05-Oct-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced CARDIAC FAILURE (Heart Decompensation) (seriousness criterion hospitalization). On 30-Oct-2021, the patient experienced ISCHAEMIC STROKE (Ischemic stroke) (seriousness criterion death). The	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		patient died on 01-Nov-2021. The reported cause of death was Ischemic stroke. An autopsy was not performed. At the time of death, CARDIAC FAILURE (Heart Decompensation) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Dosage text for suspect given as R1. Medical history include Mediocalcosis, AIT (2014), and HTA. Treatment information was not reported. Company comment: This case concerns a 92-year-old, male patient, with medical history of severe ischaemic heart disease, myocardial infarction, transient ischaemic stroke, hypertension and dyslipidemia, who experienced the unexpected, serious (fatal) and AESI of Ischaemic stroke and the unexpected, serious (hospitalization) and AESI of cardiac failure. The patient developed cardiac failure 16 days after receiving a dose of mRNA-1273 vaccine and complicated with ischaemic stroke 9 days after. The patient died approximately 27 days after vaccination. The patient received as first and second dose of his COVID-19 vaccination schedule two doses Pfizer's COVID-19 vaccine. The rechallenge was not applicable, considering the outcome. The medical history of severe ischaemic heart disease, myocardial infarction, transient ischaemic stroke, hypertension and dyslipidemia remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest) in a 62-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. In April 2021, the patient received first dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (JANSSEN COVID-19 VACCINE) (unknown route) at an unspecified dose.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 26-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant). The patient died on 18-Dec-2021. The reported cause of death was cardiac arrest for unknown cause. An autopsy was not performed. No concomitant and treatment medications were reported. It was reported that the patient had no early warning signs of myocardial infarction. On 18-DEC-2021, before noon, the patient died due to cardiac arrest. The patient was diagnosed with death due to cardiac arrest of unknown cause. Company Comment: This case concerns a 62-year-old male patient, with relevant medical history of vaccination with Janssen COVID-19 vaccine, who experienced the unexpected serious fatal event of Cardiac arrest. The event occurred approximately 23 days after the booster dose of mRNA-1273 Vaccine. The patient was diagnosed with death due to cardiac arrest of unknown cause. It was reported that an autopsy had not been performed. The patient's medical history of vaccination with Janssen COVID-19 vaccine remain a confounder for the occurrence of the event. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 24-Dec-2021. The most recent information was received on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death), CARDIAC ARREST (Cardiac arrest), INFLUENZA LIKE ILLNESS (Flu like symptoms), HEADACHE (Headache), DYSPNOEA (Dyspnoea) and OXYGEN SATURATION DECREASED (Oxygen saturation low) in a 39-year-old male patient who received mRNA-1273 (Moderna Covid-19 Vaccine) (batch no. 3005686) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: COVID-19 MRNA VACCINE BNT162B2 from 16-May-2021 to 16-Jun-2021 and COVID-19 MRNA VACCINE BNT162B2 on 13-Jul-2021.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Past adverse reactions to the above products included No adverse event with COVID-19 MRNA VACCINE BNT162B2 and COVID-19 MRNA VACCINE BNT162B2. On 16-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 INFLUENZA LIKE ILLNESS (Flu like symptoms) (seriousness criterion death) and HEADACHE (Headache) (seriousness criterion death). On 22-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced DEATH (Death) (seriousness criterion death), CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant) and DYSPNOEA (Dyspnoea) (seriousness criterion death). On an unknown date, the patient experienced OXYGEN SATURATION DECREASED (Oxygen saturation low) (seriousness criterion death). The patient died on 22-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. No treatment information was provided by the reporter. Patient not had symptoms associated with COVID-19. Patient not had a COVID-19 test On 22-Dec-2021, patient had feeling short of breath (SOB). Patient had Flu and headachy since booster on 16-Dec-2021. She had arrested and pronounced dead and pending coroner. Patient not tested positive for COVID-19 since had the vaccine Patient was unsure if enrolled in clinical trial The patient had related possible blood clots or low platelet counts (Thromboembolic event / Thrombocytopenia). The platelet count <150 Å—109/L was unknown. The D-dimer >4000 was Unknown. The anti-PF4 antibodies identified was unknown . The lot number of Vaccines for all doses were Pfizer Batch number (EW4109) May 21, Pfizer (FE1510) July 2021 , Moderna (3005686) Dec 21. Sadly , He don't have information about the patients reported cause of death. The coroner was reviewing the case. The patient presented with breathing difficulties and complained of feeling unwell since having the moderna booster. He contacted a GP where he was visiting family. Before being seen the patients breathing worsened, an ambulance was called and he was found to be low in oxygen. He then arrested and died.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		He has not been seen at out practice since 2017. He had no significant medical history and was on no regular medication. He had had no recent covid tests or reported covid symptoms to professionals. Most recent FOLLOW-UP information incorporated above includes: On 07-Jan-2022: Follow-up received included Historical Vaccine - Pfizer Biotech added, Concomitant Pfizer Biotech deleted, events (Cardiac arrest, Flu like symptoms, Headache, Short of breath, Oxygen saturation low) added.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Dec-2021 and was forwarded to Moderna on 29-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Death with central pulmonary embolization) in a 67-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 023F21A) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. The patient's past medical history included Breast cancer in 2007. Concurrent medical conditions included Vascular dementia since 2020 and Paranoid psychosis. Concomitant products included INFLUENZA VACCINE (FLUZONE [INFLUENZA VACCINE]) for an unknown indication. In 2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. In 2021, TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced PULMONARY EMBOLISM (Death with central pulmonary embolization) (seriousness criterion death). The reported cause of death was Pulmonary embolism. An autopsy was performed, but no results were provided. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Treatment medications were not reported. Company comment: This is a regulatory authority case concerning a 67-year-old female patient with medical history of breast cancer, primary vaccination with COVID-19 vaccine TOZINAMERAN (COMIRNATY) and concurrent medical conditions of vascular dementia since 2020 and Paranoid psychosis; who experienced	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		unexpected, fatal event of pulmonary embolism. The event occurred on an unknown date after the third dose of mRNA-1273 vaccine. Vaccination dates were not disclosed. The patient died on an unknown date, an autopsy was performed, but results were not provided. Patient's medical history, concurrent medical conditions and COVID-19 vaccine TOZINAMERAN (COMIRNATY) remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) in a 50-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004233) for COVID-19 vaccination. The patient's past medical history included Hypertension. Previously administered products included for COVID-19 vaccination: COMIRNATY on 25-Apr-2021 and COMIRNATY on 06-Jun-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Dec-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death, hospitalization, medically significant and life threatening). The patient died on 11-Dec-2021. The reported cause of death was Acute myocardial infarction. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. concomitant drug details and treatment drug not provided. last cardiolog. Examination 8/19 without evidence of heart disease.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 28-Dec-2021. The most recent information was received on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of HAEMOPTYSIS (Acticovid vaccination carried out on 27/11 2/12 Cough with blood sputum streaked with blood: d dimer 4831. Sending into Idea with TEP Diagnosis and Subsequent IMA Death on	21/12/2021:1st and 2nd dose comirnaty data updated. Request clinical report via email

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		15/12/21), ACUTE MYOCARDIAL INFARCTION (Acticovid vaccination carried out on 27/11 2/12 Cough with blood sputum streaked with blood: d dimer 4831. Sending into Idea with TEP Diagnosis and Subsequent IMA Death on 15/12/21), COUGH (Acticovid vaccination carried out on 27/11 2/12 Cough with blood sputum streaked with blood: d dimer 4831. Sending into Idea with TEP Diagnosis and Subsequent IMA Death on 15/12/21) and PULMONARY EMBOLISM (Acticovid vaccination carried out on 27/11 2/12 Cough with blood sputum streaked with blood: d dimer 4831. Sending into Idea with TEP Diagnosis and Subsequent IMA Death on 15/12/21) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 immunisation. Previously administered products included for COVID-19 immunisation: COMIRNATY (COMIRNATY - 10 mcg Concentrate for injectable dispersion - intramuscular use - vial (glass) on 15-Apr-2021 and COMIRNATY (COMIRNATY - 10 mcg Concentrate for injectable dispersion - intramuscular use - vial (glass) on 06-May-2021. Past adverse reactions to the above products included No adverse reaction with COMIRNATY and COMIRNATY. On 27-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Dec-2021, the patient experienced HAEMOPTYSIS (Acticovid vaccination carried out on 27/11 2/12 Cough with blood sputum streaked with blood: d dimer 4831. Sending into Idea with TEP Diagnosis and Subsequent IMA Death on 15/12/21) (seriousness criterion death), ACUTE MYOCARDIAL INFARCTION (Acticovid vaccination carried out on 27/11 2/12 Cough with blood sputum streaked with blood: d dimer 4831. Sending into Idea with TEP Diagnosis and Subsequent IMA Death on 15/12/21) (seriousness criterion death), COUGH (Acticovid vaccination carried out on 27/11 2/12 Cough with blood sputum streaked with blood: d dimer 4831. Sending into Idea with TEP Diagnosis and Subsequent IMA Death on 15/12/21) (seriousness criterion death) and PULMONARY EMBOLISM (Acticovid vaccination carried out on 27/11 2/12 Cough with blood sputum streaked with blood: d dimer 4831. Sending into Idea with TEP Diagnosis and Subsequent IMA Death on 15/12/21) (seriousness criterion death). The patient died on 15-Dec-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Fibrin D dimer: inconclusive (Inconclusive) Inconclusive.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. The patient received first and second dose of comirnaty. Most recent FOLLOW-UP information incorporated above includes: On 06-Jan-2022: Significant follow up Medical history updated, cause of death updated. On 06-Jan-2022: Translation document received on 12-JAN-2022 contains historical drug name (notes updated)	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in a 39-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. The patient's past medical history included Intelligence reduced. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 12-Jan-2021 and Comirnaty BNT162b2 on 10-Feb-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. On 03-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 10-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment medications were reported. Company Comment This case concerns a 39-year-old male patient with no relevant medical history, who experienced the serious, unexpected event of Death. The event occurred 7 days after the third dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		reporting and retained for consistency with the RA report	

20.11.20. Interaction with Other COVID-19 vaccines (Heterologous Vaccine Schedule): Pfizer: Cumulative Case Narratives Listings

Country	Report Type	ALL PTS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	NW Identifier	Batch/Lot Number
4.1(b)	Regulatory Authority	Asthenia, Cough, COVID-19, COVID-19 pneumonia, Interchange of vaccine products, Lung disorder	Serious	84.00	1008.00	Unknown	Thrombocytopenia(H); Hypertension(C); Chronic obstructive pulmonary disease(C); Generalised anxiety disorder(H)		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE			4.1(b)	326120A
	Regulatory Authority	Chest pain, Chills, Cough, COVID-19, Diarrhoea, Dyspnoea, Headache, Interchange of vaccine products, Pneumonia, Pyrexia	Serious	85.00	1140.00	Unknown			BNT162B2, BNT162B2, BNT162B2, BNT162B2, BNT162B2, BNT162B2, BNT162B2, BNT162B2, BNT162B2				343120A
	Regulatory Authority	Abdominal pain upper, Cold sweat, COVID-19 immunisation, Influenza like illness, Myocarditis, Nausea, Vomiting	Serious	22.00	254.00	Male	Comorbid(H)						FE9174
	Regulatory Authority	Cough, COVID-19 immunisation, Dyspnoea, Fatigue, Headache, Paraesthesia oral, Pharyngeal paraesthesia, Pruritus	Serious	51.00	612.00	Female			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY				
	Regulatory Authority	Abdominal distension, COV D-19 immunisation, Disturbance in attention, Fatigue, Feeling abnormal, Headache, Interchange of vaccine products, Myalgia, Postmenopausal haemorrhage, Pyrexia, Sinus pain	Serious	50.00	600.00	Female	Postmenopausal(C); Comorbid(H)	SUPROFEN, PARACETAMOL					
	Regulatory Authority	COVID-19 immunisation, Myocarditis, Pericarditis	Serious	35.00	420.00	Male	Comorbid(H)						FE9174
	Regulatory Authority	Chest pain	Serious	25.00	300.00	Female	Comorbid(H)						3004498
	Regulatory Authority	COVID-19 immunisation, Myocarditis	Serious	28.00	336.00	Male	Tobacco user(H); Cardiac disorder(H)		COM RNATY, COMIRNATY				3004224
	Regulatory Authority	COVID-19 immunisation, Impaired work ability, Pericarditis	Serious	24.00	288.00	Male	Migraine(C); Comorbid(H)						3004224
	Regulatory Authority	Hypersensitivity	Serious	57.00	644.00	Female	COMIRNATY						3004498
	Regulatory Authority	Chest pain, Myocarditis	Serious	18.00	216.00	Male	COMIRNATY(H)						
	Regulatory Authority	COVID-19 immunisation, Ejection fraction decreased, Interchange of vaccine products, Myocarditis	Serious	20.00	240.00	Male	COMIRNATY(H)						3004224
	Regulatory Authority	COVID-19 immunisation, Fatigue, Heart rate increased, Interchange of vaccine products, Myocarditis, Pyrexia	Serious	18.00	216.00	Male	COMIRNATY						FE7053
	Regulatory Authority	Erythema, Interchange of vaccine products	Serious	49.00	588.00	Female	COMIRNATY						FE6234
	Regulatory Authority	Chest pain, COVID-19 immunisation, Dyspnoea, Fatigue, General physical health deterioration, Headache, Palpitations, Pyrexia, Sinus pain	Serious	34.00	408.00	Female	COMIRNATY(H)						FE7053
	Regulatory Authority	Back pain, Chest pain, COVID-19 immunisation, Fatigue, Headache, Hypotension, Leukopenia, Nausea, Taste disorder, Thrombocytopenia	Serious	44.00	528.00	Female	COMIRNATY	LEVAX N					3004224
	Regulatory Authority	Arrhythmia, COVID-19 immunisation, Pyrexia, Transaminases increased	Serious	50.00	600.00	Female	Comorbid(H); COVID-19 immunisation						
	Regulatory Authority	Back pain, Back pain, COVID D-19 immunisation, Decreased appetite, General physical health deterioration, Haematemesis, Headache, Hypersomnia, Impaired work ability, Malaise, Nausea, Pyrexia, Rash	Serious	51.00	612.00	Male	Comorbid	COO LIVER OIL [COO LIVER OIL]					
	Regulatory Authority	Chest pain, COVID-19 immunisation, Tremor	Serious	35.00	420.00	Male	Comorbid						FE3064
	Regulatory Authority	COVID-19 immunisation, Retinal vein occlusion, Vision blurred	Serious	53.00	636.00	Female	Comorbid						FE2090
	Regulatory Authority	Chest pain, COVID-19 immunisation, Interchange of vaccine products, Myocarditis	Serious	33.00	396.00	Male			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY				3004224
	Regulatory Authority	Anaphylactic reaction, COV D-19 immunisation, Dyspnoea, Loss of consciousness, Throat tightness	Serious	50.00	600.00	Female	Food allergy; Comorbid(H)		COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY				3004498
	Regulatory Authority	COVID-19 immunisation, Myocarditis	Serious	24.00	288.00	Male	Childhood asthma(H); COMIRNATY(H)						3004498
	Regulatory Authority	COVID-19 immunisation, Generalised tonic-clonic seizure, Pyrexia	Serious	35.00	420.00	Male	Epilepsy(C); COM RNATY(H)	ORP R L LONG					3004224
	Regulatory Authority	COVID-19 immunisation, Pericarditis	Serious	47.00	564.00	Male	COMIRNATY(H)						FE7053
	Regulatory Authority	Concomitant disease aggravated, COVID-19 immunisation, Dizziness, Ear discomfort, Fatigue, Headache, Hypertension, Interchange of vaccine products, Tinnitus, Nausea, Thrombosis	Serious	47.00	564.00	Female	4.1(b) (C); COMIRNATY	BETAHIST N [BETAHISTINE MESILATE]					FE7053
	Regulatory Authority	Chest pain, COVID-19 immunisation	Serious	35.00	420.00	Female	COMIRNATY(H)	DIVISUN					3004498
	Regulatory Authority	Myocarditis	Serious	22.00	264.00	Male	COMIRNATY(H)						
	Regulatory Authority	COVID-19 immunisation, Encephalitis	Serious	37.00	444.00	Male	COMIRNATY	KEPPRA [LEVETIRACETAM]					FE9174
	Regulatory Authority	Asthenia, COVID-19 immunisation, Hospitalisation, Thrombosis, Transient ischaemic attack	Serious	57.00	684.00	Male	Non-tobacco user(H); COMIRNATY						
	Regulatory Authority	COVID-19 immunisation, Meningitis noninfective	Serious	21.00	252.00	Female	Comorbid(H)	LOETTE 28					
	Regulatory Authority	COVID-19 immunisation, Hypotension, Syncope	Serious	35.00	420.00	Male			COM RNATY, COMIRNATY, COMIRNATY				FE7053
	Regulatory Authority	Chest pain, COVID-19 immunisation, Myocarditis	Serious	28.00	312.00	Male	Comorbid						FE5295
	Regulatory Authority	COVID-19 immunisation, Pericarditis	Serious	20.00	240.00	Male	Comorbid	ADUVANZ					3004952
	Regulatory Authority	Pain in extremity, Pyrexia	Serious	18.00	216.00	Male	COMIRNATY						FE1405
	Regulatory Authority	Self's palsy, COVID-19 immunisation	Serious	45.00	540.00	Male	COMIRNATY(H)						
	Regulatory Authority	Anemia macrocytic, Anisomorphous, Hemolytic, Hemolytic anemia, Interchange of vaccine products	Serious			Female	Pain(C); Gastroesophageal reflux disease(C); Depression(C); Post-traumatic stress disorder(C); Interveternal disc protrusion(C); Drug hypersensitivity; Drug hypersensitivity	CODE NE, PERCOCET [OXYCODONE HYDROCHLORIDE, OXYCODONE TEREPHTHALATE, PARACETAMOL], BACLOFEN, CIPRALEX, MAXERAN, VITAMIN D NOS, VITAMIN B12 NOS, VITAMIN N C [ASCORBIC ACID], MULTIVITAM N [VITAMINS NOS], VALIUM, TORADOL	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				
	Regulatory Authority	Chest discomfort, Interchange of vaccine products, Tachycardia	Serious	44.00	528.00	Female		MULTIVITAM N [VITAMINS NOS], VITAMIN D [VITAMIN D NOS], VITAMIN B [VITAMIN B COMPLEX], MAGNESIUM, FISH O L	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				3004224
	Regulatory Authority	COVID-19 immunisation, Myocarditis	Serious	47.00	564.00	Female	COMIRNATY						FE9174
	Regulatory Authority	Back pain, Chest pain, Interchange of vaccine products, Pericarditis effusion, Pulmonary embolism, Pulmonary mass	Serious	59.00	708.00	Female	Food allergy; PFIZER BIONTECH COVID-19 VACCINE	ZYRTEC [CETIRIZINE HYDROCHLORIDE]					FE9174
	Regulatory Authority	Interchange of vaccine products, Off label use	Serious			Female	Rheumatoid arthritis(C); Immunosuppression(C)	ADALIMUMAB, METHOTREXATE, SULFASALAZINE	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE				
	Regulatory Authority	Confusional state, COVID-19, Hypoxia, Interchange of vaccine products, Pyrexia, Somnolence	Serious	82.00	984.00	Male	Drug hypersensitivity; Vitamin D deficiency(C); Osteoarthritis(C); Anemia(C); Hypertension(C); Lung disorder(C); Prostate cancer(C)		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE			FE329	
	Regulatory Authority	Chest pain, COVID-19 immunisation, Myocarditis	Serious	17.00	204.00	Female	COMIRNATY						3002616
	Regulatory Authority	Chest pain, COVID-19 immunisation, Malaise, Myocarditis, Pyrexia	Serious	25.00	300.00	Male	Migraine(H)	ISOPIN [VERAPAMIL]	COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY			3004498	
	Regulatory Authority	Tinnitus	Serious	36.00	432.00	Male	COVID-19(H); 4.1(b) anomaly(C)		COM RNATY				3004870
	Regulatory Authority	Acute pulmonary edema, Cardiac disorder, COVID-19 immunisation, Dyspnoea, Haematemesis, Hospitalisation, Influenza like illness, Loss of consciousness, Myocarditis, Pulmonary haemorrhage	Serious	37.00	444.00	Male	Comorbid(H)						3003604
	Spontaneous	Acne, Anaphylactic reaction, Dermatitis, Feeling hot, Inappropriate schedule of product administration, Information, Paraesthesia, Pruritus, Rash, Urticaria	Serious	36.00	792.00	Female	PFIZER BIONTECH COVID-19 VACCINE: Urticaria, Anaphylactic reaction; Hypersensitivity; Milk allergy; Food allergy; Food allergy; Food allergy; Mycotic allergy; Dust allergy; Anisomorphous; Rheumatoid arthritis	CIPRALEX, CIPROLEX, CRESTOR					343021A
	Regulatory Authority	Arrhythmia, Chest pain, COVID-19 immunisation, Injection site erythema, Myalgia, Pleurisy, Pleuritic pain, Pyrexia, Vaccination site swelling, Vaccination site warmth	Serious	31.00	372.00	Female	COMIRNATY(H); SARS-COV-2 VACCINE(H)						
	Regulatory Authority	Chest pain, COVID-19 immunisation, Heart rate increased, Pericarditis	Serious	37.00	444.00	Female	Comorbid						3005997

Case ID	Country	Report Type	ALL PFS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	MW Identifier	Batch/Lot Number	
4.1(b)	4.1(b)	Regulatory Authority	COVID-19 immunisation, Myocarditis	Serious	31.00	372.00	Male	COMIRNATY						4.1(b)	004224
		Regulatory Authority	Acute pulmonary oedema, COVID-19 immunisation, Myocarditis	Serious	37.00	444.00	Male	COMIRNATY							003804
		Regulatory Authority	Pericarditis	Serious	24.00	288.00	Male	Continuity(H)							
		Regulatory Authority	Interchange of vaccine products, Rheumatoid arthritis	Serious	49.00	588.00	Female	PFIZER BIONTECH COVID-19 VACCINE							14017
		Regulatory Authority	Pulmonary embolism	Serious	23.00	276.00	Female	COMIRNATY	ALM NA 28						003804
		Regulatory Authority	COVID-19 immunisation, Pericarditis	Serious	21.00	252.00	Male	COMIRNATY(H)							003804
		Regulatory Authority	Chest pain, COVID-19 immunisation, Dyspnoea exertional, Fatigue, General physical health deterioration, Myalgia, Pyrexia	Serious	42.00	504.00	Female	Continuity							004224
		Regulatory Authority	Cardiomyopathy, COVID-19 immunisation, Pneumonia, Pulmonary oedema, Respiratory failure, Staphylococcal skin infection	Serious	30.00	360.00	Male	Continuity(H)							003804
		Regulatory Authority	Atrial fibrillation	Serious	72.00	864.00	Male	Atrial fibrillation(C), Bipolar disorder(C), PFIZER BIONTECH COVID-19 VACCINE							14025
		Regulatory Authority	COVID-19 immunisation, Pericarditis	Serious	26.00	348.00	Male	COMIRNATY							004498
4.1(b)	4.1(b)	Regulatory Authority	Chest discomfort, COV D-19 immunisation, Dyspnoea at rest, Dyspnoea exertional, Pulmonary embolism	Serious	38.00	456.00	Male	COMIRNATY						004224	
		Regulatory Authority	COVID-19 immunisation, Malaise, Postmenopausal haemorrhage, Pyrexia	Serious	48.00	576.00	Female	Postmenopausal(C), COMIRNATY							
		Regulatory Authority	COVID-19 immunisation, Electrolyte imbalance, General physical health deterioration, Pyrexia, Respiratory failure, Sepsis	Serious	78.00	936.00	Female	COMIRNATY	EBIXA, ACETYLSALICYLSYRSE, ACTAVIS, VISCOTERAS, MORFIN, MORPHINE SULFATES, SEROCQUEL, CEFOTAX M MIP, PREDNISOLONE, HYPROSAN, METOPROLOL, SANDOZ (METOPROLOL, SUCCINATES), PARACETAMOL, METHOTREXATE, PRANOLOL, KALEOR D, CALIGRAN FORTE, PENTANYL, SANDOZ (PENTANYL), NIGER-ACETAT, TROGSE, (CYANOCOBALAM N FOLIC AC D/PYR DOKINE)				004224		
		Regulatory Authority	COVID-19 immunisation, Pyrexia, Swelling face	Serious	80.00	720.00	Female	Heart failure(C), Acute myeloid leukaemia(C), Continuity	CETIRIZ N SANDOZ, LEVAXIN, MAREVAN, PLAVIX, EZETROL, STEGOLD, TOPAMAX					004224	
		Regulatory Authority	Asthma, Chest discomfort, Interchange of vaccine products, Pruritus, Rash, Skin burning sensation	Serious	45.00	540.00	Female								
		Regulatory Authority	COVID-19 immunisation, Myocarditis, Pericarditis	Serious	24.00	288.00	Male	COMIRNATY(H)						003804	
		Regulatory Authority	Interchange of vaccine products, Tinnitus	Serious	45.00	540.00	Male	Drug hypersensitivity, Drug hypersensitivity, PFIZER BIONTECH COVID-19 VACCINE	LEVS 4.1(b) PFIZER BIONTECH COVID-19 VACCINE					003804	
		Spontaneous	Chest discomfort, Depressed mood, Dyspnoea, Interchange of vaccine products, Myocarditis, Pyrexia, Rhinorrhoea	Serious	19.00	228.00	Male	PFIZER BIONTECH COVID-19 VACCINE(H)						005897	
		Regulatory Authority	Inappropriate schedule of product administration, Infection, Transient ischaemic attack	Serious	73.00	876.00	Male	Drug hypersensitivity, Atrial fibrillation(C), Coronary artery disease(C), Gastroesophageal reflux disease(H), Hypertension(C), Hyperlipidaemia(C)	WARIVARIN, AVORSTARVAT N, CARVEDILOL, HYDRAALAZ NE, LISINAPRIL, OMEPRASOLE					004224	
		Regulatory Authority	COVID-19 immunisation, Meningitis viral	Serious	20.00	240.00	Female	COMIRNATY						004224	
4.1(b)	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective	Serious	36.00	432.00	Female								
		Regulatory Authority	COVID-19 immunisation, Dizziness, Feeling abnormal, Hypothyroidism, Impaired work ability, Palpitations, Presyncope	Serious	41.00	492.00	Male	COMIRNATY(H)	COD LIVER OIL (COD-LIVER OIL)						
		Regulatory Authority	Arthralgia, Back pain, Chest pain, COVID-19 immunisation, Dyspnoea at rest, Pyrexia	Serious	27.00	324.00	Female	Hypothyroidism(C), Continuity(H)							003804
		Regulatory Authority	COVID-19 immunisation, Dizziness, Fatigue, Feeling abnormal, Malaise, Nausea, Postmenopausal haemorrhage	Serious	47.00	564.00	Female	COMIRNATY							003804
		Spontaneous	Abdominal pain, Aphasia, Asthenia, Blood pressure increased, Chills, Confusional state, Dizziness, Dyspnoea, Feeling cold, Gait disturbance, Heart rate increased, Inappropriate schedule of product administration, Interchange of vaccine products, Memory impairment, Rhinorrhoea, Seizure	Serious	37.00	444.00	Female	PFIZER BIONTECH COVID-19 VACCINE							003804
		Regulatory Authority	Chest discomfort, Concomitant disease aggravated, COV D-19 immunisation, Dizziness, Pericarditis	Serious	39.00	468.00	Male	Emergency care examination(H), Chest discomfort(H), Chest discomfort(H), COM RNATY							
		Regulatory Authority	Asymptomatic COV D-19, COV D-19 immunisation, Incomplete course of vaccination, Occupational exposure to SARS-CoV-2, Vaccine breakthrough infection	Serious	20.00	240.00	Female								004498
		Regulatory Authority	Headache, Photophobia, Pupils unequal, Syncope	Serious	25.00	300.00	Female	COMIRNATY							004224
		Regulatory Authority	COVID-19 immunisation, Dizziness, General physical health deterioration, Headache, Pyrexia, Syncope	Serious	20.00	240.00	Male	Continuity							004224
		Regulatory Authority	Abdominal pain, COVID-19 immunisation, Dysmenorrhoea, Heavy menstrual bleeding, Hospitalisation	Serious	24.00	288.00	Female	Menstruation normal(H), Continuity, Continuity, Continuity, Continuity							004224
4.1(b)	4.1(b)	Regulatory Authority	COVID-19 immunisation, Pericarditis	Serious	39.00	468.00	Male	Continuity							004224
		Regulatory Authority	Abdominal pain upper, Colitis ulcerative, COVID-19 immunisation, Diarrhoea, Pancreatitis	Serious	18.00	216.00	Male	Colitis ulcerative(C), COM RNATY	HYRMOZ (ADALIMUMAB), PENTASA						004498
		Regulatory Authority	Blood pressure decreased, Bradycardia, Presyncope	Serious	45.00	540.00	Male	Continuity							004498
		Regulatory Authority	Diabetic ketoacidosis, Fatigue, Inappropriate schedule of product administration, Polyuria, Thirst, Type 1 diabetes mellitus, Weight decreased	Serious	19.00	228.00	Male	Type 1 diabetes mellitus(H)							004224
		Regulatory Authority	Abdominal discomfort, Abnormal behaviour, Chest discomfort, Cough, COVID-19, COVID-19 immunisation, Diarrhoea, Extra dose administered, Fatigue, Feeling abnormal, Nausea, Oedema peripheral, Pancreatic failure, Productive cough, Tracheal disorder, Urinary tract infection	Serious	81.00	972.00	Male	Drug hypersensitivity, Red man syndrome, Food allergy, Drug hypersensitivity, Dyspnoea(C), Ischaemic(C), Asthma(C), Pain(C), Urinary tract infection(C), Diarrhoea(C), Abdominal pain(C), Cardiovascular injury(H), Tracheal stenosis(H), Bicuspid aortic valve(H), Cardiac arrest(H), Colic disease(H), Hypertension(C), Hyperlipidaemia(C), Gastroesophageal reflux disease(C), Cardiovascular accident(H), Diabetes mellitus(C), Osteitis deformans(H), Vocal cord paralysis(H), Glaucoma(H), Dysphagia(H), Mitral valve stenosis(H), Cough(H), Chronic kidney disease(H), Lung disorder(H), Tracheostomy(H), Sleep apnoea syndrome(H), Gastrointestinal tube insertion, Anaemia(H), Sepsis(H), Respiratory failure(H), Asthma(H), Neuromuscular paralysis(H), Acute kidney injury(H), Acute left ventricular failure(H), Diabetic ulcer(H), Ulcer(H), Obesity(H), Decubitus ulcer(H), Serum ferritin(H), Hypothyroidism(H), Catheter management	JANKEAT, ACETAMINOPHEN, ACETYLSALICYLSYRSE, ALBUTEROL, SALBUTAMOL, ASCORBIC ACID					004224	
		Regulatory Authority	Chest pain, COVID-19 immunisation, Pericarditis	Serious	30.00	360.00	Male	COMIRNATY							003804
		Regulatory Authority	Arthralgia, Asthenia, COVID-19 immunisation, Exanthema infection, Fatigue, Heavy menstrual bleeding, Hypertension, Immune system disorder, Impaired quality of life, Menstruation irregular, Myalgia, Neuropathy	Serious	34.00	408.00	Female	Asthma(C), COMIRNATY(H)	ALVESCO						003809
		Regulatory Authority	Administration site oedema, Administration site pain, Aphasia, Chills, Fatigue, Hyperhidrosis, Monoparesis, Muscular weakness, Pyrexia	Serious	45.00	540.00	Female	COVID-19 MRNA VACC NE BNT162B2(H), COVID-19 MRNA VACCINE BNT162B2(H)							003808
		Regulatory Authority	Chest discomfort, Dizziness, Headache	Serious	39.00	468.00	Male								004224
		Regulatory Authority	Chest pain, COVID-19 immunisation	Serious	19.00	228.00	Male	COMIRNATY(H)							004224

4.1(b)

Case ID	Country	Report Type	All PTS	Cause/Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	DWI Identifier	Batch/Lot Number
4.1(b)		regulatory authority	Chest pain, Dyspnoea	Serious	35	420.00	Male	COMIRNATY						4.1(b)
		postmarketing	Interchange of vaccine products, Unreliable event, Vaccination site irritation	Serious	79	948.00	Female	Allergy to chemicals		COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACC NE BNT162B2				034224
		regulatory authority	Feeding disorder, Mouth ulceration, Oral herpes	Serious	56	872.00	Female		FEMOSTON CONTI MINI DYDROGESTERONE/ESTRADIOL HEM HYDRATE; INFLUENZA VIRUS	PFIZER BIOTECH COVID-19 VACCINE, PFIZER BIOTECH COVID-19 VACC NE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COVID-19 VACCINE				
		regulatory authority	Headache, Pyrexia	Serious	34	408.00	Male		CANESARTAN; COVID-19 MRNA VACCINE BNT162B2; OUTASTER DE MINOX D L; NERVOLOC					
		regulatory authority	Atrial fibrillation	Serious	41	492.00	Male		PFIZER BIOTECH COVID-19 VACCINE; RAM PR L					
		regulatory authority	Fatigue, Pain, Tremor, Vomiting	Serious	74	886.00	Male	Diabetes mellitus(C); Immunodeficiency(C); Vascular graft; Breast placement	AMLOD PINE; CANESARTAN; CLOP DOGREL; PFIZER BIOTECH COVID-19 VACCINE; HUMAN INSULIN; INFLUENZA VIRUS					034675
		regulatory authority	Abdominal pain upper, Anorexia, Decreased appetite, Dizziness, Fatigue, Headache, Influenza like illness, Lethargy, Myalgia, Paraesthesia, Taste disorder, Vomiting	Serious	69	828.00	Female	SARS-CoV-2 test positive(H); Cough(H); Fatigue(H); Dyspnoea(H); Influenza like illness(H); Parosmia(H)		PFIZER BIOTECH COVID-19 VACCINE, PFIZER BIOTECH COVID-19 VACC NE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COVID-19 VACCINE, PFIZER BIOTECH COVID-19 VACCINE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COVID-19 VACCINE				
		regulatory authority	Heart rate increased	Serious	60	720.00	Male		PFIZER BIOTECH COVID-19 VACCINE; ESCOMEPRAZOLE; INFLUENZA VIRUS					034675
		regulatory authority	Administration site erythema, Administration site pain, Headache, Myalgia, Pyrexia, Vertigo	Serious	23	276.00	Female	Continuity						035241
		regulatory authority	Asthma, Chest pain, Contusion, Erythema, Fatigue, Headache, Hypoaesthesia, Nausea, Neck pain, Oropharyngeal pain, Pain, Photosensitivity, Pyrexia, Skin discoloration, Skin swelling, Vaccination site bruising, Vaccination site swelling	Serious			Female	COVID-19(H); COV D-19 MRNA VACCINE BNT162B2(H); COVID-19 MRNA VACC NE BNT162B2(H)	PFIZER BIOTECH COVID-19 VACCINE					
		regulatory authority	Abdominal pain upper, Condition aggravated, Ear discomfort, Ear pain, Fatigue, Fibromyalgia, Illness, Interchange of vaccine products, Myalgia, Of label use, Pyrexia, Tinnitus	Serious	26	866.00	Female	Fibromyalgia(C); Herpes virus infection(C)		COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY; COM RNATY;				
		regulatory authority	Abdominal distension, Pain in extremity	Serious	73	876.00	Female		ALEXORONIC AC D; CALCICHEW; LEVOTHYROXINE	PFIZER BIOTECH COVID-19 VACCINE, PFIZER BIOTECH COVID-19 VACC NE				034675
		regulatory authority	Myalgia, Pain in extremity	Serious	66	792.00	Male	Hypertension(C); Steroid therapy(C); Hyperlipidic cardiomyopathy(H); Renal transplant; INSULIN DEGLUCOSE(H); Type 2 diabetes mellitus(C)		PFIZER BIOTECH COVID-19 VACCINE, PFIZER BIOTECH COVID-19 VACC NE				034675
		regulatory authority	Fatigue, Headache, Malaise	Serious	67	804.00	Female		INFLUENZA VIRUS	PFIZER BIOTECH COVID-19 VACCINE; PFIZER BIOTECH COVID-19 VACC NE; PFIZER BIOTECH COV D-19 VACC NE; PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COVID-19 VACCINE				034675
		regulatory authority	Asthma, Chills, Headache	Serious	63	756.00	Male		PFIZER BIOTECH COVID-19 VACCINE					034732
		regulatory authority	Hypoesthesia, Neuropathy peripheral, Pain in extremity, Paraesthesia	Serious	65	780.00	Male		AMTRIPRYL NE; FERROUS FUMARATE	COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2				034732
		regulatory authority	Headache, Pyrexia	Serious	52	624.00	Male	Ankylosing spondylitis(H); Abstinence from alcohol(H); Percutaneous coronary intervention(H); Non-tobacco user(H)	ENBEREL	COM RNATY; COMIRNATY				
		regulatory authority	Abdominal pain upper	Serious			Male	Gastrointestinal carcinoma(H); Transient ischaemic attack(H)	CLOP DOGREL; COVID-19 MRNA VACCINE BNT162B2; SARS-COV-2					
		regulatory authority	Pulmonary embolism, Thromboembolism	Serious	62	744.00	Male		PFIZER BIOTECH COVID-19 VACCINE					034675
		regulatory authority	Asthma, Chills, Dermatitis, Erythema, Headache, Injection site erythema, Injection site pain, Pyrexia	Serious			Female	PFIZER BIOTECH COVID-19 VACCINE						034732
		regulatory authority	Headache	Serious	45	540.00	Male		PFIZER BIOTECH COVID-19 VACCINE					
		regulatory authority	Heavy menstrual bleeding, Interchange of vaccine products, Of label use, Skin rashes, Vulvovaginal discomfort, Vulvovaginal pain	Serious			Female			COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY				
		regulatory authority	Atrial fibrillation, Back pain, Cardiac imaging procedure abnormal, Chest pain, Pericardial effusion	Serious	78	936.00	Female			PFIZER BIOTECH COVID-19 VACCINE, PFIZER BIOTECH COVID-19 VACC NE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COV D-19 VACC NE, PFIZER BIOTECH COVID-19 VACCINE				
		regulatory authority	Asthma, Dizziness, Fatigue, Headache, Malaise, Myalgia	Serious	65	760.00	Female	Interstitial lung disease(C); Systemic sclerosis; Asthma(C); Clinical trial participant(C); COVID-19	COVID-19 MRNA VACC NE BNT162B2; PEXODENAD NE	COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACC NE BNT162B2				034675
		regulatory authority	Asthenia, Headache, Influenza	Serious	44	526.00	Male	Immunodeficiency(H)	COVID-19 MRNA VACC NE BNT162B2					

Case ID	Country	Report Type	ALL PFS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	MW Identifier	Batch/Lot Number
4.1(b)	4.1(b)	Regulatory Authority	Diplopia	Serious	53.00	636.00	Male		PFIZER BIONTECH COVID-19 VACCINE, ROSUVASTATIN				4.1(b)	004875
		Regulatory Authority	Fatigue, Headache, Myalgia, Pyrexia	Serious	36.00	432.00	Male	Suspected COVID-19(h)	PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Chills, Fatigue, Headache, Nausea, Pyrexia, Tremor	Serious	81.00	732.00	Female	Hypersensitivity(h); Headache(c)	ANADIN [JACEYLSALICYLIC ACID/CAFFEINE], LORATADINE	COV D-19 MRNA VACCINE BNT162B2, COVID-19 MRNA VACCINE BNT162B2, COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACCINE BNT162B2				004732
		Regulatory Authority	Hypoaesthesia, Pain, Paresthesia	Serious	39.00	468.00	Male	Suspected COVID-19(h)	COVID-19 MRNA VACC NE BNT162B2	ZOSTAVAX, ZOSTAVAX, ZOSTAVAX, ZOSTAVAX				004742
		Regulatory Authority	Agranulocytosis, Anemia, COVID-19, COVID-19 immunisation, Fatigue, Influenza like illness, Vaccine breakthrough infection	Serious	41.00	492.00	Male	COVID-19 immunisation(h)	OMEGA 3 (FISH OIL), PANTOPRAZOL, METFORMIN, DISOPROKIL, SANDOZ, PROSCAR	COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY				004875
		Regulatory Authority	Chills, Feeling of body temperature change, Myalgia, Nasopharyngitis	Serious	85.00	780.00	Male		COVID-19 MRNA VACC NE BNT162B2, INFLUENZA VIRUS					004498
		Regulatory Authority	Central infection, Central small vessel ischaemic disease, COVID-19 immunisation, Local infection	Serious	94.00	788.00	Male	Hypercholesterolaemia(c), Tobacco user(c), Chronic myeloid leukaemia(c), COMIRNATY	SPRYCEL					004498
		Regulatory Authority	Adverse reaction, Arthralgia, Palindromic rheumatism, Peripheral swelling	Serious	27.00	324.00	Male	Arthralgia(h)	COO LIVER OIL [COD-LIVER OIL]	COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY				
		Regulatory Authority	Chest pain, Heart rate, Hypertension	Serious	37.00	444.00	Male		JAMOTRIG NE	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				
		Regulatory Authority	Chest pain, Cold sweat, Cough, COVID-19 immunisation, Dyspnoea, Headache, Myocarditis, Nasopharyngitis, Painful respiration, Pericarditis, Pyrexia	Serious	17.00	204.00	Male	COMIRNATY(h)	LEVAX N					004498
		Regulatory Authority	COVID-19 immunisation, Dyspnoea	Serious	85.00	780.00	Female	Chronic respiratory disease(h); Bacterial disease center(h); Gastric cancer(h); Community(c)						004498
		Regulatory Authority	Abortion spontaneous, COVID-19 immunisation, Frustration tolerance decreased, Menstrual disorder	Serious	33.00	396.00	Female	Pregnancy(h), COM RNATY						
		Regulatory Authority	Chest pain, COVID-19 immunisation, Dyspnoea, Fatigue, Ischaemia, Muscular weakness, Pain in extremity, Pruritus	Serious	56.00	672.00	Female			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY				004055
		Regulatory Authority	Dyspnoea	Serious	90.00	960.00	Female	COMIRNATY(h), COMIRNATY(h)	PANTOPRAZOLE, HUMALOG, TRESIBA PENF LL, SAFLUTAN, CARDIENE					002044
		Regulatory Authority	Fatigue	Serious	92.00	744.00	Male			COV D-19 MRNA VACCINE BNT162B2				
		Regulatory Authority	Rash	Serious	37.00	304.00	Male	Immunodeficiency(h) 4.1(b) (c)	PFIZER BIONTECH COVID-19 VACCINE, INFLUENZA VIRUS					004875
		Regulatory Authority	Chills, Dizziness, Fatigue, Hangover, Headache, Hyperhidrosis, Nausea	Serious	66.00	792.00	Male		ASPIRINE, COV D-19 MRNA VACCINE BNT162B2, INFLUENZA VIRUS, LISINAPREL, OMEPRAZOLE, SIMVASTATIN					004875
		Regulatory Authority	Influenza like illness	Serious	86.00	792.00	Female	Hypertension(c), Barrett's oesophagus(c), Hx of haem(c), Breast cancer(c)	AMLODIPINE, ESOMEPRAZOLE, LOSARTAN	PFIZER BIONTECH COVID-19 VACCINE				004875
		Regulatory Authority	Chills, Malaise, Pyrexia, Subcostal distention	Serious	66.00	792.00	Male	Rheumatoid arthritis(h); METHOTREXATE(h)	PFIZER BIONTECH COVID-19 VACCINE					004875
		Regulatory Authority	Pain in extremity	Serious	83.00	756.00	Male	Type 2 diabetes mellitus(c), Prostatomegaly(c), Irritable bowel syndrome(h)	ALFUZOSIN, ALLOPURINOL, ATORVASTATIN, BISOPROLOL, SILDENAFIL, CANFROT, INFLUENZA V RUS	PFIZER BIONTECH COVID-19 VACCINE				004875
		Regulatory Authority	Headache, Sneezing	Serious	83.00	756.00	Female	Acoustic neuroma(c), Breast cancer(h)	VITAMIN D NOS	PFIZER BIONTECH COVID-19 VACCINE, COM RNATY, PFIZER BIONTECH COVID-19 VACCINE, COMIRNATY				004875
		Regulatory Authority	Pain in extremity	Serious	83.00	756.00	Female		LATANOPROST, PREMQUE	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE				004732
		Regulatory Authority	Chills, Fatigue, Fatulence, Headache, Influenza like illness, Intestinal exposure during pregnancy, Myalgia, Pain in extremity, Vaccination site pain	Serious	37.00	444.00	Female	Pregnancy(c), PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE	FOLIC ACID, INFLUVAC	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE				
		Regulatory Authority	Bell's palsy, Dysarthria, Facial paralysis, Headache, Influenza like illness	Serious	82.00	864.00	Female	Clinical trial participant(h); ESOMEPRAZOLE(h); CLOP DOGREL(h); H ₂ (ISOBOR) DE MONOTRAT(h); AMLODIPINE(h); ATENOLOLO(h); RAMIPRIL(h); HYALURONIC INJECTION(h); Rheumatoid arthritis(c)		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				
		Regulatory Authority	Tremor, Vomiting	Serious	56.00	672.00	Male		COVID-19 MRNA VACC NE BNT162B2					004732
		Regulatory Authority	Abdominal pain, Dizziness, Fatigue, Headache, Influenza like illness, Injection site pain, Injection site swelling, Malaise, Nausea, Pyrexia	Serious	40.00	480.00	Male	COMIRNATY						14615
		Regulatory Authority	Hemiparesis	Serious	35.00	660.00	Male		PFIZER BIONTECH COVID-19 VACCINE, INFLUVAC					004732
		Regulatory Authority	Bell's palsy, Dry eye, Eye swelling	Serious	50.00	600.00	Male		PFIZER BIONTECH COVID-19 VACCINE, LISINAPREL					004732
		Regulatory Authority	Arthralgia, Pyrexia	Serious	81.00	732.00	Female		OMEPRazole	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE				004732
		Regulatory Authority	COVID-19, Interchange of vaccine products, SARS-CoV-2 test positive, Vaccine breakthrough infection	Serious	41.00	492.00	Female			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				04M20A, 112,20A
		Regulatory Authority	Abnormal behaviour, Computerised tomogram, Confusional state, Interchange of vaccine products, Laboratory test, Memory impairment, Seizure, Status epilepticus	Serious	89.00	828.00	Male	Drug hypersensitivity, Depression(h), Memory impairment(c)		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE				
		Regulatory Authority	Acute kidney injury, Chest X-ray abnormal, Chronic kidney disease, COVID-19, COVID-19 pneumonia, Dyspnoea, Dyspnoea worsened, Exposure to SARS-CoV-2, Hypoxia, Infection, Oxygen saturation decreased, Peripheral swelling, Pulmonary oedema, SARS-CoV-2 test positive, Ultrasound Doppler normal, Wheezing	Serious	55.00	660.00	Male	Sleep apnoea syndrome(c), Cardiomyopathy(c), Hypertension(c), Ventricular fibrillation(c), Gastroesophageal reflux disease(c), Obesity(c), Colon adenoma(c), Chronic kidney disease(c), Osteoarthritis(c), COVID-19(h), Bronchitis(h), Implantable defibrillator insertion, Laboratory		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE				017F21A
		Regulatory Authority	Anticoagulant therapy, Blood test, Computerised tomogram, Painful respiration, Pulmonary thrombosis, Thrombosis, Ultrasound Doppler normal, X-ray	Serious	41.00	492.00	Female			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE				047C21A
		Regulatory Authority	Chest pain, Dyspnoea, Electrocardiogram abnormal, Electrocardiogram ST-T change, Myocarditis, Prothrombin brain natriuretic peptide increased, Troponin I increased	Serious	37.00	444.00	Male	PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory Authority	Anaemorrhoea, Chills, COVID-19 immunisation, Fatigue, Feeling cold, Injection site pain, Injection site reaction, Malaise	Serious	32.00	384.00	Female			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY				001802, 002330, 002867
		Regulatory Authority	Arthralgia, Headache, Pyrexia	Serious	92.00	800.00	Female	COMIRNATY(h), COMIRNATY(h)						013M20A
		Regulatory Authority	Condition aggravated, COV D-19, SARS-CoV-2 test positive, Transient ischaemic attack	Serious	86.00	792.00	Female	Transient ischaemic attack(h)		COV D-19 MRNA VACCINE BNT162B2, COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACCINE BNT162B2				001884
		Regulatory Authority	Aphasia	Serious	87.00	1044.00	Female	PFIZER BIONTECH COVID-19 VACCINE(h); PFIZER BIONTECH COVID-19 VACCINE(h)						

4.1(b)

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Case ID	Country	Report Type	ALL PTS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	MM Identifier	Batch/Lot Number	
		Regulatory adverse event	Headache, Influenza like illness, Tongue coated	Serious	83.00	756.00	Male	Immunodeficiency(C)	COVID-19 MRNA VACC NE BNT162B2; FLUCELVAX TETRA (INFLUENZA VACC NE INACT BAG 4V)				4.1(b)	005237	
		Regulatory adverse event	Chest pain, Dizziness, Fatigue, Headache, Middle insomnia, Migraine, Nausea, Nightmares, Palpitations, Pyrexia, Tachycardia	Serious	33.00	396.00	Female	Asthma(C), CERELLE(H), PFIZER BIONTECH COVID-19 VACCINE(H)							
		Regulatory adverse event	Headache, Lymph node pain	Serious	82.00	824.00	Male	Multiple sclerosis(C); Immunodeficiency(C)	COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2						
		Regulatory adverse event	Chest pain, Dyspnoea	Serious	46.00	552.00	Male	Hypermobility syndrome(C)	COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2						
		Regulatory adverse event	Swelling	Serious					PFIZER BIONTECH COVID-19 VACCINE						004732
		Regulatory adverse event	Lymphoedema, Pain	Serious	46.00	552.00	Female			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE					002821; 003851
		Regulatory adverse event	Arthralgia, Rash, Vaccination site pain	Serious	81.00	732.00	Male		PFIZER BIONTECH COVID-19 VACCINE, ASPIRIN, ATORVASTATIN						004732
		Regulatory adverse event	Feeling abnormal, Headache, Heart rate increased, Pyrexia	Serious	48.00	576.00	Male		ASPIRIN (ACETYLSALICYLIC ACID); ATORVASTATIN; IBUPROFEN; CLOPIDOGREL; MIRTAZAPINE; COVID-19 VACCINE MRNA (BNT162B2)						004732
		Regulatory adverse event	Chills, Dizziness, Headache, Malaise, Myalgia	Serious	87.00	804.00	Male	Atrial fibrillation(C); Immunodeficiency(C); AMICODARONE(H); RIVAROXABAN(H)	PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory adverse event	Headache	Serious	44.00	528.00	Female		BETRALINE	COV D-19 MRNA VACCINE BNT162B2					
		Regulatory adverse event	Furukia, Rash, Rash macular, Swelling	Serious	40.00	480.00	Female	Hypersensitivity (allergic) reaction(H); Eczema(H); Seasonal allergy; Hypersensitivity; Food intolerance(H); PFIZER BIONTECH COVID-19 VACCINE	COVID-19 MRNA VACC NE BNT162B2						004875
		Regulatory adverse event	Balance disorder, Dizziness, Ear pain, Fatigue, Headache, Influenza like illness, Nausea, Neck pain, Pain in extremity, Vertigo	Serious	47.00	564.00	Male	Polycythaemia(C); Pain(H); Mental disorder(C); Deafness(C); Tinnitus(C)	AMITRIPTYLINE HYDROCHLORIDE; ASPIRIN; CLENIL MODULITE; COV D-19 MRNA VACC NE BNT162B2; PREGABALIN; TRAMADOL; VENTOLIN (SALBUTAMOL); VITAMIN D3; COVID-19 MRNA VACC NE BNT162B2						004732
		Regulatory adverse event	Back pain, Dry mouth, Fatigue, Feeling abnormal, Myalgia, Night sweats, Prolactinuria, Pyrexia, Thirst	Serious	24.00	288.00	Male		PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory adverse event	Vomiting	Serious	78.00	836.00	Male	Essential thrombocythemia(C); Suspected COVID-19(H); Immunodeficiency(C); PFIZER BIONTECH COVID-19 VACCINE	COVID-19 MRNA VACC NE BNT162B2						not known
		Regulatory adverse event	Chest pain, Dyspnoea, Fatigue, Headache, Pain in extremity, Pyrexia	Serious	40.00	480.00	Male		PFIZER BIONTECH COVID-19 VACCINE						005686
		Regulatory adverse event	Breast enlargement, Breast tenderness, Intermenstrual bleeding, Postmenopausal haemorrhage	Serious	51.00	612.00	Female	Postmenopausal(H); Amenorrhoea(H)	ESTRADOT	COM RNATY, COMRNATY, COMRNATY, COM RNATY					
		Regulatory adverse event	Muscle spasticity, Pain	Serious	57.00	684.00	Male			VAXZEVRIA; COM RNATY, VAXZEVRIA; COMRNATY					001851
		Regulatory adverse event	Chills, Nausea, Pain in extremity, Vomiting	Serious	58.00	696.00	Male	Asthma(C); Clinical trial participant(H); PERINDOPRIL (H)	COVID-19 MRNA VACC NE BNT162B2; COVID-19 VACCINE ASTRAZENECA, INFLUVAC						
		Regulatory adverse event	Burning sensation, Depressed mood, Pain	Serious	77.00	824.00	Male	INFANRIX (PV H (b)(6))	AMLODIPINE, ASPIRIN (ACETYLSALICYLIC ACID), CODEINE, COVID-19 MRNA VACCINE BNT162B2, LANOPRAZOLE, LOSARTAN, MACRODOL 3350, PREDNISOLONE, BOTANOL						004732
		Regulatory adverse event	Partial seizures, Restlessness	Serious	59.00	708.00	Male		COVID-19 MRNA VACC NE BNT162B2						
		Regulatory adverse event	Bone pain, Nausea, Pain in extremity, Tension headache	Serious	51.00	612.00	Male		COVID-19 MRNA VACC NE BIONTECH						005686
		Regulatory adverse event	Arthralgia	Serious	41.00	482.00	Female			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE					
		Regulatory adverse event	Headache, Heart rate increased, Myalgia, Pyrexia	Serious	28.00	312.00	Female		COVID-19 MRNA VACC NE BNT162B2; INFLUENZA VIRUS; LEVEST (ETHINYLESTRADIOL/LEVONORGE STREL)	COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2					
		Regulatory adverse event	Fatigue, Headache, Migraine with aura, Ocular hypersensitivity, Rash papular, Swelling	Serious	59.00	708.00	Male		PFIZER BIONTECH COVID-19 VACCINE						005237
		Regulatory adverse event	Body temperature increased, Confusional state, Insomnia, Nausea, Pyrexia	Serious	41.00	482.00	Male	Suspected COVID-19(H)	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE						004737
		Regulatory adverse event	Maternal exposure during breast feeding, Pyrexia	Serious	3.25	3.00	Male			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE					
		Regulatory adverse event	Chills, Disorientation, Dysphagia, Fatigue, Feeling cold, Formication, Gait disturbance, Headache, Irritable bowel syndrome, Loss of control of legs, Pain in extremity, Pyrexia, Tremor	Serious	72.00	864.00	Male	Suspected COVID-19(H)	COVID-19 MRNA VACC NE BNT162B2						005287
		Regulatory adverse event	Chills, Dyspnoea, Fatigue, Malaise, Nasal congestion, Nausea, Rhinorrhoea, Sneezing	Serious	37.00	444.00	Male	Kidney infection(H); Steroid therapy; Prostatitis(H); Deafness(C)	PREDNISONE, PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory adverse event	Syncope	Serious	81.00	872.00	Male		COVID-19 MRNA VACC NE BNT162B2; DONEPEZIL; COVID-19 MRNA VACCINE BNT162B2						
		Regulatory adverse event	Fatigue, Headache, Lymphadenopathy, Rash	Serious	36.00	432.00	Female	Hypothyroidism(C); Immunodeficiency(C); LEVOTHYROXINE(H); FUROSEMIDE(H); METFORMIN(H); Polycystic ovary(H); Joint swelling(H); Antihypertensive(H); Antidiabetic(H); PFIZER BIONTECH COVID-19 VACCINE(H)	COVID-19 MRNA VACC NE BNT162B2						004737
		Regulatory adverse event	Bedridden, Headache	Serious			Female	Hypothyroidism(C); Depression(C); PFIZER BIONTECH COVID-19 VACCINE(H); PFIZER BIONTECH COV D-19 VACC NE(H)							005237

Case ID	Country	Report Type	All PIS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-exposures	Case Reference	Reference Notes	FWW Identifier	Batch/Lot Number		
4.1(b)		Regulatory Authority	Chills, Fatigue, Headache, Pain, Pyrexia	Serious	34	50	Male		PFIZER BIONTECH COVID-19 VACCINE, INFLUENZA VIRUS, SODIUM VALPROATE					4.1(b)	004732	
		Regulatory Authority	Ischaemic stroke	Serious	75	940	Female	COMIRNATY(H), COMIRNATY(H)							005698	
		Regulatory Authority	Pulmonary embolism	Serious	27	324	Male	COMIRNATY(H)							004498	
		Regulatory Authority	Ischaemic stroke	Serious	81	972	Female	Abetal fibrillation(C), COM RNATY, RIVAROXABAN(H), COMIRNATY							005698	
		Regulatory Authority	Abdominal pain, Arthralgia, Back pain, Diarrhoea, Influenza like illness, Nausea, Neck pain, Pain in extremity, Urine abnormality	Serious	40	480	Female	Immunodeficiency(H), Coeliac disease(H)		INFLUENZA VIRUS, IBUPROFEN	COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY,					

Case ID	Country	Report Type	ALL PTS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	PHV Identifier	Batch/Lot Number	
4.1(b)		Regulatory Authority	Headache, Pain, Pyrexia	Serious			Male		PFIZER BIONTECH COVID-19 VACCINE					004737	
		Regulatory Authority	Angina pectoris, Arthralgia, Chest pain, Dyspnoea, Fatigue, Headache, Myocarditis, Pain in extremity, Palpitations, Tachycardia	Serious			Male	Varicose vein(s); Reynaud's phenomenon(s)	COVID-19 MRNA VACC NE BNT162B2; INFLUENZA VIRUS; NDA					075-1054	
		Regulatory Authority	Chills, Fatigue, Headache	Serious			Male		PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory Authority	Dyspepsia, Eructation, Flatulence, Nausea	Serious	23 00	276 00	Female	COVID-19 MRNA VACC NE BNT162B2(s); COVID-19 MRNA VACCINE BNT162B2(s)	RUSEVDON					004732	
		Regulatory Authority	Pyrexia	Serious	38 00	456 00	Male		COVID-19 VACCINE MRNA (BNT162B2); COVID-19 VACCINE MRNA (BNT162B2)					005688	
		Regulatory Authority	Cough, Dyspnoea, Headache, Lymphadenopathy, Pyrexia	Serious	45 00	540 00	Male	Influenza(s); PFIZER BIONTECH COVID-19 VACCINE							
		Regulatory Authority	Shoulder injury related to vaccine administration	Serious	37 00	444 00	Male		COVID-19 MRNA VACC NE BNT162B2						
		Regulatory Authority	Chills, Fear, Pain	Serious	33 00	396 00	Male		COVID-19 MRNA VACC NE BNT162B2						
		Regulatory Authority	Lymph gland infection	Serious	37 00	444 00	Male		PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory Authority	Hernia pain, Migraine, Swelling face	Serious	66 00	792 00	Female	Immunodeficiency(s); Hypotension(s); Hypersensitivity; CETIRIZINE(s)	CETIRIZIN; LANSOPRAZOLE	PFIZER BIONTECH COVID-19 VACCINE; COM RNATY; PFIZER BIONTECH COVID-19 VACCINE; COMIRNATY; PFIZER BIONTECH COVID-19 VACCINE; COM RNATY				004737	
		Regulatory Authority	Arthralgia, Chills, Fatigue	Serious	26 00	336 00	Male		PFIZER BIONTECH COVID-19 VACCINE; FAMOTIDINE; TEVA CYCLOSPORINE						
		Regulatory Authority	Body temperature increased, Chills, Dizziness, Fatigue, Myalgia	Serious	21 00	262 00	Male		COVID-19 VACCINE MRNA (BNT162B2)					07000014A	
		Regulatory Authority	Pruritus, Rash	Serious	19 00	228 00	Male		COVID-19 MRNA VACC NE BNT162B2					005287	
		Regulatory Authority	Heavy menstrual bleeding	Serious	41 00	492 00	Female		COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2						
4.1(b)		Regulatory Authority	Hallucination	Serious	40 00	480 00	Male		PFIZER BIONTECH COVID-19 VACCINE					005688	
		Regulatory Authority	Fatigue, Headache, Myalgia, Pain in extremity	Serious	30 00	360 00	Male		COVID-19 MRNA VACC NE BNT162B2					000022A	
		Regulatory Authority	Chills, Fatigue, Headache, Hyperhidrosis, Nausea, Oropharyngeal pain, Pain, Pyrexia, Rhinorrhoea, Sneezing	Serious	33 00	396 00	Female	Seasonal allergy; Food allergy	BETAMETHASONE VALERATE; CLOBETASONE BUTYRATE; FLUCLOXACILL N; FUZIDIN (FUSIDIC ACID)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE			005287		
		Regulatory Authority	Abdominal pain upper, Fatigue, Headache, Hypersensitivity, Injection site pain, Insomnia, Myalgia, Oropharyngeal pain, Pruritus, Urinaria	Serious	19 00	228 00	Female	Dairy intolerance(s); Endometriosis(s); Influenza(s); (s); Food allergy; PFIZER BIONTECH COVID-19 VACCINE; Appendicitis	PFIZER BIONTECH COVID-19 VACCINE; DEBOSISTREL; LEVONORGESTREL						
		Regulatory Authority	Headache, Pain	Serious	35 00	420 00	Male		PFIZER BIONTECH COVID-19 VACCINE; INFLUENZA VACCINE; PFIZER BIONTECH COVID-19 VACCINE					005688	
		Regulatory Authority	Fatigue, Live birth, Maternal exposure during pregnancy	Serious	35 00	420 00	Female	Pregnancy(s); Immunodeficiency(s); Coeliac disease(s)	FOLIC ACID; INFLUENZA VIRUS	COM RNATY; COMIRNATY; COMIRNATY					
		Regulatory Authority	Fatigue, Headache, Pain in extremity, Tremor	Serious	0 50	0 00	Male		COVID-19 MRNA VACC NE BNT162B2; ISOPROPANOL; COVID-19 MRNA VACC NE BIONTECH					00014A	
		Regulatory Authority	Cardiac arrest, Oedema peripheral, Parkinson's disease	Serious	91 00	1092 00	Male	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Parkinson's disease(s); Hypotension(s)	NONSP; ANTI-PARK NSON; COLECALC FEROL; DOPAM NE; APOMORPHINE					005243	
		Regulatory Authority	Myocardial infarction	Serious	46 00	552 00	Male	COMIRNATY							
		Regulatory Authority	Back pain, Headache, Nausea, Pyrexia	Serious	32 00	384 00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory Authority	Faeces discoloured, Foetal exposure during pregnancy, Gwaiba, Mucous stools, Somnolence	Serious	0 08	1 00	Male		PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory Authority	Arthralgia, Back pain, Breast pain, Chills, Cold sweat, Cough, Eye pain, Fatigue, Hypopnoea, Migraine, Nausea, Peripheral swelling, Pyrexia	Serious	18 00	216 00	Female							005688	
		Regulatory Authority	COVID-19 pneumonia	Serious	64 00	768 00	Male							004721A	
		Regulatory Authority	Deep vein thrombosis, Peripheral swelling, Ultrasound Doppler abnormal	Serious	52 00	624 00	Female			PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE					
4.1(b)		Regulatory Authority	Loss of consciousness	Serious	32 00	384 00	Male			COM RNATY; COMIRNATY					
		Regulatory Authority	Cerebral haemorrhage, COVID-19 immunisation, Hemiparesis	Serious	92 00	1104 00	Male	Cominty; Influenza vaccine	NAUREVAN					0040204	
		Regulatory Authority	Motor neurone disease	Serious	65 00	720 00	Female			COM RNATY				0020184; 003181; 0044980	
		Regulatory Authority	Arthralgia, Chills, Fatigue, Headache, Malaise, Myalgia, Nausea, Pyrexia, Rash	Serious	54 00	648 00	Male			COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNAT					

Case ID	Country	Report Type	All PTS	Case Seriousness	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	RNN Identifier	Batch/Lot Number	
4.1(b)	H.L. PINES	Regulatory Authority	Chills alternative, COVID-19 immunisation	Serious	37.00	Male		SALOFALK GR	COM RNATY, COMIRNATY				4.1(b)	
		Regulatory Authority	Chills, Fatigue, Malaise, Myalgia, Nausea, Pyrexia	Serious	36.00	Female			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY					
		Spontaneous	Abdominal pain, Impaired work ability, Inflammatory marker increased	Serious	37.00	Male	PFIZER BIONTECH COVID-19 VACCINE							
		Regulatory Authority	COVID-19 Immunisation, Myocarditis	Serious	16.00	Male			COM RNATY, COMIRNATY					
		Regulatory Authority	Abdominal pain upper, Fatigue, Myalgia, Nausea	Serious	37.00	Female			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY		004730			
		Regulatory Authority	Cardiac Arrhythmia, Concomitant disease aggravated, COVID-19 immunisation	Serious	70.00	Female	Cardiac Arrhythmia(H); Comorbidity(H)	COO LIVER OIL [COO-LIVER OIL]; PERFECT CARE OMEGA 3; OLIVE OIL						
		Regulatory Authority	Asthenia, Chills, Fatigue, Headache, Injection site reaction, Malaise, Nausea, Pain in extremity, Pyrexia	Serious	21.00	Female			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COMRNATY;		004695			
		Regulatory Authority	Chills, Fatigue, Headache, Injection site reaction, Malaise, Myalgia, Nausea, Pyrexia	Serious	35.00	Female	COMIRNATY(H); COMIRNATY(H)					004695		
		Regulatory Authority	Chills, Fatigue, Headache, Injection site reaction, Malaise, Myalgia, Pyrexia	Serious	35.00	Female	COMIRNATY(H); COMIRNATY(H)					004730		
		Regulatory Authority	Anamnestic, Heavy menstrual bleeding, Myocarditis	Serious	31.00	Female	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE							
4.1(b)	FRANCE	Regulatory Authority	Chest pain, Dyspnoea, Fatigue, Palpitations, Pyrexia	Serious	18.00	Male	Hypoplastic left heart syndrome(C); Immuno-deficiency(H)	NARXEN, PFIZER BIONTECH COVID-19 VACCINE, ENLAPEPI L MALEATE						
		Regulatory Authority	Osteochondritis, Disease recurrence	Serious	32.00	Female	Endometriosic(C); Osteochondritic(H)		COM RNATY, COMIRNATY				004635	
		Regulatory Authority	Dizziness, Myalgia, Vomiting	Serious	79.00	Male		[REDACTED] RANAM; [REDACTED]					006323	
		Regulatory Authority	Chest pain, Dyspnoea, Oropharyngeal pain, Oxygen saturation decreased	Serious	34.00	Male			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY				00461e	
		Regulatory Authority	Condition aggravated, COV D-19 Immunisation, Impaired self-care, Quasi-parasite	Serious	58.00	Male	Rheumatoid arthritis(C); Wheelchair user(C); Multiple sclerosis(C); Comorbidity						003804	
		Regulatory Authority	Deep vein thrombosis	Serious	24.00	Male	PFIZER BIONTECH COVID-19 VACCINE(H)	SALBUTAMOL					003181	
		Regulatory Authority	Hypertension	Serious	84.00	Female	COMIRNATY; COM RNATY						1A0221A	
		Regulatory Authority	Chills, Headache, Hypohidrosis, Malaise, Nausea, Pyrexia, Syncope, Vomiting	Serious	22.00	Female	COMIRNATY; COM RNATY						301081	
		Regulatory Authority	Asthma, Chills, Head injury, Syncope	Serious	58.00	Female	Depression(H); Wolff-Parkinson-White syndrome(C); COMIRNATY(H); COMIRNATY(H)						18044	
		Regulatory Authority	Atrial fibrillation, Asthma, Dyspnoea exertional, Fatigue, Muscle fatigue, Myalgia	Serious	50.00	Male	COVID-19(H); COM RNATY; COMIRNATY	AMELO PINE, METOPROLOL; LOSARTAN					170221A	
4.1(b)	FRANCE	Regulatory Authority	Influenza, COVID-19 Immunisation, Ear pain, Fatigue, Injection site reaction, Lymphadenopathy, Malaise, Pyrexia, Swelling	Serious	28.00	Female	COMIRNATY; COM RNATY							004698
		Regulatory Authority	Deep vein thrombosis, Myalgia, Tachycardia	Serious	84.00	Female	PFIZER BIONTECH COVID-19 VACCINE(H); PFIZER BIONTECH COVID-19 VACCINE(H)	[REDACTED] OMEPRAZOL A						00578985
		Regulatory Authority	Myocardial Ischaemia	Serious	56.00	Female	COMIRNATY(H); COMIRNATY(H)							005689
		Regulatory Authority	Cardiac arrest, Intestinal obstruction, Sepsis	Serious	44.00	Female	Gene mutation(H); Lung disorder(H); Obesity(H); Intellectual disability(H)		COM RNATY, COMIRNATY, COMIRNATY					
		Regulatory Authority	Iscosmia	Serious	58.00	Female	COMIRNATY							004692; 004692
		Regulatory Authority	Atrial fibrillation, COVID-19 Immunisation, Headache, Injection site pain, Injection site reaction, Lymph node pain, Malaise, Myalgia, Nausea, Pyrexia	Serious	41.00	Female	Comorbidity(H); Comorbidity(H)							
		Regulatory Authority	Menstruation irregular, Ovarian cyst	Serious	47.00	Unknown		[REDACTED]	COM RNATY, COMIRNATY					17g21w
		Regulatory Authority	COVID-19, Drug ineffective	Serious	41.00	Female			COM RNATY, COMIRNATY					
		Spontaneous	Abdominal pain, Arterial hypertension, Chest discomfort, Chills, Eye pain, Headache, Hyperkalemia, Malaise, Myalgia, Neck pain, Pain, Photophobia, Pyrexia, Rednesses, Tachycardia, Vomiting	Serious	35.00	Female	PFIZER BIONTECH COVID-19 VACCINE	VALLACLOVIC, PROZAC						
		Regulatory Authority	Fatigue, Injection site reaction, Malaise, Musculoskeletal stiffness, Myalgia, Pain in extremity, Pyrexia	Serious	23.00	Female	COMIRNATY; COM RNATY							
4.1(b)	FRANCE	Regulatory Authority	Atrial fibrillation, Chills, COVID-19 Immunisation, Fatigue, Headache, Injection site reaction, Malaise	Serious	48.00	Male	Comorbidity(H); Comorbidity(H); Mite allergy							004688
		Regulatory Authority	COVID-19 immunisation, Fatigue, Malaise, Myalgia	Serious	24.00	Female	COMIRNATY; COM RNATY							04f21A
		Regulatory Authority	Chest pain, Pain in extremity, Pyrexia, Rash	Serious	45.00	Male	Diabetes mellitus(C); COM RNATY(H); COMIRNATY(H)							004730
		Regulatory Authority	Atrial fibrillation, C-reactive protein increased, Chills, Fatigue, Headache, Injection site reaction, Malaise, Myalgia, Nausea, Pyrexia	Serious	30.00	Female	COMIRNATY; COM RNATY							004730
		Regulatory Authority	Atrial fibrillation, Back pain, Chills, Extensive swelling of vaccinated limb, Fatigue, Headache, Hot flash, Injection site reaction, Lymphadenopathy, Malaise, Migraine, Myalgia, Nausea, Pruritic skin disorder	Serious	30.00	Female	COMIRNATY(H); COMIRNATY(H); Food allergy; Allergic to animal, Mite allergy, Seasonal allergic, Non-tobacco user; Social alcohol drinker	NUVARING, INLIVA R; MOMETASONE; DALFALGAN						
		Regulatory Authority	Abdominal pain upper, Chills, COVID-19 immunisation, Decreased appetite, Fatigue, Headache, Injection site reaction, Myalgia, Nausea, Pyrexia	Serious	47.00	Female	Comorbidity(H); Comorbidity(H); Hypertension(C)							
		Regulatory Authority	Atrial fibrillation, Chills, COVID-19 Immunisation, Extensive swelling of vaccinated limb, Fatigue, Headache, Malaise, Myalgia, Pyrexia	Serious	28.00	Female	Comorbidity(H); Comorbidity(H)							004695
		Regulatory Authority	Chills, Fatigue, Feeling cold, Palpitations, Pyrexia	Serious	30.00	Male	COMIRNATY(H); COMIRNATY(H); Obesity(C)	JARDANCE; METFORMAX; NOBETEN						004680
		Regulatory Authority	Dyspnoea, Hypertension, Pulmonary embolism	Serious	81.00	Male	COMIRNATY; COM RNATY	FRATEC-8						005294
		Regulatory Authority	Atrial fibrillation, Chills, COVID-19 Immunisation, Fatigue, Malaise, Myalgia, Nausea	Serious	47.00	Male	COMIRNATY; COM RNATY							2A6_4301081
4.1(b)	FRANCE	Regulatory Authority	Oxygen saturation decreased, Pyrexia, Tachycardia	Serious	47.00	Male	Polycythaemia(H); Atrial Arrhythmia(H); COMIRNATY(H); COMIRNATY(H)							00921A
		Regulatory Authority	Abdominal pain upper, Atrial fibrillation, Asthenia, Chest discomfort, Dizziness, Dry eyes, Extrapyramides, Eye pain, Headache, Heart rate irregular, Injection site reaction, Malaise, Myalgia, Nausea, Neck pain, Pain, Peripheral oedema, Photosensitivity reaction, Poor quality sleep, Vomiting	Serious	87.00	Male	COMIRNATY(H); Liver disorder(C)		COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COMRNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COMRNATY, COMIRNATY					

Country	Report Type	ALL PTS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	MW Identifier	Batch/Lot Number	
4.1(b)	FRANCE	Regulatory Authority	Cardiac failure, ischaemic stroke	Serious	82.00	1104.00	Male	COMIRNATY; COM RNATY; Myocardial Ischaemia(H); Myocardial infarction(H); Dyslipidaemia(H); Osteoarthritis(H); Carotid endarterectomy; Carotid endarterectomy; Prostatic operation	BISOPROLOL; CLOP DOGREL; ATORVASTATIN; COVERAM; FUROSEMIDE; ZYMAD; BLOODOSINE; PARACETAMOL				14031	
	4.1(b)	Regulatory Authority	Facial paralysis	Serious	83.00	798.00	Female	COMIRNATY; COM RNATY						14012
		Regulatory Authority	Aphasia, Cerebral infection, Coordination abnormal	Serious	74.00	888.00	Male	Hypercholesterolaemia(C); Hypertension(C); PFIZER BIONTECH COVID-19 VACCINE(H); PFIZER BIONTECH COVID-19 VACCINE(H)	SAGRAVIT TOTAL (MINERALS AND VITAMINS NOS); HYDROCHLOROTHIAZIDE					
		Regulatory Authority	Maternal exposure during pregnancy, Tinnitus	Serious			Female	Pregnancy(H)	PFIZER BIONTECH COVID-19 VACCINE	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE				
		Regulatory Authority	Chest pain, Chills, Fatigue, Headache, Lymph node pain, Myalgia, Nausea, Photophobia, Pyrexia, Sore pain	Serious	37.00	444.00	Female			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE			005688	
		Regulatory Authority	Arthralgia, Dyspnoea, Headache, Heart rate, Stress, Influenza, Nervousness, Tremor	Serious			Female	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE						00022A
		Regulatory Authority	Chills, Contusion, Ear pain, Myalgia	Serious	29.00	348.00	Female	Suspected COVID-19(H); COV D-19 MRNA VACCINE BNT162B2(H); COVID-19 MRNA VACC NE BNT162B2(H)						
		Regulatory Authority	Asthma, Cardiac disorder, Chest pain, Chills, Dyspnoea, Fatigue, Loss of consciousness, Lymphadenopathy, Pain, Palpitations, Periorbital swelling, Pyrexia, Swelling, Syncope, Tachycardia, Vascular headache	Serious	38.00	456.00	Male	Cough(C); Asthma(C); Brain operation	COVID-19 MRNA VACC NE BNT162B2					
		Regulatory Authority	Fatigue, Headache, Pyrexia	Serious	37.00	444.00	Male	COVID-19 MRNA VACC NE BNT162B2(H)						00040A
		Regulatory Authority	Fatigue	Serious	27.00	324.00	Male		PFIZER BIONTECH COVID-19 VACCINE					00022A
		Regulatory Authority	Cerebrovascular accident, Headache	Serious			Male		COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; INFLUENZA VIRUS				004875	
		Regulatory Authority	Musculoskeletal stiffness, Photophobia, Tinnitus	Serious	38.00	456.00	Male		COVID-19 MRNA VACC NE BNT162B2					
		Regulatory Authority	Chills, Fatigue, Headache, Lymphadenopathy, Nausea, Pyrexia, Vaccination site pain	Serious	30.00	360.00	Female		BECLOMETASONE DIPROPIONATE; LORATADINE; SODIUM CHROMOLICATE	COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY; COMIRNATY			00022A	
		Regulatory Authority	Dizziness postural	Serious	57.00	684.00	Male	Subarachnoid haemorrhage(H); Arteriovenous malformation(H); Hemiplegia(H)	COVID-19 MRNA VACC NE BNT162B2					005688
		Regulatory Authority	Chills, Dizziness, Pyrexia, Tachycardia	Serious	28.00	336.00	Male	Suspected COVID-19(H)	COVID-19 MRNA VACC NE BNT162B2					
		Regulatory Authority	Arthralgia, Neck pain	Serious	34.00	408.00	Male		COVID-19 MRNA VACC NE BNT162B2					
		Regulatory Authority	Dermoses, Fatigue, Headache, Lymphadenopathy, Malaise, Muscular weakness, Pyrexia, Vomiting	Serious			Male		COVID-19 MRNA VACC NE BNT162B2; INFLUENZA VIRUS				005688	
		Regulatory Authority	Abdominal pain upper, Blood pressure increased, Chest discomfort, Chest pain, Dyspnoea, Fatigue, Headache, Heart rate increased, Nausea, Palpitations, Pyrexia	Serious	46.00	552.00	Female	COVID-19 MRNA VACC NE BNT162B2(H)	COVID-19 MRNA VACC NE BNT162B2				004737	
		Regulatory Authority	Dizziness, Feeling hot, Syncope	Serious	27.00	324.00	Female	COVID-19 VACCINE MRNA (BNT162B2)(H); COVID-19 VACCINE MRNA (BNT162B2)(H)	BETNOVATE; CETIRIZINE; DERMOL (BENZALKONIUM CHLORIDE)CHLORHEXIDINE HYDROCHLORIDE; ISOPROPYL MYRISTATE; PARAFIN LIQUID; DURAPHAT; LEVEST (ETHNYLESTRADIOL/LEVONORGE STREL); PROPIONACOL.					
		Regulatory Authority	Abdominal discomfort, Dyspnoea, Myalgia	Serious	33.00	396.00	Male		PFIZER BIONTECH COVID-19 VACCINE; BERTRALINE				005287	
		Regulatory Authority	Arthralgia, Fatigue, Headache, Injection site pain, Lymph node pain, Myalgia, Pyrexia	Serious	28.00	336.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE				00014A	
		Regulatory Authority	Pain in extremity	Serious	61.00	732.00	Female			COV D-19 MRNA VACCINE BNT162B2			005237	
		Regulatory Authority	Arthralgia, Fatigue, Headache, Nausea, Pyrexia	Serious	52.00	624.00	Male		COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2				00014A	
		Regulatory Authority	Dry skin, Erythema, Rash	Serious	28.00	336.00	Male		PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Chills, Mastitis, Maternal exposure during breast feeding, Myalgia, Nausea, Pyrexia	Serious	33.00	396.00	Female	Breast feeding(C)	FLUCLOXACILLIN	COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY			005688	
		Regulatory Authority	Fatigue, Headache, Nausea, Pain in extremity, Pyrexia, Vomiting	Serious	29.00	348.00	Male	Asthma(C)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE				005688	
		Regulatory Authority	Chest discomfort, Lip swelling	Serious	28.00	336.00	Female	Dermal filler injection; RESTYLANE(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	SYNPHASE				005287	
		Regulatory Authority	Chest discomfort, Chest pain, Chills, Dizziness, Dyspnoea, Fatigue, Night sweats, Piloerection, Pyrexia, Tremor	Serious	25.00	300.00	Female	Heavy menstrual bleeding(H); Dysmenorrhoea(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; CONTRACEPTIVE HD04	DRET NE				005688	
		Regulatory Authority	Dizziness, Palpitations, Syncope, Unresponsive to stimuli	Serious	23.00	276.00	Female	PFIZER BIONTECH COVID-19 VACCINE(H); PFIZER BIONTECH COVID-19 VACCINE(H)	DULOJET NE; RIGEV DON (ETHNYLESTRADIOL/LEVONORGE STREL)				005688	
		Regulatory Authority	Back pain, Fatigue, Feeling cold	Serious			Male	Suspected COVID-19(H)	PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Facial paralysis, Myalgia	Serious	34.00	408.00	Male		PFIZER BIONTECH COVID-19 VACCINE				005688	
		Regulatory Authority	Cyst, Heavy menstrual bleeding	Serious	36.00	432.00	Female	Heavy menstrual bleeding(C)	INFLUENZA VIRUS; NORETH NDRONE; TRANEXAMIC AC D; YASMIN	COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2			005287	
		Regulatory Authority	Abdominal pain upper, Arthralgia, Asthenia, Chest pain, Chills, Decreased appetite, Dermoses, Dyspnoea, Ear pain, Eye pain, Fatigue, Gait disturbance, Haematochezia, Headache, Hyperhidrosis, Lymphadenopathy, Pain in extremity, Palpitations, Pyrexia, Tachycardia	Serious	39.00	468.00	Male			COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COV D-19 MRNA VACCINE BNT162B2; COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACC NE BNT162B2				

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4.1(b)		Regulatory Authority	Pain, Pain in extremity, Rheumatological examination	Serious	50.00	500.00	Male	Rheumatic disorder(s)		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE			4.1(b)	
		Regulatory Authority	Dyspnoea, Fatigue, Heart rate, Palpitations, Pyrexia, Tachycardia	Serious	51.00	512.00	Female			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE				00020A
		Regulatory Authority	Angioedema, Lip swelling	Serious	52.00	524.00	Male		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Chills, Diarrhoea, Fatigue, Hyperhidrosis, Presyncope	Serious	29.00	249.00	Male		COVID-19 MRNA VACC NE BNT162B2, CODEINE, FLUCLOXACILLIN					00022A
		Regulatory Authority	Chills, Headache, Pain, Pyrexia	Serious	31.00	372.00	Male		COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACCINE BNT162B2					005688
		Regulatory Authority	Fatigue, Headache, Migraine, Oropharyngeal pain, Pain, Pyrexia	Serious	28.00	336.00	Male	Ankylosing spondylitis(s)	AMTR PITYLINE, COVID-19 MRNA VACCINE BNT162B2, ETORICOXIB, PARACETAMOL					005688
		Regulatory Authority	Fatigue, Headache, Siness, Pain	Serious	47.00	394.00	Male		COVID-19 MRNA VACC NE BNT162B2	COV D-19 MRNA VACCINE BNT162B2, COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACCINE BNT162B2, COVID-19 MRNA VACC NE BNT162B2				
		Regulatory Authority	Injection site pain, Lethargy, Lymphadenopathy, Malaise, Musculoskeletal chest pain, Myalgia, Nausea, Pyrexia, Syncope	Serious	39.00	498.00	Male	Suspected COVID-19(s); Immunodeficiency(s); Steroid therapy, BECLOMETASONE(s)	CETIRIZIN, POSTAIR, PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Malaise, Tachycardia	Serious	42.00	304.00	Female			COV D-19 MRNA VACCINE BNT162B2, COVID-19 MRNA VACC NE BNT162B2				005688
		Regulatory Authority	Vaginal haemorrhage	Serious	31.00	372.00	Female			PFIZER BIONTECH COVID-19 VACCINE				
		Regulatory Authority	Chills, Dry mouth, Eye pain, Headache, Muscle spasms, Pain	Serious	33.00	396.00	Male	Suspected COVID-19(s); Clinical trial participant(s)	COVID-19 MRNA VACC NE BNT162B2, INFLUENZA VIRUS					
		Regulatory Authority	Arthralgia, COVID-19, Pyrexia	Serious	37.00	444.00	Male		COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACCINE BNT162B2					
		Regulatory Authority	Chest pain, Chills, Dizziness, Dyspnoea, Fatigue, Lymphadenopathy, Maternal exposure during breast feeding, Nausea, Palpitations, Pyrexia, Tachycardia, Tremor, Tremor	Serious	26.00	348.00	Female	Breast feeding(s); PFIZER BIONTECH COVID-19 VACCINE(s); PFIZER BIONTECH COVID-19 VACCINE(s)	AMTR PITYLINE					005688
		Regulatory Authority	Diarrhoea, Pain, Pyrexia, Vomiting	Serious	40.00	480.00	Male	Asthma(s); Suspected COVID-19(s); Steroid therapy: VENTOLIN (SALBUTAMOL SULFATE)(s); CLENIL MODULITE(s); RAMPREL(s); Hypertension(s)	COVID-19 MRNA VACC NE BNT162B2					004737
		Regulatory Authority	Asthenia, Chest discomfort, Eye pain, Fatigue, Headache, Insomnia, Pain, Pain in extremity	Serious	27.00	324.00	Male		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Headache, Hyperhidrosis, Insomnia	Serious	36.00	432.00	Male		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE					005688 / 00014A
		Regulatory Authority	Arthralgia, Headache	Serious	31.00	372.00	Male		PFIZER BIONTECH COVID-19 VACCINE, INFLUENZA VIRUS					
		Regulatory Authority	Chills, Fatigue, Headache, Joint stiffness, Lymphadenopathy, Neck pain, Pyrexia	Serious	30.00	360.00	Male		PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Chills, Headache, Myalgia, Pyrexia	Serious	31.00	372.00	Male		PFIZER BIONTECH COVID-19 VACCINE, INFLUENZA VIRUS, PFIZER BIONTECH COVID-19 VACCINE					005688
		Regulatory Authority	Axillary pain, Chills, Fatigue, Myalgia, Nasal congestion, Oropharyngeal pain, Pruritus	Serious	32.00	424.00	Male		ASACLOFEN, ATORVASTATIN, KOLANTICIN, LANOPRAZOL	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				00040A
		Regulatory Authority	Arthralgia, COVID-19, Pain in extremity	Serious			Male	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE						005688
		Regulatory Authority	Migraine, Pyrexia, Rash	Serious	26.00	312.00	Female			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				005688
		Regulatory Authority	Chills, Hallucination, Headache, Pyrexia	Serious	30.00	360.00	Male	Blood donation(s)	PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Chills, Dyspnoea, Headache, Heart rate increased, Injury associated with device, Insomnia, Myalgia, Pyrexia	Serious	25.00	300.00	Male		COVID-19 MRNA VACC NE BNT162B2					
		Regulatory Authority	Dizziness postural	Serious	35.00	420.00	Male	Cerebral palsy(s); Hydrocephalus(s); Scoliosis(s); Visual impairment(s)	PFIZER BIONTECH COVID-19 VACCINE					005688
		Regulatory Authority	Chills, Fatigue, Headache, Myalgia, Pyrexia, Vomiting	Serious			Male		COVID-19 MRNA VACC NE BNT162B2					
4.1(b)	UNITED KINGDOM	Regulatory Authority	Cardiac arrest, Death, Dyspnoea, Headache, Influenza like illness, Oxygen saturation decreased	Serious	39.00	498.00	Male	COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACCINE BNT162B2						005688
4.1(b)		Regulatory Authority	Nausea, Pain in extremity, Pyrexia	Serious	45.00	540.00	Male		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory Authority	Injection site pain, Lymphadenopathy	Serious	37.00	444.00	Male		COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACCINE BNT162B2					005688
		Regulatory Authority	Fatigue, Lymphadenopathy, Nausea, Pain	Serious	30.00	360.00	Male		COVID-19 MRNA VACC NE BNT162B2					
		Regulatory Authority	Abdominal pain upper, COVID-19, Fatigue, Headache, Injection site pain, Oropharyngeal pain	Serious	44.00	528.00	Male	Suspected COVID-19(s)	CETIRIZIN, HYDROCHLORIDE, JAPAN	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				
		Regulatory Authority	Heart rate increased, Influenza like illness, Lymphadenopathy, Pain	Serious	19.00	228.00	Female		BERTRALINE	COM RNATY, COMRNATY, COMRNATY, COM RNATY, COMRNATY, COMRNATY				005688

Case ID	Country	Report Type	ALL PTS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	PRV Identifier	Batch/Lot Number		
4.1(b)	GERMANY	Regulatory Authority	Chills, Cold sweat, Confusional state, Headache, Hot flush, Migraine, Pyrexia	Serious	28.00	336.00	Male		COVID-19 MRNA VACC NE BNT162B2					4.1(b)	00014A	
		Regulatory Authority	Fatigue, Headache, Myalgia	Serious	22.00	264.00	Male		RUDESONIDE, CETIRIZ NE, PFIZER BIONTECH COVID-19 VACCINE						00014A	
		Regulatory Authority	Chills, Headache, Influenza like illness, Malaise, Nausea	Serious	24.00	288.00	Female	Suspected COVID-19(H)		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				00014A		
		Regulatory Authority	Chills, Fatigue, Pain in extremity	Serious	48.00	552.00	Male		PFIZER BIONTECH COVID-19 VACCINE						008325	
		Regulatory Authority	Asthenia, Decreased appetite, Diarrhoea, Headache, Heart rate increased, Night sweats, Oropharyngeal pain, Pyrexia	Serious	35.00	420.00	Male	Asthma(C), VENTOLIN ACCUHALER(H), BERET DE(H)	COMIRNATY, COM RNATY, BERETIDE, VENTOLIN ACCUHALER							
		Regulatory Authority	Arthralgia, Axillary pain, Chills, Insomnia, Malaise, Nausea, Pyrexia	Serious	38.00	456.00	Male	Spinal cord injury(C)	CO-CODAMOL, COVID-19 MRNA VACCINE BNT162B2							
		Regulatory Authority	Fatigue, Feeling drunk, Hangover, Migraine, Myalgia, Pain in extremity	Serious	31.00	372.00	Male		PFIZER BIONTECH COVID-19 VACCINE							
		Regulatory Authority	Dizziness, Fatigue, Headache, Nausea, Pain in extremity, Pain of skin, Vomiting	Serious	35.00	420.00	Male		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE						005688	
		Regulatory Authority	Back pain, Chills, Fatigue, Headache, Hyperhidrosis, Pain in extremity, Photophobia, Pyrexia, Sweating fever	Serious	25.00	300.00	Male	Pericarditis(H), Myocarditis(H), Asthma(C)	COVID-19 MRNA VACC NE BNT162B2						005688	
		Regulatory Authority	Chills, Dizziness, Fatigue, Malaise, Myalgia, Nausea, Syncope	Serious	20.00	240.00	Male		COVID-19 MRNA VACC NE BNT162B2, INFLUENZA VIRUS, SERTRALINE						0014A	
4.1(b)	GERMANY	Regulatory Authority	Back pain, Fatigue, Feeling cold, Haemorrhage, Heavy menstrual bleeding, Hyperhidrosis, Myalgia, Pain of skin, Sensative skin, Vomiting	Serious	29.00	348.00	Female			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE				002621, 003851		
		Regulatory Authority	Chest pain, Fatigue, Peripheral swelling, Pyrexia	Serious	34.00	408.00	Male		COVID-19 MRNA VACC NE BNT162B2							
		Regulatory Authority	Maternal exposure during pregnancy, Nausea, Pyrexia	Serious	36.00	432.00	Female	Pregnancy(C)		COM RNATY, COMIRNATY, COMIRNATY					005688	
		Regulatory Authority	Syncope	Serious	50.00	600.00	Male	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE							14026	
		Regulatory Authority	Pulmonary embolism	Serious	27.00	304.00	Female	Breast cancer(H), Vascular dementia(C), Psychotic disorder(C)	FLUZONE [INFLUENZA VACCINE]	COM RNATY					00321A	
		Regulatory Authority	Acute myocardial infarction	Serious	30.00	360.00	Male	Hypertension(H), COMIRNATY, COM RNATY							004233	
		Regulatory Authority	Axillary pain, Influenza, Injection site pain, Lymphadenopathy, Pain, Pyrexia	Serious	30.00	360.00	Male		COVID-19 MRNA VACC NE BNT162B2							
		Regulatory Authority	Arthralgia, Chills, Fatigue, Injection site reaction, Malaise, Myalgia, Pyrexia	Serious	20.00	240.00	Male	COMIRNATY, COM RNATY	MUCONIDINE, NEBIVOLOLO, ALPRAZOLAM-GA, ZOPICLONE						005688	
		Regulatory Authority	Chills, Fatigue, Headache, Influenza like illness, Pain in extremity	Serious	32.00	384.00	Male		COVID-19 MRNA VACC NE BNT162B2							
		Regulatory Authority	Chest pain, Dizziness, Dyspnoea, Palpitations, Pyrexia, Tachycardia	Serious	16.00	192.00	Male	Pericarditis(H)	PFIZER BIONTECH COVID-19 VACCINE, INFLUENZA VIRUS							
4.1(b)	GERMANY	Regulatory Authority	Chest pain, Dizziness, Fatigue, Headache, Hypertension, Malaise, Nausea, Palpitations, Pyrexia	Serious	30.00	360.00	Female	Palpitations(C), Echocardiogram, Chest pain(C), Electrocardiogram, COVID-19 MRNA VACC NE BNT162B2(H), Dyspnoea(H)							005232	
		Regulatory Authority	Angina pectoris, Chest discomfort, Facial paralysis, Hypersensitivity, Hypoaesthesia, Maternal exposure during pregnancy, Pyrexia, Tachypnoea	Serious	38.00	456.00	Female	Pregnancy(H)	LANSOPRAZOLE, QVAR, VENTOLIN [SALBUTAMOL]	PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE					005287	
		Regulatory Authority	Agonist, Eye pain, Fatigue, Headache, Hyperhidrosis, Injection site pain, Injection site swelling, Loss of personal independence in daily activities, Nausea, Pyrexia	Serious	48.00	576.00	Female	COMIRNATY								
		Regulatory Authority	Asthenia, Dyspnoea, Pericardial effusion, Pleural effusion	Serious	27.00	304.00	Female	COMIRNATY(H), COMIRNATY(H)							005687	
		Regulatory Authority	Arthralgia, Arthritis, Gout, Pyrexia	Serious	32.00	384.00	Male			PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE, PFIZER BIONTECH COV D-19 VACC NE					005287	
		Regulatory Authority	Maternal exposure during breast feeding, Myalgia	Serious	34.00	408.00	Female	Breast feeding(C)		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COV D-19 VACC NE						
		Regulatory Authority	Fatigue, Headache, Pain, Pyrexia, Tremor	Serious	37.00	444.00	Male		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE						00059A	
		Regulatory Authority	Abdominal pain upper, Chills, Illness	Serious	41.00	492.00	Female	Pain in extremity(H), Chills(H), Hives/urtic(H), KADCYLAR, ASTRAZENCA COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE	COVID-19 MRNA VACC NE BNT162B2, COVID-19 VACCINE ASTRAZENCA, INFLUENZA VIRUS, KADCYLA, PARACETAMOL							
		Regulatory Authority	Blood pressure decreased, Chills, Feeling cold, Injection site reaction, Malaise, Nausea, Pain in extremity, Pyrexia	Serious	36.00	432.00	Female	COMIRNATY, COM RNATY	DAFALGAN							14022
		Regulatory Authority	Anaphylactic shock, Asthenia, Dizziness, Dyspnoea, Erythema, Gait disturbance, Laryngeal oedema, Oxygen saturation decreased, Pain in extremity, Pruritus, Pyrexia, Rash, Skin burning sensation, Syncope, Tremor	Serious	43.00	516.00	Female			COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COMIRNATY, COM RNATY, COMIRNATY, COM						

Case ID	Country	Report Type	All PFS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	PRV Identifier	Batch/Lot Number	
4.1(b)		Regulatory Authority	Chest pain, Dyspnoea, Hypoaesthesia, Influenza like illness, Pericarditis, Pyrexia, Syncope	Serious	29.00	348.00	Male	empromendibular joint syndrome(H); Tuberculosis(H)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					4.1(b)	
		Regulatory Authority	Atrial fibrillation, COVID-19, SARS-CoV-2 test positive	Serious	71.00	352.00	Male	Acute kidney injury(H); Benign prostatic hyperplasia(H); Gout(H); Hypertension(H); Urinary tract infection(C); Drug hypersensitivity		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE			30A21A; 21B21A		
		Regulatory Authority	Angina pectoris, Arrhythmia, Chest pain, COVID-19 immunisation	Serious	38.00	456.00	Male						004498		
		Regulatory Authority	COVID-19, Vaccine breakthrough infection	Serious	69.00	328.00	Female			PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACC NE					
		Regulatory Authority	Rash, Urticaria	Serious	61.00	732.00	Male	Drug intolerance(H); Hypertension(H); COMIRNATY(H); COMIRNATY(H)	JACOPIN; SIMVASTATIN	TACHIPRINA; TACHIPRINA			17Q21A		
		Regulatory Authority	Chest pain, Left ventricular dysfunction, Myocarditis, Palpitations, Tachycardia	Serious	21.00	252.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE						
		Regulatory Authority	Fatigue, Pain	Serious	19.00	228.00	Female			COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2			005689		
		Regulatory Authority	Muscle spasms, Oxygen saturation abnormal, Pallor, Pyrexia	Serious	66.00	706.00	Male	COVID-19(H); Asthma(C); Rubber sensitivity; COMIRNATY; COMIRNATY							
		Regulatory Authority	Chills, Urticaria	Serious	25.00	300.00	Male		COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2				005237		
		Regulatory Authority	Abdominal pain, Body temperature increased, Chills, COV D-19 immunisation, Fatigue, Injection site reaction, Malaise, Myalgia, Nausea, Pyrexia	Serious	50.00	800.00	Male	COMIRNATY(H); COMIRNATY(H)					004955		
Regulatory Authority	Chills, Fatigue, Headache, Myalgia, Pyrexia	Serious	62.00	744.00	Male		ABITRIPTYL; NE; COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; RASIM PRIL								
Regulatory Authority	Pain	Serious	63.00	756.00	Male		COVID-19 MRNA VACC NE BNT162B2					004876			
4.1(b) ITALY	Regulatory Authority	Acute myocardial infarction, Cough, Haemoptysis, Pulmonary embolism	Serious	79.00	348.00	Male	COMIRNATY(H); COMIRNATY(H)							005887	
4.1(b)	Regulatory Authority	Deep vein thrombosis, Pulmonary embolism	Serious	79.00	348.00	Female	Dilatocardiomy(C); Deep vein thrombosis(C); Rheumatoid arthritis(C); Diverticulitis(C); COMIRNATY; COM RNATY	ESICLOXON 4.1(D); 4.1(D); METHOTREXATE SODIUM; PREGABALIN; LIGANDIA; CLAMISANTAN MEDICOMIL; PANTOPRAZOLE SODIUM BISQUHYDRATE; PREGABALIN; ZYLORIC					005687		
	Regulatory Authority	Chills, Fatigue, Maternal exposure during pregnancy	Serious	34.00	408.00	Female	Pregnancy(C)		FOLIC ACID	COM RNATY; COMIRNATY; COMIRNATY				005287	
	Regulatory Authority	Chest discomfort, Chest pain	Serious	29.00	348.00	Female	PFIZER BIONTECH COVID-19 VACCINE(H); PFIZER BIONTECH COVID-19 VACCINE(H)							005686	
	Regulatory Authority	Headache, Influenza, Pain in extremity, Pyrexia, Sleep disorder	Serious	40.00	480.00	Male	Suspected COVID-19(H)		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					005686	
	Regulatory Authority	Fatigue, Malaise, Nausea	Serious	34.00	408.00	Male			PFIZER BIONTECH COVID-19 VACCINE; INFLUENZA VACCINE					005686	
	Regulatory Authority	Altered state of consciousness, Anorexia, COV D-19 immunisation, Diarrhoea, Erythema, Face oedema, Hyporesponsive to stimuli, Unresponsive to stimuli	Serious	36.00	432.00	Female	COMIRNATY							005688	
	Regulatory Authority	Cough, Decreased appetite, Dyspnoea, Fatigue, Headache, Influenza, Myalgia, Pain of skin, Pyrexia, Sensative skin	Serious	35.00	420.00	Male			PFIZER BIONTECH COVID-19 VACCINE						
	Regulatory Authority	Headache, Insomnia, Pain in extremity	Serious	35.00	420.00	Male			PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE						
	Regulatory Authority	Vertigo	Serious	63.00	756.00	Male			PFIZER BIONTECH COVID-19 VACCINE						
	Regulatory Authority	Dry mouth, Headache, Myalgia, Pyrexia	Serious			Male			PFIZER BIONTECH COVID-19 VACCINE						
	Regulatory Authority	Vomiting	Serious			Male			PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE						
	Regulatory Authority	Headache, Pyrexia, Swelling of eyelid	Serious	31.00	372.00	Male			PFIZER BIONTECH COVID-19 VACCINE					005688	
	Regulatory Authority	Heart rate increased, Palpitations, Pyrexia, Tachycardia	Serious	40.00	480.00	Male			PFIZER BIONTECH COVID-19 VACCINE; FEXOFENADINE					00304737	
	Regulatory Authority	Chills	Serious			Male			COVID-19 MRNA VACC NE BNT162B2					00026A	
	Regulatory Authority	Pulmonary embolism	Serious	59.00	708.00	Male	Sleep apnoea syndrome(C); Myocardial infarction(H); Hypertension(H); Implantable defibrillator insertion; Angioplasty	COMIRNATY							
	Regulatory Authority	Diarrhoea, Headache, Myalgia, Nausea, Pyrexia, Vomiting	Serious	26.00	312.00	Male	Suspected COVID-19(H)		PFIZER BIONTECH COV D-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					00022A	
	Regulatory Authority	Syncope	Serious	28.00	336.00	Male			COVID-19 MRNA VACC NE BNT162B2					005237	
4.1(b) GERMANY	Regulatory Authority	Sudden death	Serious	39.00	468.00	Male	Mental impairment(H); COMIRNATY(H); COMIRNATY(H)							00F21A	
4.1(b)	Regulatory Authority	Headache, Myalgia, Pyrexia, Vomiting	Serious	40.00	480.00	Female	COMIRNATY; COM RNATY(H)							17Q21A	
	Regulatory Authority	Chest pain, Chills, Pyrexia	Serious	35.00	420.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE						005688	
	Regulatory Authority	Chills, Dizziness postural, Headache, Nausea, Pain in extremity	Serious	23.00	276.00	Male		LEMS P (ASCONIC AC-D-PARACETAMOL-PHENYLEPHRINE HYDROCHLORIDE;SODIUM CITRATE)	PFIZER BIONTECH COVID-19 VACCINE; COM RNATY; PFIZER BIONTECH COVID-19 VACCINE; COMIRNATY; PFIZER BIONTECH COVID-19 VACCINE; COM RNATY; PFIZER BIONTECH COV D-19 VACC NE; COMIRNATY; PFIZER BIONTECH COVID-19 VACCINE; COM RNATY				005688		
	Regulatory Authority	Fatigue, Pyrexia, Swelling	Serious			Male	Suspected COVID-19(H)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE							
	Regulatory Authority	Fatigue, Headache, Migraine, Nausea, Night sweats	Serious	18.00	216.00	Female	Suspected COVID-19(H)		COV D-19 MRNA VACCINE BNT162B2; COMIRNATY; COV D-19 MRNA VACCINE BNT162B2; COM RNATY; COVID-19 MRNA VACCINE BNT162B2; COMIRNATY; COVID-19 MRNA VACCINE BNT162B2; COMIRNATY						

4.1(b)

4.1(b)

Case ID	Country	Report Type	All PTS	Case Seriousness	Patient Age (years)	Patient Sex	Patient Gender	Medical History	Concomitant Medications	Co-exposures	Case Reference	Reference Notes	PII Identifier	Batch/Lot Number
		Regulatory authority	Pain, Pyrexia	Serious	30.00	360.00	Male	Type 1 diabetes mellitus(C); Immunodeficiency(C)	PFIZER BIONTECH COVID-19 VACCINE				4.1(b)	
		Regulatory authority	Condition aggravated, Migraine, Visual impairment, Viralus Rotavirus	Serious	50.00	600.00	Male	MAXALT(H); ASPIRIN (ACETYLSALICYLIC ACID)(H)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; INFLUENZA VIRUS					004674
		Regulatory authority	Chest pain, Fatigue, Heart rate increased, Palpitations, Tachycardia	Serious	20.00	240.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					005889
		Regulatory authority	Abdominal pain, Arthralgia, Asthenia, Back pain, Chest pain, Dyspnoea, Fatigue, Flushing, Heart rate increased, Musculoskeletal chest pain, Myalgia, Pain in extremity, Palpitations, Paraesthesia, Pyrexia, Tachycardia, Tremor	Serious	28.00	336.00	Male		ADVATE; PFIZER BIONTECH COVID-19 VACCINE					00014A
		Regulatory authority	Arthralgia, Chills, Fatigue, Headache, Injection site reaction, Malaise, Myalgia	Serious	33.00	396.00	Male	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE						142220
		Regulatory authority	Chills, Dyspnoea, Fatigue, Headache, Pyrexia	Serious	30.00	360.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					000022A
		Regulatory authority	Dizziness, Fatigue	Serious	40.00	480.00	Female	PFIZER BIONTECH COVID-19 VACCINE	COVID-19 MRNA VACC NE BNT162B2; LYMECYCLINE; NEDPLAXON; SERITRALINE; COV D-19 MRNA VACC NE BNT162B2					
		Regulatory authority	Epilepsia, Headache	Serious	35.00	420.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory authority	Chills, Contusion, COV D-19, Dizziness, Ear pain, Fatigue, Haemorrhoids, Headache, Myalgia, Myocarditis, Rhinorrhoea	Serious	25.00	348.00	Female	Suspected COVID-19(H)		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE				
		Regulatory authority	Fatigue, Headache	Serious	27.00	324.00	Male		COVID-19 MRNA VACC NE BNT162B2					005688
		Regulatory authority	Dysmenorrhoea, Heavy menstrual bleeding, Menstrual disorder, Menstruation irregular	Serious	35.00	420.00	Female		INFLUENZA VIRUS; RIGEV DON JETHNYLESTRADIOL/LEVONORGESTREL; SERITRALINE	COV D-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACCINE BNT162B2; COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2				
		Regulatory authority	Bell's palsy, Ear pain, Extraocular muscle paresis, Facial paresis, Hypoaesthesia oral	Serious	37.00	444.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					005688
		Regulatory authority	Rash pustular	Serious	19.00	228.00	Male	Infectious mononucleosis(C)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					000022A
		Regulatory authority	Fatigue	Serious			Unknown		ROSUVASTATIN	PFIZER BIONTECH COVID-19 VACCINE				000022A
		Regulatory authority	Chills, Fatigue, Hallucination, Headache, Insomnia, Myalgia	Serious	41.00	492.00	Male	Anxiety(C)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; SERITRALINE					005689
		Regulatory authority	Dehydration, Fatigue, Headache, Myalgia, Myocarditis, Oropharyngeal pain, Sinus pain	Serious			Female	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	PFIZER BIONTECH COVID-19 VACCINE					000026A
		Regulatory authority	Chills, Headache	Serious	27.00	324.00	Male		COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2					
		Regulatory authority	Dizziness, Dyspnoea, Feeling of body temperature change, Heart rate abnormal, Malaise, Paraesthesia, Wheezing	Serious	28.00	336.00	Male	Suspected COVID-19(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	INFLUENZA VIRUS					005237
		Interim review	Epilepsy, Interchange of vaccine products	Serious	46.00	552.00	Male	Epilepsy(H); PFIZER BIONTECH COVID-19 VACCINE				4.1(b)	4.1(b)	
		Regulatory authority	Fatigue, Maternal exposure during pregnancy, Pyrexia	Serious	32.00	384.00	Female	Pregnancy(C)	POLICAR D	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COV D-19 VACC NE				
		Regulatory authority	Peripheral swelling	Serious	33.00	396.00	Female	COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2						
		Regulatory authority	Body temperature decreased, Headache, Hyperhidrosis, Myalgia, Paraesthesia, Petit mal epilepsy, Pyrexia, Vomiting	Serious	29.00	348.00	Male	Syncope(C); Animal bite(H); Haemaphysalis(H)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					005688
		Regulatory authority	Thromboas	Serious	50.00	600.00	Male	Immunodeficiency(C)		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE				
		Regulatory authority	Dizziness, Hyperhidrosis, Hypocsaemia, Paraesthesia	Serious	32.00	384.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					005689
		Regulatory authority	Back pain, Headache, Insomnia, Lethargy, Night sweats, Pain, Pain in extremity	Serious	27.00	324.00	Male		COVID-19 MRNA VACC NE BNT162B2					000050A
		Regulatory authority	Chest pain, Fatigue, Myocarditis, Palpitations	Serious	31.00	372.00	Male		PFIZER BIONTECH COVID-19 VACCINE; COVID-19 VACCINE MODERNA					002332
		Regulatory authority	Headache, Nausea	Serious			Male		COVID-19 MRNA VACC NE BNT162B2					
		Regulatory authority	Pain in extremity, Sciatica	Serious	77.00	824.00	Male		PFIZER BIONTECH COVID-19 VACCINE	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COV D-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE				004737
		Regulatory authority	Hypoaesthesia	Serious	48.00	576.00	Male		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE					
		Regulatory authority	Headache, Pain in extremity	Serious	25.00	300.00	Female	Suspected COVID-19(H)		COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY; COMIRNATY; COM RNATY; COMIRNATY				005688
		Regulatory authority	Headache, Hyperhidrosis, Nausea, Tinnitus	Serious	38.00	456.00	Male		COVID-19 MRNA VACC NE BNT162B2; COVID-19 MRNA VACCINE BNT162B2					00014A
		Regulatory authority	Hypoaesthesia, Vision blurred	Serious	48.00	576.00	Female	Suspected COVID-19(H)		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACC NE; PFIZER BIONTECH COV D-19 VACC NE				
		Regulatory authority	Deep vein thrombosis, Pain in extremity	Serious	25.00	300.00	Male	Asthma(C); Non-tobacco user(H)	PFIZER BIONTECH COVID-19 VACCINE; PIRITON; SALBUTAMOL					
		Regulatory authority	Chills, Erythema, Fatigue, Muscle strain, Myalgia, Tenderness	Serious	27.00	324.00	Male	Eczema(C); Autism spectrum disorder(C); Clinical trial participant(H)	PFIZER BIONTECH COVID-19 VACCINE; VITAMIN C (ASCORBIC ACID)					00014A
		Regulatory authority	COVID-19 immunisation, Dyspnoea, Palpitations, Pulmonary embolism, Respiratory failure	Serious	31.00	372.00	Female	Fibromyalgia(H); Sinusitis(H); Overweight(H); COMIRNATY	VENTOLINE ROTACAPS; PARACETS PLUS; NASONEX; VASIBIN					003804

Case ID	Country	Report Type	ALL PTS	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	Case Reference	Reference Notes	MM Identifier	Batch/Lot Number
4.1(b)		regulatory authority	Cynproxa, Exposure via breast milk, Fatigue, Heart rate increased, Pyrexia, Somnolence, Tachycardia	Serious	3:57	3:50	Male		PFIZER BIONTECH COVID-19 VACCINE				4.1(b)	00014A
		regulatory authority	Angina pectoris, Chest pain	Serious	31:00	372:00	Male		COVID-19 MRNA VACC NE BNT162B2, INFLUENZA VIRUS					
		regulatory authority	Abdominal pain upper, Chills, Fatigue, Headache, Influenza like illness, Nausea, Pain, Pyrexia, Somnolence, Vomiting	Serious	40:00	480:00	Male	PFIZER BIONTECH COVID-19 VACCINE(1)						000688
		regulatory authority	Nasopharyngitis	Serious	28:00	336:00	Male		COVID-19 MRNA VACC NE BNT162B2, COVID-19 MRNA VACCINE BNT162B2					00009A
		regulatory authority	Arthralgia, Fatigue, Headache, Musculoskeletal stiffness, Pyrexia	Serious	26:00	312:00	Male		COVID-19 MRNA VACC NE BNT162B2					000688
		regulatory authority	Chills, Ear pain, Fatigue, Headache, Muscle aches, Pain in extremity, Pyrexia	Serious	35:00	408:00	Male		PFIZER BIONTECH COVID-19 VACCINE, PFIZER BIONTECH COVID-19 VACCINE					00014A
		regulatory authority	Chills, Extensive swelling of vaccinated limb, Fatigue, Headache, Injection site reaction, Malaise, Myalgia, Palpitations, Pyrexia	Serious	46:00	552:00	Female	COMIRNATY, COM RNATY						004730

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number 4.1(b)) on 05-May-2021. The most recent information was received on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PARAESTHESIA (Tingling), ARTHRALGIA (Feeling very achey in joints and limbs), PAIN IN EXTREMITY (Pain in extremity), SENSORY DISTURBANCE (Abnormal physical sensation), NASOPHARYNGITIS (Cold symptoms), VARICOSE VEIN (I suffer from varicose veins which have been especially sore of late.), INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administration) and FATIGUE (Fatigue) in a 48-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 3003608 and 3001659) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. Concurrent medical conditions included Endometriosis (Diagnosed in 2019 but its most likely I have had this since I was a teenager.), Raynaud's disease (Diagnosed aged 16.), Food allergy (I have had food allergies (some severe) diagnosed age 25.), Varicose veins (Patient reports varicose veins being especially sore lately), Anaphylactic reaction to food (Caused through food allergies.), Migraine (Since I was a teenager.) and Abstains from recreational drugs. Concomitant products included CODEINE PHOSPHATE, PARACETAMOL (CO-CODAMOL) for Bladder pain, DESOGESTREL (CERELLE) from 03-Aug-2018 to an unknown date for Endometriosis, ESTRADIOL (EVOREL) for Hormone replacement therapy. On 25-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 02-Jan-2022, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 26-Apr-2021, after starting mRNA-1273 (Moderna Covid-19 Vaccine), the patient experienced FATIGUE (Fatigue) (seriousness criterion medically significant). On 07-May-2021, the patient experienced ARTHRALGIA (Feeling very achey in joints and limbs) (seriousness criterion medically significant). 07-May-2021, the patient experienced PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion medically significant). On an unknown date, the patient experienced PARAESTHESIA (Tingling) (seriousness criterion medically significant), SENSORY DISTURBANCE (Abnormal physical sensation) (seriousness criterion medically significant), NASOPHARYNGITIS (Cold symptoms) (seriousness criterion medically significant), VARICOSE VEIN (I suffer from varicose veins which have been especially sore of late.) (seriousness criterion medically significant) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administration) (seriousness criterion medically significant). The patient was treated with PARACETAMOL for Pain, at an unspecified dose and frequency and IBUPROFEN for Pain, at an unspecified dose and frequency. At the time of the report, PARAESTHESIA (Tingling) and NASOPHARYNGITIS (Cold symptoms) outcome was unknown, ARTHRALGIA (Feeling very achey in joints and limbs), PAIN IN EXTREMITY (Pain in extremity), SENSORY DISTURBANCE (Abnormal physical sensation) and FATIGUE (Fatigue) was resolving, VARICOSE VEIN (I suffer from varicose veins which have been especially sore of late.) had not resolved and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administration) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Apr-2021, SARS-CoV-2 test: negative (Negative) Negative and no - negative covid-19 test (Negative) Negative. In June 2021, Scan: normal (normal) Scan was done for the legs to rule out DVT - all clear.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On an unknown date, SARS-CoV-2 test: negative (Negative) More information is available with the sender about this lab test. On an unknown date, Scan: normal (normal) All clear, deep vein thrombosis ruled out. The action taken with mRNA-1273 (Moderna Covid-19 Vaccine) (Intramuscular) was unknown. Patient experience very achy in joints and limbs from the past few days 7-10 May, varicose veins which have been especially sore of late and leg pains and tingling especially in the evening and overnight. patient rarely drink alcohol, maybe once a month. Treatment medication information included HRT patch Evorel 50 for the buzzing legs. For the event joint ache the event stop date was mentioned as 10 May 2021 Company comment This regulatory authority case of inappropriate schedule of product administration concerns a 48-year-old female patient with relevant medical history of varicose veins who experienced serious unexpected events of fatigue, arthralgia, pain in extremity, paraesthesia, nasopharyngitis, sensory disturbance, varicose vein. The event fatigue occurred one day after the first dose, arthralgia, pain in extremity occurred 12 days after the first dose, whereas time to onset for remaining events was not provided however, based on the information provided, the events occurred after the first dose of Spikevax. Per RA SD, action taken and rechallenge were assessed as unknown however, information provided suggest that the rechallenge was negative as there was no recurrence of the events after the second dose. Patient's varicose veins are possible confounder for the event of varicose veins. The benefit-risk relationship of drug is not affected by this report. The events' seriousness assessed as per Regulatory Authority reporting however, there was no information in the source document supporting RA's seriousness assessment.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 06-Jan-2022: Follow-up received on 06-Jan-2022 included Co suspect information was added.	
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 06-May-2021. The most recent information was received on 09-Jan-2022 and was forwarded to Moderna on 09-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CELLULITIS (Cellulitis), MYALGIA (Muscle ache) and HEADACHE (Headache) in a 45-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3001659) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. Patient has not had symptoms associated with COVID-19 Patient is not pregnant, Patient is not currently breastfeeding. Concurrent medical conditions included Hay fever. Concomitant products included LEVONORGESTREL (MIRENA) from 01-Jul-2010 to an unknown date for Contraception, LORATADINE (LORATADIN) from 01-May-2005 to an unknown date for Hay fever. On 25-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 05-Jan-2022, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 25-Apr-2021, the patient experienced MYALGIA (Muscle ache) (seriousness criterion medically significant). On 26-Apr-2021, the patient experienced HEADACHE (Headache) (seriousness criterion medically significant). On 03-May-2021, the patient experienced CELLULITIS (Cellulitis) (seriousness criterion medically significant). On 27-Apr-2021, MYALGIA (Muscle ache) had resolved. On 28-Apr-2021, HEADACHE (Headache) had resolved. On 11-May-2021, CELLULITIS (Cellulitis) had resolved.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Apr-2021, SARS-CoV-2 test: negative (Negative) No-Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Treatment information not provided. Patient has not tested positive for COVID-19 since having the vaccine. Company comment: This case concerns a 45 -year-old female patient with no relevant medical history, who experienced serious, unlisted, events of cellulitis, myalgia, and headache. The event myalgia occurred on the same day, the event headache occurred 2 days after, and the event cellulitis occurred 9 days after first dose of Moderna COVID-19 Vaccine. The rechallenge was unknown as the date only for the 1st dose was provided. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Serious criteria for the events -myalgia and headache were assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events were serious/IME. Most recent FOLLOW-UP information incorporated above includes: On 26-Oct-2021: Follow-up received on 26-Oct-2021 contains no new information On 03-Jan-2022: Follow-up received on 03-Jan-2021 contains no new information On 09-Jan-2022: Follow up contains significant information. Suspect product (COMIRNATY) was added.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of OSTEOPENIA (osteopenia), SPINAL COMPRESSION FRACTURE (Vertebral compression), INTERCHANGE OF VACCINE PRODUCTS (No 2nd dose of the Moderna vaccine was given to the patient, the patient instead received one dose of the Pfizer vaccine to complete their vaccine schedule.) and OFF LABEL USE (No 2nd dose of the Moderna vaccine was given to the patient, the	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		patient instead received one dose of the Pfizer vaccine to complete their vaccine schedule.) in a 74-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001946) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 immunisation. The patient's past medical history included Myocardial infarction in 2009, Bladder cancer in 2015, Allergic reaction to analgesics (Voltaren) since an unknown date, Raynaud's syndrome and Stent placement in 2009. Previously administered products included for Product used for unknown indication: Vaxigrip (Batch no: N3H76 2V) on 24-Nov-2016, Vaxigrip (Batch no: P2A64 1M) on 12-Nov-2017, Vaxigrip Tetra (Batch no: R3J22 7V) on 07-Nov-2018, Vaxigrip Tetra (Batch no: T3J085 V) on 12-Dec-2019 and Vaxigrip Tetra (Batch no: U3K121V) on 10-Nov-2020. Concurrent medical conditions included Drug allergy (Voltaren), Perfume sensitivity, Sciatica since 2001, Lumbago since 2001, Smoker (Smokes approximately one pack daily), Alcohol use (Drinks on average one liter of red wine weekly), Benign prostatic hyperplasia and Chronic obstructive pulmonary disease (Chronic obstructive pulmonary disease (COPD) Stage 1.). Concomitant products included FELODIPINE (PLENDIL) from 1998 to an unknown date for Raynaud's syndrome, PARACETAMOL (ALVEDON) from 2000 to an unknown date and NAPROXEN from 2002 to an unknown date for Sciatica, ACETYLSALICYLIC ACID (TROMBYL) and RAMIPRIL for an unknown indication. On 12-May-2021 at 10:00 AM, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 30-Jun-2021, the patient received second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 12-May-2021, the patient experienced CONFUSIONAL STATE (the patient felt confused in the head, like their	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		thoughts are not clear), NIGHT SWEATS (Sweated profusely at night), ASTHENIA (feeling weak, but they are not in pain), DYSPNOEA (difficulty breathing/trouble breathing), CHEST PAIN (4.1(b)), HYPERHIDROSIS (sweated profusely at night) and NAUSEA (feeling nauseous). On 12-May-2021 at 10:30 AM, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced DIZZINESS (dizziness), DISORIENTATION (disorientation in my head), VISION BLURRED (blurred vision) and HEADACHE (4.1(b)). On 02-Jun-2021 at 9:00 PM, the patient experienced CHEST PAIN (pain laterally and bilaterally across the thorax and down towards the abdomen). On 30-Jun-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (No 2nd dose of the Moderna vaccine was given to the patient, the patient instead received one dose of the Pfizer vaccine to complete their vaccine schedule.) (seriousness criterion hospitalization) and OFF LABEL USE (No 2nd dose of the Moderna vaccine was given to the patient, the patient instead received one dose of the Pfizer vaccine to complete their vaccine schedule.) (seriousness criterion hospitalization). On an unknown date, the patient experienced OSTEOPENIA (osteopenia) (seriousness criterion hospitalization) and SPINAL COMPRESSION FRACTURE (Vertebral compression) (seriousness criterion medically significant). On 12-May-2021 at 11:30 AM, DISORIENTATION (disorientation in my head) and VISION BLURRED (blurred vision) had resolved. On 13-May-2021, CHEST PAIN (4.1(b)) had resolved. At the time of the report, OSTEOPENIA (osteopenia), SPINAL COMPRESSION FRACTURE (Vertebral compression), CONFUSIONAL STATE (the patient felt confused in the head, like their thoughts are not clear), NIGHT SWEATS (Sweated profusely at night), ASTHENIA (feeling weak, but they are not in pain), DYSPNOEA (difficulty breathing/trouble breathing), HYPERHIDROSIS (sweated profusely at night) and NAUSEA (feeling nauseous) outcome was unknown, INTERCHANGE OF VACCINE PRODUCTS (No 2nd dose of the Moderna vaccine was given to the patient, the patient instead received one dose of the Pfizer vaccine to complete their vaccine schedule.) and OFF	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		LABEL USE (No 2nd dose of the Moderna vaccine was given to the patient, the patient instead received one dose of the Pfizer vaccine to complete their vaccine schedule.) had resolved, CHEST PAIN (pain laterally and bilaterally across the thorax and down towards the abdomen) had not resolved and DIZZINESS (dizziness) and HEADACHE (4.1(b)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Jun-2021, C-reactive protein: <1 (Low) Test Result:<1. On 02-Jun-2021, Electrocardiogram: normal (normal) Test Result:Sinus rhythm normal at 79 beats/minute.. On 02-Jun-2021, Electrocardiogram PR interval: normal (normal) Test Result:Normal. On 02-Jun-2021, Haemoglobin: 123 (High) Test Result:123. On 02-Jun-2021, Heart rate: 43 (Low) Test Result:43 (Low) The telemetry shows the patient's pulse occasionally going down towards 43, but continued sinus rate. On 02-Jun-2021, Pain assessment: 4 (Low) Test Result:4. On 02-Jun-2021, Troponin T: 16 (normal) Test Result:16. On 02-Jun-2021, Ultrasound scan: normal (normal) Test Result:Normal. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Treatment for the event included Naproxen. On an unknown date lab test CRP and Haemoglobin was done with unknown result. This report refers to a case of Interchange of vaccine products and Off-label use for mRNA-1273 (lot # 3001946) with associated adverse events. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. For the events osteopenia and Spinal compression fracture: Further information regarding temporal association is necessary to assess causality.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Clarification regarding the reported hospitalization for Interchange of vaccine products and Off-label use has been requested. Most recent FOLLOW-UP information incorporated above includes: On 19-Aug-2021: Follow up received contains new events and seriousness for Osteopenia, medical history and laboratory data was added and action taken was updated.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of INFLUENZA LIKE ILLNESS (syndrome grippal) in a 44-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001653) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. No Medical History information was reported. On 04-Apr-2021, the patient started TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 30-Apr-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 30-Apr-2021, the patient experienced PRODUCT ADMINISTRATION ERROR (4.1(b)). On 01-May-2021, the patient experienced INFLUENZA LIKE ILLNESS (syndrome grippal) (seriousness criterion disability). On 30-Apr-2021, PRODUCT ADMINISTRATION ERROR (4.1(b)) had resolved. At the time of the report, INFLUENZA LIKE ILLNESS (syndrome grippal) was resolving. Treatment details not provided. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was not applicable. Sender's (Case) Safety Report Unique Identifier: 4.1(b) Company Comment: Causality for event Product administration error is not applicable.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Based on the current available information and temporal association between the use of the product and the start date of the event syndrome grippal, a causal relationship cannot be excluded.	
4.1(b)		This spontaneous case was reported by a nurse and describes the occurrence of VACCINATION SITE PAIN (Injection site pain), PYREXIA (Fever), HEADACHE (headache), NAUSEA (nausea) and FATIGUE (fatigue) in a 42-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No medical history was provided by the reporter. Concurrent medical conditions included Food allergy. Concomitant products included ETANERCEPT (ENBREL) and Vitamin D for an unknown indication, METHOTREXATE and ZINC. On 13-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form and dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) at an unspecified dose. On 16-Apr-2021, the patient experienced HEADACHE (headache), NAUSEA (nausea) and FATIGUE (fatigue). On an unknown date, the patient experienced VACCINATION SITE PAIN (Injection site pain) and PYREXIA (Fever). At the time of the report, VACCINATION SITE PAIN (Injection site pain), PYREXIA (Fever), HEADACHE (headache), NAUSEA (nausea) and FATIGUE (fatigue) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-May-2021, Electrocardiogram: normal (normal) normal.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) dosing remained unchanged. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route), the reporter did not provide any causality assessments. Concomitant products were not provided/unknown. Treatment medication were not reported/unknown. Company comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to 4.1(b) (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 17-May-2021: Follow-up received on 17-May-21. Additional information included lab data and co-suspect drug.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of VACCINATION COMPLICATION (he had a reaction to the Moderna vaccine that caused him to go to the hospital) in an adult male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form and dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On an unknown date, the patient experienced VACCINATION COMPLICATION (he had a reaction to the Moderna vaccine that caused him to go to the hospital) (seriousness criterion hospitalization) and INTERCHANGE OF VACCINE	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		PRODUCTS (Two different doses administrated). At the time of the report, VACCINATION COMPLICATION (he had a reaction to the Moderna vaccine that caused him to go to the hospital) outcome was unknown and INTERCHANGE OF VACCINE PRODUCTS (Two different doses administrated) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. No treatment medications were reported. Company Comment : Based on the current available information and temporal association between the use of the product and the start date of the event Vaccination Complication, a causal relationship cannot be excluded. A causality assessment of Interchange of Vaccination Products is not applicable. Most recent FOLLOW-UP information incorporated above includes: On 06-Aug-2021: Follow-up received provided reporter contact details, patient details and additional events. Case upgraded to serious.	
4.1(b)	4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of SARS-COV-2 TEST POSITIVE (SARS-CoV-2 test positive) in an 84-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, the patient started TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) 1	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		dosage form. On 26-Mar-2021, the patient experienced WRONG PRODUCT ADMINISTERED (Wrong vaccine administered). On 16-Apr-2021, the patient experienced SARS-COV-2 TEST POSITIVE (SARS-CoV-2 test positive) (seriousness criterion hospitalization). The patient was hospitalized on 16-Apr-2021 due to SARS-COV-2 TEST POSITIVE. On 26-Mar-2021, WRONG PRODUCT ADMINISTERED (Wrong vaccine administered) had resolved. At the time of the report, SARS-COV-2 TEST POSITIVE (SARS-CoV-2 test positive) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Apr-2021, SARS-CoV-2 test positive: positive (Positive) Positive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant information was reported. No treatment information was reported. Upon internal review on 28 Jun 2021, event coding and narrative was updated. Causality for the SARs CoV-2 test is not applicable. Based on the current available information and temporal association between the use of the product and the start date of the event of lack of efficacy, a causal relationship cannot be excluded. The causality for the events of SARs CoV-2 test and wrong product administered is assessed as not applicable. Most recent FOLLOW-UP information incorporated above includes: On 25-May-2021: Event coding and narrative was updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) 4.1(b) (Reference number: 4.1(b) on 25-	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		May-2021 and was forwarded to Moderna on 25-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEPRESSED LEVEL OF CONSCIOUSNESS (Depressed level of consciousness) in a 25-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On 11-Jan-2021, the patient started TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) at an unspecified dose. On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Mar-2021, the patient experienced DEPRESSED LEVEL OF CONSCIOUSNESS (Depressed level of consciousness) (seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), MIGRAINE (Migraine), PAIN (Pain), NAUSEA (Nausea) and CHILLS (Chills). At the time of the report, DEPRESSED LEVEL OF CONSCIOUSNESS (Depressed level of consciousness), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), MIGRAINE (Migraine), PAIN (Pain), NAUSEA (Nausea) and CHILLS (Chills) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were provided. No treatment information was provided.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		This report refers to a case of Interchange of vaccine products with Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination and mRNA-1273, lot # 016B21A is assessed as not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a pharmacist and describes the occurrence of COGNITIVE DISORDER (Cognitive deterioration), ASTHENIA (Asthenia) and CONDITION AGGRAVATED (Disease aggravation) in an 83-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3001442 and 300042734) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: COMIRNATY (Biontech manufacturing GMBH and J07BX03) on 29-Mar-2021. Concurrent medical conditions included Hypertension, Unspecified cerebrovascular disease, Cognitive disorder and Hypothyroidism. Concomitant products included RIVASTIGMINE for an unknown indication. On 29-Mar-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 26-Apr-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 27-Apr-2021, the patient experienced COGNITIVE DISORDER (Cognitive deterioration) (seriousness criterion hospitalization), ASTHENIA (Asthenia) (seriousness criterion hospitalization) and CONDITION AGGRAVATED (Disease aggravation) (seriousness criterion hospitalization). At the time of the report, COGNITIVE DISORDER (Cognitive deterioration), ASTHENIA (Asthenia) and CONDITION AGGRAVATED (Disease aggravation) was resolving. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.	4.1(b)

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient received another brand for the first dose on 29 March 2021. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 25-May-2021: Translated received. Dose 1 information was added.. On 01-Jun-2021: Follow up 1 added, which included no new information. On 14-Jun-2021: Follow-up information received on 14 Jun 2021 has no new information.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of ANGIOEDEMA (Oedema Quincke's) and PARAESTHESIA (Facial paraesthesia) in a 42-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001653) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. Concurrent medical conditions included Factor V Leiden carrier. On 04-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 10-Jun-2021, the patient started TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 04-May-2021, the patient experienced ANGIOEDEMA (Oedema Quincke's) (seriousness criterion medically significant) and PARAESTHESIA (Facial paraesthesia) (seriousness criterion medically significant). At the time of the report, ANGIOEDEMA (Oedema Quincke's) and PARAESTHESIA (Facial paraesthesia) had resolved.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) was withdrawn on an unknown date. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant, treatment medication provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 28-Jun-2021: Outcome of events updated(from not recovered to recovered) ,co suspect added	
4.1(b)	4.1(b)	This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 27-May-2021. The most recent information was received on 27-May-2021 and was forwarded to Moderna on 02-Jun-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of CEREBRAL VENOUS SINUS THROMBOSIS (4.1(b) [REDACTED]). [REDACTED] D-Dimer 0,87 mcg/ml), HEADACHE (4.1(b) [REDACTED]) and NAUSEA (4.1(b) [REDACTED]) in a 33-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001937) for COVID-19 vaccination. Concurrent medical conditions included Migraine without aura (4.1(b) [REDACTED]). On 30-Apr-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 04-May-2021, the patient experienced CEREBRAL VENOUS SINUS THROMBOSIS (4.1(b) [REDACTED]).	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		4.1(b) [REDACTED] D-Dimer 0,87 mcg/ml) (seriousness criteria hospitalization and medically significant), HEADACHE (4.1(b) [REDACTED]) (seriousness criterion hospitalization) and NAUSEA (4.1(b) [REDACTED]) (seriousness criterion hospitalization). At the time of the report, CEREBRAL VENOUS SINUS THROMBOSIS (4.1(b) [REDACTED]) D-Dimer 0,87 mcg/ml), HEADACHE (4.1(b) [REDACTED]) and NAUSEA (4.1(b) [REDACTED]) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-May-2021, Blood fibrinogen: 0.87 mcg/ml (Inconclusive) 4.1(b) [REDACTED], D-Dimer 0,87 mcg/ml. On 04-May-2021, Fibrin D dimer: 0.87 mcg/ml (Inconclusive) 4.1(b) [REDACTED], D-Dimer 0.87 mcg/ml. On 04-May-2021, Platelet count: inconclusive (Inconclusive) in 4.1(b) [REDACTED] For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company Comment : Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Translation is pending.	
4.1(b) [REDACTED]	4.1(b) [REDACTED]	This case was received via 4.1(b) [REDACTED] (Reference number: 4.1(b) [REDACTED]) on 01-Jun-2021 and was forwarded to Moderna on 01-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of GASTROINTESTINAL HAEMORRHAGE (Gastrointestinal haemorrhage) in an 88-year-old female patient who received mRNA-1273	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		(Moderna COVID-19 Vaccine) (batch no. ER8736) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On 02-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced GASTROINTESTINAL HAEMORRHAGE (Gastrointestinal haemorrhage) (seriousness criteria hospitalization and medically significant). 02-Apr-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products). At the time of the report, GASTROINTESTINAL HAEMORRHAGE (Gastrointestinal haemorrhage) and INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was provided. No treatment medication was provided. It was reported that, the patient received PFIZER BIONTECH COVID-19 VACCINE on 02-Apr-2021. Company Comment : Very limited information regarding this event has been provided at this time. Since it is a RA case, further information has not been requested.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 01-Jun-2021 and was forwarded to Moderna on 01-Jun-2021. This regulatory authority case was reported by an other health care professional and	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		describes the occurrence of DIABETES MELLITUS (Diabetes mellitus) in a 73-year-old patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 1805025) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for COVID-19 vaccination. Concurrent medical conditions included Diabetes, Blood pressure high and Cancer surgery. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form and TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) (unknown route) at an unspecified dose. On 29-Mar-2021, the patient experienced DIABETES MELLITUS (Diabetes mellitus) (seriousness criterion medically significant), HYPERTENSION (Hypertension) and CANCER SURGERY (Cancer surgery). At the time of the report, DIABETES MELLITUS (Diabetes mellitus), HYPERTENSION (Hypertension) and CANCER SURGERY (Cancer surgery) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a pharmacist and describes the occurrence of DEEP VEIN THROMBOSIS (4.1(b)) and	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		THROMBOPHLEBITIS SUPERFICIAL (4.1(b)) in a 48-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. Previously administered products included for an unreported indication: Comirnaty. Concurrent medical conditions included (4.1(b)) disease. Concomitant products included PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOPRAZOLE ACTAVIS), CALCIUM CARBONATE, COLECALCIFEROL (CALCIDURAN VIT. D3), POVIDONE (COMPENSAN [POVIDONE]) and EMTRICITABINE, TENOFOVIR ALAFENAMIDE FUMARATE (DESCOVY) for an unknown indication. On 19-Mar-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 25-Mar-2021 at 7:00 AM, the patient experienced DEEP VEIN THROMBOSIS (4.1(b)) (seriousness criterion medically significant) and THROMBOPHLEBITIS SUPERFICIAL (4.1(b)) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (4.1(b)) and THROMBOPHLEBITIS SUPERFICIAL (4.1(b)) had not resolved. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered DEEP VEIN THROMBOSIS (4.1(b)) and THROMBOPHLEBITIS SUPERFICIAL (4.1(b)) to be possibly related.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was not applicable. Treatment information was not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Very limited information regarding these events has been provided at this time. No further information is expected at this time. Most recent FOLLOW-UP information incorporated above includes: On 04-Jun-2021: Translation received on 11-JUN-2021 and does not contain any new information.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 08-Jun-2021 and was forwarded to Moderna on 08-Jun-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) and MENTAL STATUS CHANGES (Mental status changes) in a 92-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. The patient's past medical history included Breast cancer. Concurrent medical conditions included Allergy to animal (Horse derived products), Hypertension, GERD, Prediabetes, Atherosclerosis of aorta and Polymyalgia rheumatica. Concomitant products included ACYCLOVIR [ACICLOVIR], OMEPRAZOLE, ALENDRONATE SODIUM (FOSAMAX), LISINOPRIL, VITAMIN D3 and ASPIRIN [ACETYLSALICYLIC ACID] for an unknown indication.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 14-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 19-Feb-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria hospitalization prolonged and life threatening) and MENTAL STATUS CHANGES (Mental status changes) (seriousness criteria hospitalization prolonged and life threatening). At the time of the report, ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) and MENTAL STATUS CHANGES (Mental status changes) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Feb-2021, Troponin: increased (High) Increased. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of DRUG INTERACTION (4.1(b)), HYPERTENSION (4.1(b)), NAUSEA (4.1(b)) and TINNITUS (4.1(b)) in a 54-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001659) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. No Medical History information was reported.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 08-Feb-2021, the patient started TOZINAMERAN (COMIRNATY) (unknown route) 4.1(b). On 10-May-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 13-May-2021, the patient experienced DRUG INTERACTION 4.1(b) (seriousness criterion disability), HYPERTENSION 4.1(b) (seriousness criterion disability), NAUSEA 4.1(b) (seriousness criterion disability) and TINNITUS 4.1(b) (seriousness criterion disability). On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). At the time of the report, DRUG INTERACTION 4.1(b), HYPERTENSION 4.1(b) and TINNITUS 4.1(b) had not resolved, NAUSEA 4.1(b) was resolving and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) had resolved. No concomitant medications are reported by the reporter. No treatment information is provided. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Lab data HIGH BLOOD PRESSURE with no test result reported. Company Comment Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. For the event "interchange vaccine product" causality is assessed as not applicable. Most recent FOLLOW-UP information incorporated above includes: On 21-Jun-2021: Translation received on 06-AUG-2021 contains No new information.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
	4.1(b) [REDACTED]	VITREOUS DETACHMENT (Vitreous detachment) in a 67-year-old female patient who received mRNA-1273 (Moderna Covid-19 Vaccine) (batch no. 3001657) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. The patient's past medical history included Asthma in 1987. Concurrent medical conditions included Allergy to nuts. Concomitant products included CALCIUM, COLECALCIFEROL, COPPER, MAGNESIUM, MANGANESE, ZINC (CALTRATE PLUS [CALCIUM;COLECALCIFEROL;COPPER;MAGNESIUM;MANGANESE;ZINC]) and KRILL OIL for an unknown indication. On 27-Apr-2021, the patient received first dose of mRNA-1273 (Moderna Covid-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Jun-2021, the patient received second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 27-Apr-2021, after starting mRNA-1273 (Moderna Covid-19 Vaccine), the patient experienced VITREOUS DETACHMENT (Vitreous detachment) (seriousness criterion medically significant). On 17-Jun-2021, the patient experienced INTENTIONAL DOSE OMISSION (Intentional dose omission). On 17-Jun-2021, INTENTIONAL DOSE OMISSION (Intentional dose omission) had resolved. At the time of the report, VITREOUS DETACHMENT (Vitreous detachment) had not resolved. No treatment information provided. It was reported that one hour after receiving the vaccine patient reports eye floaters diagnosed a vitreous detachment by the patient's ophthalmologist which is still ongoing. Patient also took the Pfizer vaccine for her second dose on 17-Jun-2021.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Although a temporal association exists, provided information is not adequate to assess the causal association between the event of vitreous detachment and mRNA-1273. The detailed medical history and diagnostic report has not been provided. Causality for the event of wrong product administered remains as not applicable. Significant FU received, based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 13-Jul-2021: follow-up received to include patient details, event and event outcome, medication history and concomitant medications are updated. On 13-Jul-2021: Non-significant follow-up On 05-Aug-2021: Follow Up information was received on 06-Aug-2021 and contains No new information.	
4.1(b)	4.1(b)	Whooping cough vaccine had between 16 and 17 weeks (approx. 9/10 weeks prior to first dose) Patient is not enrolled in clinical trial Patient does not think vaccination had an adverse effect on any aspect of the pregnancy Details of previous pregnancies: Also taking aspirin (150mg/day), iron supplements, and 10mg of omeprazole when required. Patient was exposed to the vaccine Third-trimester (29-40 weeks). Details of scans or investigations: MCDA twins	
4.1(b)	4.1(b)	This case was received via 4.1(b) 4.1(b) (Reference number: 4.1(b) on 22-Jun-2021 and was forwarded to Moderna on 22-Jun-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of HOSPITALISATION (hospitalization) in a 78-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Previously administered products included for an unreported indication: PNEUMOCOCCAL VACCINE. Concurrent medical conditions included Heart disorder. Concomitant products included APIXABAN (ELIQUIS), DILTIAZEM, TAMSULOSIN and FINASTERIDE for an unknown indication. On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 08-Mar-2021, the patient experienced HOSPITALISATION (hospitalization) (seriousness criterion hospitalization). On an unknown date, the patient experienced WRONG PRODUCT ADMINISTERED (Wrong product administered/Pfizer). At the time of the report, HOSPITALISATION (hospitalization) and WRONG PRODUCT ADMINISTERED (Wrong product administered/Pfizer) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Pfizer vaccine given in the Right arm. No treatment information was provided. This report refers to a case of wrong product administered for mRNA-1273 with associated hospitalization. Limited information regarding the hospitalization has been provided at this time and a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 22-Jun-2021 and was forwarded to Moderna on 22-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CEREBROVASCULAR ACCIDENT (Cerebrovascular accident) and SUBARACHNOID HAEMORRHAGE (Subarachnoid haemorrhage) in a 71-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On 04-Apr-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form and dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 23-Apr-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Cerebrovascular accident) (seriousness criteria hospitalization and medically significant) and SUBARACHNOID HAEMORRHAGE (Subarachnoid haemorrhage) (seriousness criteria hospitalization and medically significant). At the time of the report, CEREBROVASCULAR ACCIDENT (Cerebrovascular accident) and SUBARACHNOID HAEMORRHAGE (Subarachnoid haemorrhage) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment information was provided. Company Comment : Limited information regarding the events has been provided at this time and is insufficient for causality assessment.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of CELLULITIS (needle from the 2nd dose caused a bacterial infection (cellulitis)) in a 73-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 042D21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		COVID-19 VACCINE) for COVID-19 vaccination. No medical history information was reported. On 30-Mar-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 23-Jun-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. In June 2021, the patient experienced CELLULITIS (needle from the 2nd dose caused a bacterial infection (cellulitis)) (seriousness criterion medically significant), OROPHARYNGEAL PAIN (sore throat), SKIN WARM (the arm was hot to the touch), RASH ERYTHEMATOUS (further toward elbow there were other red patches about an inch wide & 3 inches tall), VACCINATION SITE WARMTH (the area was about the size of a peach and starting to radiate warmth) and VACCINATION SITE SWELLING (the area was about the size of a peach). On 23-Jun-2021, the patient experienced DIZZINESS (dizzy) and PAIN IN EXTREMITY (Her arm was sore & tender/achy). On 24-Jun-2021, the patient experienced CHEST DISCOMFORT (felt constriction around her chest) and VACCINATION SITE ERYTHEMA (a small red circle around the injection site). On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (1st dose was by Pfizer). The patient was treated with CLINDAMYCIN (oral) ongoing from 28-Jun-2021 for Cellulitis, at a dose of 3 UNK. At the time of the report, CELLULITIS (needle from the 2nd dose caused a bacterial infection (cellulitis)), DIZZINESS (dizzy), PAIN IN EXTREMITY (Her arm was sore & tender/achy), CHEST DISCOMFORT (felt constriction around her chest), SKIN WARM (the arm was hot to the touch), RASH ERYTHEMATOUS (further toward elbow there were other red patches about an inch wide & 3 inches tall), VACCINATION SITE WARMTH (the area was about the size of a peach and starting to radiate warmth), VACCINATION SITE ERYTHEMA (a small red circle around the injection site), VACCINATION SITE SWELLING (the area was about the size of a peach) and INTERCHANGE OF VACCINE PRODUCTS (1st dose was by Pfizer) outcome was	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		unknown and OROPHARYNGEAL PAIN (sore throat) had resolved. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use not reported. It was reported that the patient felt dizzy immediately after the Moderna shot. By Saturday, the injection site area was about the size of a peach and started to radiate warmth. By Monday morning, the patient's arm was hot to the touch, achy, and further toward elbow, there were other red patches about an inch wide & 3 inches tall. On 28-Jun-2021 the patient went to the emergency because the needle from the 2nd dose caused a bacterial infection (cellulitis). Treatment medication included: Clindamycin pills of unknown strength at the emergency. The patient was prescribed Clindamycin 300mg with instructions of taking one four times daily for 5 days. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.	
4.1(b)	4.1(b)	This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 30-Jun-2021. The most recent information was received on 19-Jul-2021 and was forwarded to Moderna on 19-Jul-2021. This spontaneous case was reported by a pharmacist and describes the occurrence of EXTRA DOSE ADMINISTERED (Received 5 Covid Vaccines in the span of a month) and MEDICATION ERROR (Medication error) in a 77-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The patient's past medical history included Stroke (Left punctate thalamic stroke) in January 2021, Coronary artery disease, Myocardial infarction, Dyslipidemia, Diabetes mellitus and Hypertension. Concurrent medical conditions included Drug allergy (Allergy to enalapril), Penicillin allergy and Food allergy (Allergy to tomatoes). On 19-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Jan-2021, the patient received dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) dosage form. On 28-Jan-2021, received dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) dosage was changed to dosage form. On 16-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Feb-2021, received dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) dosage was changed to dosage form. On an unknown date, the patient experienced EXTRA DOSE ADMINISTERED (Received 5 Covid Vaccines in the span of a month) (seriousness criterion hospitalization) and MEDICATION ERROR (Medication error) (seriousness criterion hospitalization). The patient was hospitalized from 12-May-2021 to 19-May-2021 due to EXTRA DOSE ADMINISTERED and MEDICATION ERROR. The patient was treated with Rehabilitation therapy for Extra dose administered and Rehabilitation therapy for Medication error. At the time of the report, EXTRA DOSE ADMINISTERED (Received 5 Covid Vaccines in the span of a month) had resolved and MEDICATION ERROR (Medication error) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not provided by reporter. The patient was in rehabilitation center from 19-May-2021 to 28-May-2021.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		It was reported that the patient was hospitalized on 22-Jun-2021. No treatment information was provided. This report refers to a case of extra doses administered which resulted in a total of 5 Covid vaccines being given with an interval of approximately 1- 2 weeks apart, who was hospitalized 3 months after receiving the vaccines, with adverse event of Hospitalization. Very limited information has been provided at this time. Further information has been requested. Most recent FOLLOW-UP information incorporated above includes: On 19-Jul-2021: Follow up ADR form appended. Included patient initials, gender, date of birth, demographics, allergy history, medical history, dates of vaccination, of suspect and co-suspect vaccines, contact details of vaccination facilities. On 20-Jul-2021: Follow up received included no new information.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of HALLUCINATION (Hallucinations), DELIRIUM (Delirium) and PSYCHOTIC DISORDER (Psychotic episodes) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for an unreported indication: PFIZER BIONTECH COVID-19 VACCINE (First dose). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced HALLUCINATION (Hallucinations) (seriousness criterion medically significant), DELIRIUM (Delirium) (seriousness criterion medically significant), PSYCHOTIC DISORDER (Psychotic episodes) (seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (My sister received the moderns vaccine as the second dose. First was Pfizer), PARANOIA (Paranoia) and CONFUSIONAL STATE (Confusion). At the time of the report,	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		HALLUCINATION (Hallucinations), DELIRIUM (Delirium), PSYCHOTIC DISORDER (Psychotic episodes), INTERCHANGE OF VACCINE PRODUCTS (My sister received the moderns vaccine as the second dose. First was Pfizer), PARANOIA (Paranoia) and CONFUSIONAL STATE (Confusion) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant products used were not provided by the reporter. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDIAL INFARCTION (Myokardinfarkt) in a 76-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Prediabetes (HgA1c 5.9%) and COVID-19 in December 2020. Previously administered products included for COVID-19 vaccination: Pfizer on 10-Feb-2021. Family history included Family history of cardiovascular disorder. Concurrent medical conditions included Hypertension arterial and Hypercholesterolemia. On 26-Mar-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 27-Mar-2021, the patient experienced MYOCARDIAL INFARCTION 4.1(b) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, MYOCARDIAL INFARCTION 4.1(b) had resolved with sequelae.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Apr-2021, Electrocardiogram: sinus rhythm (normal) Sinus rhythm :87/min, indifference type, ST segment elevations V2 to V5. On 06-Apr-2021, N-terminal prohormone brain natriuretic peptide: 7740 (Inconclusive) 7740 ng/L. On 06-Apr-2021, Troponin: 497 (Inconclusive) 497ng/L. On 14-Apr-2021, Magnetic resonance imaging heart: abnormal (abnormal) MRI heart at rest native, with CM. On 22-Apr-2021, Angiocardiogram: abnormal (abnormal) Coronary artery disease - Severely impaired pump function of dilated left ventricle (LVEF 26%) with cardiac apex aneurysm impaired pump function of right ventricle (RVEF 47%) -Transmural scar with microvascular obstruction (MVO) anteroseptal basal, anteroseptal and anterior mid-cavitary as well as circular of the apex, correlating to the RIVA flow area - Full viability of the remaining segments of the left ventricular myocardium - Thrombus in the cardiac apex aneurysm Small-volume hemodynamically irrelevant pericardial effusion.. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Relevant concomitant medications were not reported. Ejection fraction was measured and the report mentions a severely impaired pump function of dilated left ventricle (LVEF 26%) with cardiac apex aneurysm with impaired pump function of the right ventricle (RVEF 47%). The reporter states that the patient took the first Comirnaty vaccine on 10 Feb 2021 after the 1st COVID vaccination, patient suddenly felt ill and drenched in sweat and felt a strong pressure pain on the entire chest and also had severe shortness of breath, dizziness, and panic. Treatment medication was not provided by the reporter.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Very limited information regarding the event has been provided at this time. Further information is not expected. Most recent FOLLOW-UP information incorporated above includes: On 01-Jul-2021: Translation received on 09 Jul 2021, added patient medical history ,Lab test , Pfizer vaccine .	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of PARTIAL SEIZURES (Focal seizures), CARDIOMEGALY (Heart enlarged) and BLINDNESS UNILATERAL (legally blind in left eye) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 024M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. The patient's past medical history included Pregnancy (Pregnancy with last month of period). Concurrent medical conditions included Blood pressure high (Spike in blood pressure.) and Migraine. Concomitant products included AMLODIPINE and METOPROLOL for Blood pressure. On 18-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 18-Mar-2021, the patient received second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On an unknown date, the patient experienced PARTIAL SEIZURES (Focal seizures) (seriousness criterion medically significant), CARDIOMEGALY (Heart enlarged) (seriousness criterion medically significant), BLINDNESS UNILATERAL (legally blind in left eye) (seriousness criterion medically significant), HYPERTENSION (Hypertension/blood pressure is 200/110), GAIT DISTURBANCE (cannot walk), FEELING ABNORMAL (she felt like she was going to die), MALAISE (Sick/ am still sick), DIZZINESS (Light headed), EYE PAIN (Eye hurt), HEART RATE INCREASED (Pulse spikes to 158), HEADACHE	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		(Headache), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products/was given one moderna then the pfizer shot) and FATIGUE (Fatigue). At the time of the report, PARTIAL SEIZURES (Focal seizures), BLINDNESS UNILATERAL (legally blind in left eye), HYPERTENSION (Hypertension/blood pressure is 200/110), GAIT DISTURBANCE (cannot walk), FEELING ABNORMAL (she felt like she was going to die), DIZZINESS (Light headed), EYE PAIN (Eye hurt), HEART RATE INCREASED (Pulse spikes to 158), HEADACHE (Headache) and FATIGUE (Fatigue) outcome was unknown, CARDIOMEGALY (Heart enlarged) and MALAISE (Sick/ am still sick) had not resolved and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products/was given one moderna then the pfizer shot) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: high (High) High-hypertension and 200/110 (High) 200/110. On an unknown date, Heart rate: 158 (High) pulse spikes to 158 [High pulse rate]. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Lab data include CBC, CBC with differential , CMP and Troponin I . Treatment history was not reported . Company Comment: This case concerns a 73 year old female with history of high blood pressure who experienced serious unexpected events of partial seizures, cardiomegaly, and unilateral blindness on unknown date. Patient received second dose of 18Mar2021. Medical history of HTN is a confounder. Rechallenge is not applicable. The benefit-risk relationship is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 23-Jul-2021: Follow up received contains No new information	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 27-Sep-2021: Followup information received wherein lab data and events were added.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MUSCULOSKELETAL PAIN (Arthromyalgia), VACCINATION ERROR (Vaccination error), BRONCHOSPASM (Bronchospasm), PARAESTHESIA (Paraesthesia), MUSCULAR WEAKNESS (Weakness of limbs), PYREXIA (Fever) and DYSPNOEA (Dyspnea) in a 19-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3002183 and 3002623) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) injection, powder, for suspension for COVID-19 vaccination. No Medical History information was reported. On 15-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 04-Jun-2021, the patient started TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 01-Jul-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 01-Jul-2021, the patient experienced MUSCULOSKELETAL PAIN (Arthromyalgia) (seriousness criteria hospitalization and life threatening), VACCINATION ERROR (Vaccination error) (seriousness criteria hospitalization and life threatening), BRONCHOSPASM (Bronchospasm) (seriousness criteria hospitalization and life threatening), PARAESTHESIA (Paraesthesia) (seriousness criteria hospitalization and life threatening), MUSCULAR WEAKNESS (Weakness of limbs) (seriousness criteria hospitalization and life threatening), PYREXIA (Fever) (seriousness criteria hospitalization and life threatening) and DYSPNOEA (Dyspnea) (seriousness criteria hospitalization and life threatening). On 01-Jul-2021, VACCINATION ERROR (Vaccination error) had resolved. At the time of the report, MUSCULOSKELETAL PAIN (Arthromyalgia), BRONCHOSPASM (Bronchospasm), PARAESTHESIA (Paraesthesia), MUSCULAR WEAKNESS	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		(Weakness of limbs), PYREXIA (Fever) and DYSпноEA (Dyspnea) outcome was unknown. mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) was withdrawn on 01-Jul-2021. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Relevant concomitant medications were not reported. Treatment information was not provided. This report refers to a case of vaccination error (another vaccine administered between the 2 doses of vaccine) with no associated AEs at that that time. Based on the current available information and temporal association between the use of the product (2nd dose of vaccine) and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 13-Jul-2021: Follow up received on 20-Jul-2021, no new information was recorded On 14-Jul-2021: Additional information received on 14-Jul-2021: Does not contain any new information	
4.1(b)	4.1(b)	This case was received via 4.1(b) 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FLUTTER (Cardiac flutter) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. EN6207) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Concurrent medical conditions included Drug allergy (Sulfa) and Allergy to antibiotic (most antibiotics). Concomitant products included LORATADINE, PSEUDOEPHEDRINE SULFATE (CLARITIN-D) and FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]) for an unknown indication. On 12-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 13-Mar-2021, the patient experienced CARDIAC FLUTTER (Cardiac flutter) (seriousness criterion medically significant), PALPITATIONS (Palpitations), INFLUENZA LIKE ILLNESS (Influenza like illness), PYREXIA (Pyrexia) and FATIGUE (Fatigue). At the time of the report, CARDIAC FLUTTER (Cardiac flutter), PALPITATIONS (Palpitations), INFLUENZA LIKE ILLNESS (Influenza like illness), PYREXIA (Pyrexia) and FATIGUE (Fatigue) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Lab tests included Cardiac monitoring, Electrocardiogram, Holter Test. Results were not provided. No treatment medication details was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This case was received via another Manufacturer (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. The license partner had received the report from United States FDA VAERS (Reference number: 4.1(b) This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) and COVID-19 (COVID-19) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for an unknown indication. The patient's past medical history included Quadruple vessel bypass graft (Quadruple heart bypass) in 2004. Concurrent medical conditions included Chronic lymphocytic leukemia (had blood infusions last summer, last one was on July07), Heart disorder (Chronic), Chronic kidney disease and Blood pressure high (High blood pressure). On 04-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form and second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 08-May-2021, the patient experienced COVID-19 (COVID-19) (seriousness criteria death and hospitalization). The patient died on 08-May-2021. The reported cause of death was covid-19 illness. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Apr-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route), the reporter did not provide any causality assessments. No concomitant medication was provided. No treatment medication was provided.	
4.1(b)	4.1(b)	Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a physician and describes the occurrence of BLOOD DISORDER (Blood disorder) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form and dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On an unknown date, the patient experienced BLOOD DISORDER (Blood disorder) (seriousness criterion life threatening). At the time of the report, BLOOD DISORDER (Blood disorder) outcome was unknown. Unknown The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product was not provided by the reporter. Treatment information was not provided. Very limited info provided and further FU is required to clarify the SAE.	
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 14-Jul-2021. The most recent information was received on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of TREMOR (Shaking), HYPERHIDROSIS (Sweating) and FATIGUE (Fatigue) in a 43-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 3002621 and 3001659) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. The patient's past medical history included Immunodeficiency (Has an illness or condition, not listed above, which reduces the immune response (e.g. immunodef...) since an unknown date. Concurrent medical conditions included Coeliac disease in October 2021.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Concomitant products included DESOGESTREL (CERELLE) from 01-Jun-2018 to an unknown date for Contraception, INFLUENZA VACCINE (INFLUENZA VIRUS) from 01-Oct-2020 to an unknown date for an unknown indication. On 27-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 29-Jun-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 09-Dec-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) Dose 3b. On 29-Jun-2021, the patient experienced TREMOR (Shaking) (seriousness criterion medically significant), HYPERHIDROSIS (Sweating) (seriousness criterion medically significant) and FATIGUE (Fatigue) (seriousness criterion medically significant). On 30-Jun-2021, TREMOR (Shaking), HYPERHIDROSIS (Sweating) and FATIGUE (Fatigue) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Apr-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Patient was recently diagnosed with Coeliac on Oct-2021 Patient was not enrolled in clinical trial and the Indication for FLU VACCINE was Extra protection for working in a school. Company Comment This is a regulatory case concerning a 43-year-old female patient with medical history of Immunodeficiency and Coeliac disease, who experienced the serious unexpected, according CCDS, events of tremor, hyperhidrosis and fatigue. The events occurred the same day after the second dose of mRNA-1273 vaccine and recovered. The rechallenge is unknown according to SD. The patient received third dose of COMIRNATY.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		There is no information about AEs after third dose. The medical history of Immunodeficiency and Coeliac disease remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 27-Dec-2021: Significant follow-up received on 27-DEC-2021. Non-company suspect 'COMIRNATY' was added.	
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 15-Jul-2021. The most recent information was received on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of LIMB DISCOMFORT (Heaviness in arm) and CHILLS (Shivers) in a 19-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 3004668 and 3003608) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. No Medical History information was reported. On 07-Jul-2021, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 19-Sep-2021, received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 27-Dec-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 07-Jul-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced LIMB DISCOMFORT (Heaviness in arm) (seriousness criterion medically significant). On 19-Sep-2021, the patient experienced CHILLS (Shivers) (seriousness criterion medically significant). On 08-Jul-2021, LIMB DISCOMFORT (Heaviness in arm) had resolved. At the time of the report, CHILLS (Shivers) was resolving.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Concomitant medications were not provided by the reporter. Treatment information was not provided. Patient had not tested positive for COVID-19 since having the vaccine and Patient was not enrolled in clinical trial. Patient did not had symptoms associated with COVID-19. Most recent FOLLOW-UP information incorporated above includes: On 06-Oct-2021: Follow up received contains no new information On 07-Jan-2022: Followup contains significant information , Co-suspect product added.	
4.1(b)	4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of MENSTRUATION DELAYED (Delayed period) in a 32-year-old patient of an unknown gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. The patient's past medical history included Suspected COVID-19 from 13-Jan-2021 to 07-Feb-2021. Previously administered products included for Product used for unknown indication: SAYANA PRESS. In April 2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 13-May-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		In May 2021, the patient received dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) at an unspecified dose. On 01-Jun-2021, the patient experienced MENSTRUATION DELAYED (Delayed period) (seriousness criterion medically significant). At the time of the report, MENSTRUATION DELAYED (Delayed period) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. The patient had spotting but it's been two months now and informed to her doctor. The patient took the first dose in April and her period were fine and regular then. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Very limited information regarding this events has been provided at this time. No further information is expected at this time. A co-suspect drug TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) is relevant in this case.	
4.1(b)	4.1(b)	This spontaneous case was reported by a pharmacist and describes the occurrence of PERICARDITIS (Developed Pericarditis after Moderna dose) in a 38-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 052C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. Concurrent medical conditions included DVT (after first dose of Pfizer vaccine) in 2021. Concomitant products included IRON for an unknown indication.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 17-May-2021, the patient received dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 12-Jul-2021, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (Developed Pericarditis after Moderna dose) (seriousness criterion medically significant), WRONG PRODUCT ADMINISTERED (Pfizer as first dose and Moderna as second dose) and INTERCHANGE OF VACCINE PRODUCTS (Pfizer as first dose and Moderna as second dose). At the time of the report, PERICARDITIS (Developed Pericarditis after Moderna dose), WRONG PRODUCT ADMINISTERED (Pfizer as first dose and Moderna as second dose) and INTERCHANGE OF VACCINE PRODUCTS (Pfizer as first dose and Moderna as second dose) outcome was unknown. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient was treated in the emergency room for DVT. Treatment was not specified. On 12-Jul-2021 the patient received Moderna vaccine as her second dose. On an unreported date after receiving the Moderna vaccine, unspecified tests confirmed the patient had pericarditis. Treatment information, if any, was not provided by the reporter. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Causality for the event interchange of vaccine products was assessed as not applicable.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of HAEMORRHAGE (incessant bleeding) in a 39-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The occurrence of	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form and first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On an unknown date, the patient experienced HAEMORRHAGE (incessant bleeding) (seriousness criterion medically significant) and OFF LABEL USE (1st dose Pfizer Covid-19vaccine; 2nd dose Moderna Covid-19 vaccine). At the time of the report, HAEMORRHAGE (incessant bleeding) and OFF LABEL USE (1st dose Pfizer Covid-19vaccine; 2nd dose Moderna Covid-19 vaccine) outcome was unknown. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Concomitant information was not provided. Treatment information was not provided. It was reported that patient was on 17th day since getting Moderna Covid-19 vaccine. Patient had Pfizer Covid-19 vaccine as her 1st dose. Very limited information regarding the events have been provided at this time. Intermixing of different types of covid 19 have yet to be studied. Patient's use of different types of mRNA vaccines may be a confounding factor to the event hemorrhage. Most recent FOLLOW-UP information incorporated above includes: On 30-Jul-2021: follow up received and contain no new information.	
4.1(b)	4.1(b)	Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		(fainted three minutes after the first shot) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 100 mcg and dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 60 mcg. On an unknown date, the patient experienced SYNCOPE (fainted three minutes after the first shot) (seriousness criterion medically significant) and ILLNESS 4.1(b) got really sick after the second shot of the Moderna Vaccine). At the time of the report, SYNCOPE (fainted three minutes after the first shot) and ILLNESS 4.1(b) got really sick after the second shot of the Moderna Vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In July 2021, Blood test: normal (normal) IgG antibodies were present. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant medications were not provided. Treatment information was not provided. Patient stated that she never got sick as she never took second shot. She stated Moderna dose was too high and she should had to robust protection with moderna vaccine as she read it was 80% effective. Patient was asking advise. This case concerns an adult patient of unknown age and gender with a serious unexpected event of syncope, and nonserious	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		illness. Syncope latency 3 minutes after first dose mRNA-1273. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 24-Jul-2021: Follow-up information received contains, New event and Co-suspect drug added. Lab details added conservatively as per the SD. On 03-Aug-2021: FU received - NNI FU	
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of POLYMENORRHOEA (Menstrual cycle shortened) in a 22-year-old female patient who received mRNA-1273 (Moderna Covid-19 Vaccine) (batch no. 044D21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for COVID-19 vaccination. The patient's past medical history included Lactation decreased. Concurrent medical conditions included Pain menstrual. Concomitant products included IBUPROFEN (ADVIL [IBUPROFEN]) from 03-Jun-2021 to 03-Jun-2021 for Pain menstrual. On 06-Jun-2021, the patient started TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) (unknown route) 1 dosage form. On 14-Jul-2021, received second dose of mRNA-1273 (Moderna Covid-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna Covid-19 Vaccine) (unknown route) 1 dosage form. On 28-Jun-2021, the patient experienced POLYMENORRHOEA (Menstrual cycle shortened) (seriousness criterion medically significant). On an unknown date, the patient experienced WRONG PRODUCT ADMINISTERED (wrong product administered). At the time of the report, POLYMENORRHOEA (Menstrual cycle shortened) was resolving and WRONG	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		PRODUCT ADMINISTERED (wrong product administered) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Jan-2021, SARS-CoV-2 test: Negative. Patient's menstrual cycle was very regular 31-33 days. After her first dose (Pfizer) it was only 28 days, and after her second dose (Moderna), she felt that her period was just about to start, and this cycle would only be about 25 days. She had not have a cycle this short in years, and with periods lasting about 8-10 days, this was a lot. Treatment information was not provided. Company Comment This report refers to a case of wrong product administered with first dose with Pfizer vaccine and with an associated AE of polymenorrhoea. Very limited information regarding these events have been provided at this time. No further information is expected.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC FLUTTER (Heart fluttering) in a 21-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3001659) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product COVID-19 VACCINE MRNA (BNT162B2) for COVID-19 vaccination. The patient's past medical history included Lactation decreased, Acne and Steroid therapy (Taking regular steroid treatment (e.g. orally or rectally)). Concomitant products included LYMECYCLINE for Acne. On 13-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Jul-2021, the patient started COVID-19 VACCINE MRNA (BNT162B2) (Intramuscular) 1 dosage form. On 17-Jul-2021, the patient experienced CARDIAC FLUTTER (Heart	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		fluttering) (seriousness criterion medically significant) and PALPITATIONS (Heart pounding). 17-Jul-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products). On an unknown date, the patient experienced CHEST PAIN (pain in chest), PAIN (pain), CHILLS (shivers) and FATIGUE (fatigue). On 17-Jul-2021, CARDIAC FLUTTER (Heart fluttering) and PALPITATIONS (Heart pounding) had resolved. At the time of the report, CHEST PAIN (pain in chest) had resolved, PAIN (pain), CHILLS (shivers) and FATIGUE (fatigue) had not resolved and INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products) outcome was unknown. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) was unknown. Patient was taking one tablet a day called Lymecycline for acne treatment. She had stopped taking it just before she had received the Pfizer vaccine. Patient received the Pfizer vaccine (2nd dose). In the evening she experienced the expected shivers, fatigue, and achiness. Then, she went to sleep and woke up in the middle of the night with pains in chest. It felt like a tiny knife was stabbing the heart and she couldn't move. Every time she tried to move the stabbing pain either persisted or became worse. This lasted for about 10 minutes and then started to subside. The patient is reporting this because she never experienced heart pains and she not experiencing high-stress levels. No treatment information was provided. This is a case of Revaccination with different COVID-19 vaccine with adverse events. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
	4.1(b) [REDACTED]	DEAFNESS (Hearing loss) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. Concurrent medical conditions included Hearing loss. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEAFNESS (Hearing loss) (seriousness criterion medically significant), TINNITUS (bilateral tinnitus rushed into my head), DIZZINESS (Dizziness), VERTIGO (Vertigo-like dizziness) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). At the time of the report, DEAFNESS (Hearing loss) outcome was unknown, TINNITUS (bilateral tinnitus rushed into my head), DIZZINESS (Dizziness) and VERTIGO (Vertigo-like dizziness) had not resolved and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) had resolved. Concomitant medications were not reported. Treatment medications were not reported. Patient initially administered with Pfizer BIONTECH COVID-19 vaccine and started experiencing Tinnitus. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		causal relationship cannot be excluded. However, more information is required for further assessment.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Knocked her out) in a 53-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. The patient's past medical history included Stress in 2020. Concurrent medical conditions included Walking difficulty (Used walker and wheelchair.) and Memory disturbance (Patient had memory problem but not have MS.). Concomitant products included FAMPRIDINE (FAMPYRA) for Walking difficulty, OCRELIZUMAB (OCREVUS) and CANDESARTAN for an unknown indication. On 04-May-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 30-Jun-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Jun-2021, the patient experienced FATIGUE (Tired). On 01-Jul-2021, the patient experienced MOBILITY DECREASED (Was immobile/could not lift her feet). On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Knocked her out) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Had 1st dose of pfizer and 2 nd dose moderna). At the time of the report, LOSS OF CONSCIOUSNESS (Knocked her out), MOBILITY DECREASED (Was immobile/could not lift her feet), INTERCHANGE OF VACCINE PRODUCTS (Had 1st dose of pfizer and 2 nd dose moderna) and FATIGUE (Tired) outcome was unknown.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No treatment medications were reported. It was reported that, the patient had sore arm after the first dose and the second dose knocked her out. The patient was immobile and had to use walker to move around upstairs to go to walls upstairs. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, underlying medical history of walking difficulty (use of walker and wheelchair) and use concomitant medication are a confounder.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (Blacked out) in a 23-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 092D21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. The patient's past medical history included Pain in arm. On 01-Jun-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 14-Jul-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Blacked out) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (Flu-like symptoms), INTERCHANGE OF VACCINE PRODUCTS (first dose of Pfizer on 1Jun2021; received second dose as Moderna on 14Jul2021) and PAIN IN EXTREMITY (Sore arm). At the time of the report, LOSS OF CONSCIOUSNESS (Blacked out),	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		INFLUENZA LIKE ILLNESS (Flu-like symptoms), INTERCHANGE OF VACCINE PRODUCTS (first dose of Pfizer on 1Jun2021; received second dose as Moderna on 14Jul2021) and PAIN IN EXTREMITY (Sore arm) outcome was unknown. No concomitant medication was provided. No treatment medication was provided.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of DEPRESSED LEVEL OF CONSCIOUSNESS 4.1(b) in a 58-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3003605) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. The patient's past medical history included Hypothyroidism. Concurrent medical conditions included Nickel sensitivity, Drug allergy, Latex allergy, Myopia and Presbyopia. On 09-Jul-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) .5 milliliter in total. On an unknown date, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 09-Jul-2021, the patient experienced DEPRESSED LEVEL OF CONSCIOUSNESS 4.1(b) (seriousness criterion medically significant), PRESBYOPIA 4.1(b) , the first episode of LACRIMATION INCREASED 4.1(b)	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		4.1(b) the second episode of LACRIMATION INCREASED (4.1(b)) DIARRHOEA (4.1(b)) , FATIGUE (4.1(b)) and INJECTION SITE SWELLING (4.1(b)) . At the time of the report, DEPRESSED LEVEL OF CONSCIOUSNESS (4.1(b)) , PRESBYOPIA (4.1(b))), the last episode of LACRIMATION INCREASED (4.1(b)) DIARRHOEA (4.1(b)) , FATIGUE (4.1(b)) and INJECTION SITE SWELLING (4.1(b))) was resolving.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		No relevant concomitant medications were reported. Patient reported she experienced deterioration in presbyopia on the same day of the vaccination after receiving 2nd dose of comirnaty. She was scheduled eye examination. No treatment information was provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Concomitant medical conditions (myopia and presbyopia) could be potentially confounders for the events. Comirnaty could be potentially Co-suspect for the events. Most recent FOLLOW-UP information incorporated above includes: On 29-Jul-2021: Follow-up received on 05-Aug -2021: Historical condition updated. Co-suspect (Comirnaty) added.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of HYPOXIA (blood oxygen dropped to 50% and oxygen levels are now at 70%), DYSPNOEA (difficulty breathing/could not breathe right), PULMONARY OEDEMA (fluid in their lungs), PERICARDIAL EFFUSION (fluid around their heart), HEART DISEASE CONGENITAL (Congenital heart failure) and CARDIAC FAILURE (Congenital heart failure) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 001A21A and 025L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. Concomitant products included ATORVASTATIN, ACETYLSALICYLIC ACID (ASPIRIN 81), APIXABAN, AMLODIPINE BESYLATE, CARVEDILOL, LOSARTAN, FUROSEMIDE, POTASSIUM CHLORIDE and MAGNESIUM OXIDE for an unknown indication.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 01-Feb-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 22-Feb-2021, received second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) dosage was changed to 1 dosage form. On 25-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In 2021, the patient experienced HYPOXIA (blood oxygen dropped to 50% and oxygen levels are now at 70%) (seriousness criteria hospitalization and medically significant) and DYSPNOEA (difficulty breathing/could not breathe right) (seriousness criterion hospitalization). On an unknown date, the patient experienced PULMONARY OEDEMA (fluid in their lungs) (seriousness criterion medically significant), PERICARDIAL EFFUSION (fluid around their heart) (seriousness criterion medically significant), HEART DISEASE CONGENITAL (Congenital heart failure) (seriousness criterion medically significant), CARDIAC FAILURE (Congenital heart failure) (seriousness criterion medically significant), FEAR (feared/scared), COVID-19 IMMUNISATION (got both doses of the Moderna vaccine on the left arm and also both doses of the Pfizer vaccine on the opposite arm) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Moderna first dose was administered on 7 or 17 Jan2021, lot#025L20A (expiry date 25Jun2021), and the second on 25Feb2021). The patient was hospitalized for 5 days due to DYSPNOEA and HYPOXIA. At the time of the report, HYPOXIA (blood oxygen dropped to 50% and oxygen levels are now at 70%) and DYSPNOEA (difficulty breathing/could not breathe right) had not resolved, PULMONARY OEDEMA (fluid in their lungs), PERICARDIAL EFFUSION (fluid around their heart), HEART DISEASE CONGENITAL (Congenital heart failure), CARDIAC FAILURE (Congenital heart failure), FEAR (feared/scared) and COVID-19 IMMUNISATION (got both doses of the Moderna vaccine on the left arm and also both doses of the Pfizer vaccine on the	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		opposite arm) outcome was unknown and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Moderna first dose was administered on 7 or 17 Jan2021, lot#025L20A (expiry date 25Jun2021), and the second on 25Feb2021) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Oxygen saturation: 50% (Low) blood oxygen dropped to 50%. and 70% (Low) oxygen levels are now at 70%. HCP told the patient they have too much antibodies on their system. Patient had labs done last Monday and was still waiting on the results. Patient was on oxygen. HCP was treating the Patient for Congenital heart failure. Company Comment: This is a case of inappropriate schedule of vaccine administered and covid 19 immunisation (revaccination with different covid 19 vaccine) with associated adverse events of hypoxia, dyspnoea, pulmonary oedema, pericardial effusion, heart disease congenital and cardiac failure. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information is expected. Most recent FOLLOW-UP information incorporated above includes: On 01-Oct-2021: Follow up received on 01-Oct-2021 contains no new information.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 03-Aug-2021 and was forwarded to Moderna on 03-Aug-2021. Based on the current case data, this case has been classified as invalid. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (COVID-19) and DRUG INEFFECTIVE (Drug ineffective) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 immunisation. The patient's past medical history included No adverse event. In 2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. In 2021, received second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Jul-2021, the patient experienced COVID-19 (COVID-19) (seriousness criterion medically significant), DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion medically significant), UPPER RESPIRATORY TRACT INFECTION (Upper respiratory tract infection) and PYREXIA (Pyrexia). At the time of the report, COVID-19 (COVID-19), DRUG INEFFECTIVE (Drug ineffective), UPPER RESPIRATORY TRACT INFECTION (Upper respiratory tract infection) and PYREXIA (Pyrexia) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Jul-2021, SARS-CoV-2 test: positive (Positive) Positive. On an unknown date, Body temperature: 4.1(b) (High) Reported as fever 4.1(b). The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. The patient medical history and concomitant medications were not reported. The reporter stated that three patients, all since 01Jul2021, with PCR-confirmed COVID-19. Isolates sent for genotypic profiling-	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		probably get results next winter. 2 with relatively mild URI symptoms but fever 4.1(b) (+). All received mRNA vaccine (Pfizer x 2, Moderna x 1) between Feb2021 and Apr2021. None with classic immunocompromising conditions but 1 was a robust 76. The events vaccination failure and COVID-19 were assessed as serious (medically significant). Therapeutic measures were taken as a result of events include TLC (tender loving care) with every other day follow-up. The outcome of the events was unknown. Information about batch/lot number has been requested. Company Comment: This case concerns a patient with no known identifiers with adverse events of COVID-19, Upper Respiratory Tract Infection, Drug Ineffective, and Pyrexia with unknown days of Latency after mRNA-1273 vaccination and with co-suspect PFIZER-BIONTECH COVID-19 mRNA VACCINE injection for COVID-19 immunization. There is very limited information available as temporal association cannot be established (missing dates of administration of both Moderna COVID Vaccine and PFIZER-BIONTECH COVID-19 mRNA VACCINE). This is also a case with an associated adverse event of COVID-19. Based on the mechanism of action of mRNA-1273 the event COVID-19 is unlikely related to the vaccine. Seriousness criteria for the events of COVID-19 and Drug Ineffective as Medically Significant was captured by regulatory authority, however based on medical judgement the case is non serious. No further information is expected at this time.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (I can feel a superficial blood clot at the bottom of my leg and I am still on Xarelto) in a 51-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 045D21A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 immunisation.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Concurrent medical conditions included Coagulation disorder, Celiac disease, Hypothyroidism and Deep vein thrombosis since 20-Jun-2021. Concomitant products included RIVAROXABAN (XARELTO) for DVT, LEVOTHYROXINE SODIUM (SYNTHROID), CETIRIZINE HYDROCHLORIDE (REACTINE [CETIRIZINE HYDROCHLORIDE]), CITALOPRAM, BUPROPION and POTASSIUM for an unknown indication. On 19-May-2021, the patient started TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) at an unspecified dose. On 02-Jul-2021, the patient received second dose of mRNA-1273 (Moderna Covid-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (I can feel a superficial blood clot at the bottom of my leg and I am still on Xarelto) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (dose 1 pfizer dose 2 moderna). At the time of the report, THROMBOSIS (I can feel a superficial blood clot at the bottom of my leg and I am still on Xarelto) and INTERCHANGE OF VACCINE PRODUCTS (dose 1 pfizer dose 2 moderna) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Jun-2021, SARS-CoV-2 test: negative (Negative) The patient's COVID-19 test through nasal swab was negative. After 30 days receiving Pfizer vaccine on 19 May 2021, the patient got a deep vein thrombosis and superficial blood clot. The patient went to hospital. Prior to vaccination, the patient was not diagnosed with the COVID-19 and since vaccination the patient had been tested for COVID-19. Company comment: This report refers to a case of Interchange of vaccine products for mRNA-1273, lot # 045D21A with associated event of thrombosis. Based on the current	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Patient history of coagulopathy and recent event of deep vein thrombosis may be confounding. Further information is expected.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 10-Aug-2021 and was forwarded to Moderna on 10-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ARRHYTHMIA (Arrhythmia) and PYREXIA (Pyrexia) in a 15-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 078C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On 23-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 23-Jul-2021, the patient experienced ARRHYTHMIA (Arrhythmia) (seriousness criteria hospitalization and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). On an unknown date, the patient experienced PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (Inappropriate age at vaccine administration). On 23-Jul-2021, INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) had resolved. At the time of the report, ARRHYTHMIA (Arrhythmia) and PYREXIA (Pyrexia) outcome was unknown and PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (Inappropriate age at vaccine administration) had resolved.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Jul-2021, Heart rate: increased High. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant products were not provided. Treatment medication were not reported. 4 hours after moderna vaccination patient was hospitalized with fever, rapid heart rate and arrhythmia. Company Comment: This report refers to a case of product administered to patient of inappropriate age (15-year-old) for mRNA-1273 (lot number 078C21A) with associated AEs reported arrhythmia, pyrexia, interchange of vaccine products and product administered to patient of inappropriate age. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of IMMOBILE (Was immobile next morning) in a female patient of an unknown age who received mRNA-1273 (Moderna Covid-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. Concomitant products included FAMPRIDINE (FAMPYRA), CANDESARTAN and OCRELIZUMAB (OCREVUS) for an unknown indication. On 04-May-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 30-Jun-2021, the patient received second dose of mRNA-1273 (Moderna Covid-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced IMMOBILE (Was immobile next morning)	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		(seriousness criterion medically significant), GAIT DISTURBANCE (Couldnot lift her feet and had to use walker to move upstairs), WALKING AID USER (Use walker to move upstairs/drag with the walls to move upstairs), FATIGUE (Tired), INTERCHANGE OF VACCINE PRODUCTS (First dose of Pfizer/Second dose moderna) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (First dose Pfizer May4th /Second dose Moderna June30th). At the time of the report, IMMOBILE (Was immobile next morning), GAIT DISTURBANCE (Couldnot lift her feet and had to use walker to move upstairs), WALKING AID USER (Use walker to move upstairs/drag with the walls to move upstairs) and FATIGUE (Tired) outcome was unknown and INTERCHANGE OF VACCINE PRODUCTS (First dose of Pfizer/Second dose moderna) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (First dose Pfizer May4th /Second dose Moderna June30th) had resolved. Treatment information was not provided. Company Comment:Very limited information regarding these events has been provided at this time. Further information has been requested. The PFIZER BIONTECH COVID-19 VACCINE is a co-suspect product in this case	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 12-Aug-2021. The most recent information was received on 24-Sep-2021 and was forwarded to Moderna on 24-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM 4.1(b) and PULMONARY INFARCTION 4.1(b) in a 57-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004952) for Vaccination. The occurrence of additional non-serious events is detailed below.	No further information regarding the event is available at the time of report.

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination. The patient's past medical history included Pulmonary embolism (Prior pulmonary embolism after leg fracture, date unknown.) and Physical examination (Suspected DVT, but normal D-dimer (1,1) and no DVT found at the time.) on 18-Jun-2021. Concurrent medical conditions included Prothrombin mutation G20210A (Heterozygous mutation). On 29-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient received dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 29-Jul-2021, the patient experienced MALAISE (4.1(b)) , CHILLS (4.1(b)) , PYREXIA (4.1(b)) and COVID-19 IMMUNISATION (4.1(b)). On 01-Aug-2021, the patient experienced PULMONARY EMBOLISM (4.1(b)) (seriousness criteria hospitalization and medically significant) and PULMONARY INFARCTION (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, PULMONARY EMBOLISM (4.1(b)) , PULMONARY INFARCTION (4.1(b)) , MALAISE (4.1(b)) , CHILLS (4.1(b)) , PYREXIA (4.1(b)) and COVID-19 IMMUNISATION (4.1(b)) was resolving.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Aug-2021, Blood gases: abnormal (abnormal) pH 7.45, pCO2 5.0, pO2 10.7, Lactate 0.7. On 03-Aug-2021, C-reactive protein: 98 mg/l (High) 98 mg/L. On 03-Aug-2021, Computerised tomogram: abnormal (abnormal) Bilateral pulmonary embolisms and pulmonary infarction of superior left lobe. On 03-Aug-2021, Fibrin D dimer: 2.7 (normal) 2.7 mg/L (milligram per litre). On 03-Aug-2021, Troponin: 19 ng/l (High) High. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PULMONARY INFARCTION 4.1(b) MALAISE 4.1(b) , CHILLS 4.1(b) and PYREXIA 4.1(b) to be possibly related and COVID-19 IMMUNISATION 4.1(b)) to be not related. No further causality assessment was provided for PULMONARY EMBOLISM 4.1(b). The concomitant medications were not reported. The treatment information was not provided. Company Comment: This case concerns a 57-year-old, male patient with previous relevant medical history of prothrombin mutation and pulmonary embolism, who experienced the unexpected events of pulmonary embolism, pulmonary infarction, malaise, pyrexia, and chills. Revaccination with different COVID-19 vaccine is also reported. Pulmonary embolism and pulmonary infarction occurred 3 days after the dose of Spikevax. The rechallenge was not applicable as no additional dose is expected to be given. The medical history of prothrombin mutation and pulmonary embolism remains a confounder for pulmonary embolism and	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		pulmonary infarction. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 24-Sep-2021: Significant follow up received on 24-SEP-21, updating new lab data and event. On 24-Sep-2021: Additional translation information received on 30-Sep-2021, does not contain any new information (NNI).	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 13-Aug-2021 and was forwarded to Moderna on 13-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of PAIN IN EXTREMITY (MAJOR PAIN IN LEGS) in a 29-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included Drug use for unknown indication with Comirnaty. Concomitant products included ETHINYLESTRADIOL, LEVONORGESTREL (MICROGYNON [ETHINYLESTRADIOL;LEVONORGESTREL]) for Contraception, MULTIVITAMINS [VITAMINS NOS] for an unknown indication. On 30-Jul-2021 at 8:00 AM, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient started TOZINAMERAN (COMIRNATY) (unknown route) at an unspecified dose. On 30-Jul-2021, the patient experienced PAIN IN EXTREMITY (MAJOR PAIN IN LEGS) (seriousness criterion hospitalization). On an unknown date, the patient experienced FEELING COLD (FEELING COLD), RETCHING (RETCHING), INFLUENZA LIKE ILLNESS (FLU LIKE SYMPTOMS), BACK	Contact with healthcare professionals: Physician. Patient reports about no diseases and healthy lifestyle. Patient reports about problems with keeping legs still, due to MAJOR PAIN IN LEGS. Patient reports about visiting a physician, due to the condition, and was then referred to hospital.

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		PAIN (BACK PAIN), DYSSTASIA (DIFFICULTY IN STANDING), COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE), NECK PAIN (NECK PAIN), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine product), HEADACHE (HEAD PAIN) and NAUSEA (NAUSEA). At the time of the report, PAIN IN EXTREMITY (MAJOR PAIN IN LEGS) was resolving and FEELING COLD (FEELING COLD), RETCHING (RETCHING), INFLUENZA LIKE ILLNESS (FLU LIKE SYMPTOMS), BACK PAIN (BACK PAIN), DYSSTASIA (DIFFICULTY IN STANDING), COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE), NECK PAIN (NECK PAIN), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine product), HEADACHE (HEAD PAIN) and NAUSEA (NAUSEA) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. Treatment details not provided. Company Comment: For the event Pain in extremity, based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Very limited information regarding the remaining events onset dates has been provided at this time and insufficient to assess the temporal association. A causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 26-Aug-2021 and was forwarded to Moderna on 26-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of PALPITATIONS (PALPITATIONS), DIZZINESS (DIZZINESS), PAIN (RADIATING PAIN), CHEST PAIN (THORAX PAIN) and PERICARDITIS (PERICARDITIS) in a 51-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004670) for Vaccination. The occurrence of additional non-serious events is detailed below.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The patient's past medical history included Hospitalization (According to the reporter, the patient had similar ailments during hospitalization in 2018.) in 2018. Previously administered products included for Vaccination: Comirnaty (5'capped mRNA encoding full length SARS-CoV-2 spike protein). Past adverse reactions to the above products included No adverse event with Comirnaty. On 23-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Jul-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). On 05-Aug-2021, the patient experienced PALPITATIONS (PALPITATIONS) (seriousness criterion hospitalization), DIZZINESS (DIZZINESS) (seriousness criterion hospitalization), PAIN (RADIATING PAIN) (seriousness criterion hospitalization), CHEST PAIN (THORAX PAIN) (seriousness criterion hospitalization) and PERICARDITIS (PERICARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, PALPITATIONS (PALPITATIONS), DIZZINESS (DIZZINESS), PAIN (RADIATING PAIN), CHEST PAIN (THORAX PAIN) and PERICARDITIS (PERICARDITIS) outcome was unknown and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Aug-2021, C-reactive protein: negative (Negative) Negative. On 12-Aug-2021, Echocardiogram: abnormal (abnormal) Non-significant amount of pericardial fluid outside the right ventricle.. On 12-Aug-2021, Electrocardiogram: abnormal (abnormal) Light, concave ST elevations in II, III aVF and V4-V6. ECG unchanged from 2018, but the reporter suspects that it may have been pericarditis also then.. On 12-Aug-2021, Fibrin D dimer: negative (Negative) Negative. On 12-Aug-2021, Troponin T: negative (Negative) Negative.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not reported. Treatment information was not reported. Company comment: Very limited information regarding this events has been provided at this time. Based on the temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 26-Aug-2021: Translated document received on 31-AUG-2021 has no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEMIANAESTHESIA 4.1(b) in a 52-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003602) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. No Medical History information was reported. On 26-May-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 23-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Jun-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product). On 24-Jun-2021, the patient experienced HEMIANAESTHESIA 4.1(b) (seriousness	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		criterion medically significant). On 23-Jun-2021, INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product) had resolved. At the time of the report, HEMIANAESTHESIA (4.1(b)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Aug-2021, Magnetic resonance imaging head: abnormal (abnormal) Minor microangiopathic paraventricular medullary abnormalities. No fresh ischemia, no plaques, no mass.. On 12-Aug-2021, Magnetic resonance imaging neck: normal (normal) Stretching of the cervical spine with flat intervertebral disc protrusions in the segments cervical vertebra IV / cervical vertebra and cervical vertebra V / cervical vertebra VI. There is also a left intraforaminal focal herniation in contact with the exiting C6 nerve root on the left. No intraspinal mass, regular presentation of the cervical spinal cord. On an unknown date, Platelet count: normal (normal) within the normal range. For mRNA-1273 (Spikevax) (Unknown), the reporter considered HEMIANAESTHESIA (4.1(b)) to be possibly related. No further causality assessment was provided for INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product). Concomitant product was not provided. Treatment information was not provided. Company Comment: This case concerns a 52-year-old female patient who received mRNA-1273(2nd dose) as well as PFIZER BIONTECH COVID-19 (1st dose) (vaccine interchange) and experienced hemianesthesia 1 day after Mrna-1273 vaccine. Based on temporal association between hemianesthesia and the product use, causal relationship cannot be excluded. The event of vaccine interchange is assessed as not applicable. Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Received the Translation document contain no new information	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 30-Aug-2021: Follow-up received contains lab test,outcome of event updated On 30-Aug-2021: FU translation upload, lab test details added.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 27-Aug-2021. The most recent information was received on 06-Sep-2021 and was forwarded to Moderna on 06-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of RIGHT VENTRICULAR DYSFUNCTION (Right ventricular dysfunction), DEEP VEIN THROMBOSIS (Deep vein thrombosis leg), PULMONARY EMBOLISM (Saddle PE) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 61-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. Concurrent medical conditions included Insomnia. Concomitant products included MIRTAZAPINE for Insomnia, ATORVASTATIN, PANTOPRAZOLE SODIUM SESQUIHYDRATE (SOMAC) and TEMAZEPAM (TENOX [TEMAZEPAM]) for an unknown indication. On 07-May-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Aug-2021, the patient started TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 04-Aug-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). On 15-Aug-2021, the patient experienced RIGHT VENTRICULAR DYSFUNCTION (Right ventricular dysfunction) (seriousness criterion life threatening), DEEP VEIN THROMBOSIS (Deep vein thrombosis leg) (seriousness criteria medically significant and life threatening), PULMONARY EMBOLISM (Saddle PE) (seriousness criteria medically significant and life threatening) and COVID-19	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion life threatening). At the time of the report, RIGHT VENTRICULAR DYSFUNCTION (Right ventricular dysfunction), DEEP VEIN THROMBOSIS (Deep vein thrombosis leg), PULMONARY EMBOLISM (Saddle PE) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had not resolved and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment details was not reported by the reporter. Company comment: This is a case of interchange of vaccine products (Moderna and Pfizer) with serious events right ventricular dysfunction, pulmonary embolism and deep vein thrombosis onset latency of 3 months and 9 days. Case causality is confounded by increased risk due to underlying hypertension and concomitant use of mirtazapine. Most recent FOLLOW-UP information incorporated above includes: On 06-Sep-2021: Follow up received on 06-SEP-2021 contains significant information event revaccination with different COVID-19 vaccine was updated, and added patient medical history.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Aug-2021 and was forwarded to Moderna on 27-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (PERIMYOCARDITIS) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004959) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination. The patient's past medical history included Streptococcal infection (The patient had a streptococcal throat infection in the time period when he received the first vaccine dose with Comirnaty (01/Jul/2021).) in 2021. On 11-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient received dose of TOZINAMERAN (COMIRNATY) (unknown route) at an unspecified dose. On 14-Aug-2021, the patient experienced MYOCARDITIS (PERIMYOCARDITIS) (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), OFF LABEL USE (Revaccination with different COVID-19 vaccine) and INTERCHANGE OF VACCINE PRODUCTS (Revaccination with different COVID-19 vaccine). At the time of the report, MYOCARDITIS (PERIMYOCARDITIS) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) was resolving and OFF LABEL USE (Revaccination with different COVID-19 vaccine) and INTERCHANGE OF VACCINE PRODUCTS (Revaccination with different COVID-19 vaccine) outcome was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment was reported. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes:	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 27-Aug-2021: Translation received on 01-SEP-21, Additional translation information received does not contain any new information (NNI)	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 31-Aug-2021 and was forwarded to Moderna on 31-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 PNEUMONIA (COVID-19 pneumonia), DIARRHOEA (Diarrhoea), PYREXIA (Pyrexia), RHINORRHOEA (Rhinorrhoea) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 04A21A and 001A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy, End stage renal disease (ESRD on hemodialysis.), Atrial fibrillation, BK viremia, Hypothyroidism and Hypertension. On 25-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Mar-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 25-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 12-Apr-2021, received second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) dosage was changed to 1 dosage form. On 30-Jul-2021, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria hospitalization and medically significant), DIARRHOEA (Diarrhoea) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization) and RHINORRHOEA (Rhinorrhoea) (seriousness	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		criterion hospitalization). 30-Jul-2021, the patient experienced DRUG INEFFECTIVE (Lack of drug effect). On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion hospitalization). At the time of the report, COVID-19 PNEUMONIA (COVID-19 pneumonia), DIARRHOEA (Diarrhoea), PYREXIA (Pyrexia), RHINORRHOEA (Rhinorrhoea), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) and DRUG INEFFECTIVE (Lack of drug effect) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Feb-2021, SARS-CoV-2 test: positive (Positive) Positive. On 30-Jul-2021, Body temperature: 4.1(b) [REDACTED] On 30-Jul-2021, SARS-CoV-2 test: positive (Positive) Positive. On an unknown date, Body temperature: 4.1(b) [REDACTED]. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company comment This report refers to a case of Interchange of vaccine products and lack of drug effect (batch nos. O4A21A and 001A21A) with associated AEs. Based on the current available information, the mRNA-1273 does not contain a virus capable of causing infection and with the occurrence of COVID-19 pneumonia after vaccination, the causality of this event is assessed as not applicable. For the rest of the events, based on the current available information a causal relationship cannot be excluded. However, concomitant Tozinameran could be potentially co-suspects for the events.	
4.1(b) [REDACTED]	4.1(b) [REDACTED]	This case was received via 4.1(b) [REDACTED] (Reference number: 4.1(b) [REDACTED]) on 31-Aug-2021 and was forwarded to Moderna on 31-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		LIMB DISCOMFORT (Arm discomfort) in a 30-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for an unknown indication. The patient's past medical history included Lactation decreased. On 30-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 25-Aug-2021, the patient started TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) (unknown route) 1 dosage form. On 30-Jun-2021, the patient experienced LIMB DISCOMFORT (Arm discomfort) (seriousness criterion medically significant). On 25-Aug-2021, the patient experienced HYPERHIDROSIS (Sweating) and DRY THROAT (Dry throat). On 26-Aug-2021, the patient experienced FEELING OF BODY TEMPERATURE CHANGE (Feeling hot and cold), MYALGIA (Muscle ache) and HEADACHE (Headache). On 27-Aug-2021, the patient experienced RHINORRHOEA (Runny nose). On 02-Jul-2021, LIMB DISCOMFORT (Arm discomfort) had resolved. On 27-Aug-2021, FEELING OF BODY TEMPERATURE CHANGE (Feeling hot and cold) and MYALGIA (Muscle ache) had resolved. On 28-Aug-2021, HYPERHIDROSIS (Sweating) had resolved. On 29-Aug-2021, RHINORRHOEA (Runny nose) had resolved. At the time of the report, DRY THROAT (Dry throat) and HEADACHE (Headache) was resolving. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. The treatment history was not reported. The concomitant was not reported. Patient has not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Company Comment: Based on the current available information which shows a temporal association between the use of mRNA-1273 and the onset of the events, a causal relationship cannot be excluded. Headache, and myalgia are consistent with the product known safety profile	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 01-Sep-2021. The most recent information was received on 01-Sep-2021 and was forwarded to Moderna on 04-Sep-2021. This regulatory authority case was reported by a consumer and describes the occurrence of DEEP VEIN THROMBOSIS (4.1(b)) and PULMONARY EMBOLISM (Pulmonary thromboembolism) in a 56-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004669) for SARS-CoV-2 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. No Medical History information was reported. On 24-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and TOZINAMERAN (COMIRNATY) (unknown route) at an unspecified dose. On 24-Jul-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine product). On 03-Aug-2021, the patient experienced DEEP VEIN THROMBOSIS (4.1(b)) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PULMONARY EMBOLISM (Pulmonary thromboembolism) (seriousness criterion medically significant). The patient was hospitalized from 04-Aug-2021 to 12-Aug-2021 due to DEEP VEIN THROMBOSIS. At the time of the report, DEEP VEIN	the first dose of the Comirnaty vaccine was performed at 10:09 a.m. in the left shoulder. The patient had no other similar episodes. Hospitalized on 04-Aug-2021 and remained until 12-Aug-2021 Please find attached the available documentation attached, update of Sep 27, 2021 see attached documentation

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		THROMBOSIS 4.1(b) had not resolved and PULMONARY EMBOLISM (Pulmonary thromboembolism) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine product) outcome was unknown. Concomitant product use was not provided by the reporter. No treatment information was provided. The patient received first dose of Comirnaty vaccine on left shoulder. The patient did not have any similar episodes. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However Comirnaty vaccine could be a co-suspect drug for the events. Most recent FOLLOW-UP information incorporated above includes: On 01-Sep-2021: Translation received on 04-Sep-2021, Co-suspect vaccine and start date and end date of hospitalization were added. On 17-Sep-2021: Follow up received is NNI. On 17-Sep-2021: Follow-up received contains no new information. On 05-Oct-2021: Follow-up contains non-significant information. On 05-Oct-2021: Translation received on 07-Oct-2021 contains non new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 02-Sep-2021 and was forwarded to Moderna on 02-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of ISCHAEMIC STROKE 4.1(b) (CMP) in a 61-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002188) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: Comirnaty on 21-Apr-2021. Past adverse reactions to the above products included No adverse event with Comirnaty. Concurrent medical conditions included Hypertension, Left-to-right cardiac shunt	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		(according to transesophageal echocardiography) and Foramen ovale patent. On 19-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-May-2021, after starting mRNA-1273 (Spikevax), the patient experienced ISCHAEMIC STROKE 4.1(b) CMP (seriousness criteria hospitalization and medically significant). At the time of the report, ISCHAEMIC STROKE 4.1(b) CMP) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Fibrin D dimer: 4.46mg/l (abnormal) abnormal. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. Treatment for the events were not provided. The cause of ischaemic stroke was assumed as a combination of risk factors - suspected not yet confirmed thrombophilic condition with post-vaccination complication. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Sep-2021 and was forwarded to Moderna on 04-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEADACHE (FRONTAL HEADACHE) and HEADACHE (TEMPORAL HEADACHE) in a 23-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004952) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty.	4.1(b) 4.1(b) 4.1(b) 4.1(b) 4.1(b) 4.1(b)

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		On 06-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 06-Aug-2021, the patient experienced HEADACHE (FRONTAL HEADACHE) (seriousness criterion hospitalization) and HEADACHE (TEMPORAL HEADACHE) (seriousness criterion hospitalization). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). At the time of the report, HEADACHE (FRONTAL HEADACHE) and HEADACHE (TEMPORAL HEADACHE) was resolving and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Computerised tomogram head: (normal) No pathological findings. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered HEADACHE (FRONTAL HEADACHE) and HEADACHE (TEMPORAL HEADACHE) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). No concomitant medications were provided. Treatment medications was not provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This is a case of interchange of vaccine product but coding has been retained as reported by RA. Comirnaty vaccine is a co suspect for the events. Most recent FOLLOW-UP information incorporated above includes: On 04-Sep-2021: Translated document was received on 08-Sep-2021; included no new information.	4.1(b)

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
			4.1(b)
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 02-Sep-2021. The most recent information was received on 02-Sep-2021 and was forwarded to Moderna on 08-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of DEEP VEIN THROMBOSIS (DEEP VEIN THROMBOSIS) in a 49-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004670) for Vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination. The patient's past medical history included Trauma (Trauma to left leg approximately 2 months before the patient developed deep vein thrombosis) in June 2021. On 18-Jun-2021, the patient started TOZINAMERAN (COMIRNATY) (Intramuscular) Dose no. in series 1. On 29-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 18-Jun-2021, 41days before starting mRNA-1273 (Spikevax), the patient experienced	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). On 05-Aug-2021, the patient experienced DEEP VEIN THROMBOSIS (DEEP VEIN THROMBOSIS) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). At the time of the report, DEEP VEIN THROMBOSIS (DEEP VEIN THROMBOSIS) was resolving, COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Fibrin D dimer: positive (Positive) positive. In August 2021, Ultrasound scan: abnormal (abnormal) Findings of deep vein thrombosis left leg. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. Treatment for the events were not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, underlying medical history of trauma in leg and interchange of vaccine products are cofounders. Most recent FOLLOW-UP information incorporated above includes: On 02-Sep-2021: Translation doc received on 08SEP2021, changed the lab data ultrasound NOS from negative to abnormal and indication of use for suspected Moderna vaccine from COVID-19 Vaccination to Vaccination	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Sep-2021 and was forwarded to Moderna on 03-Sep-2021.	* Myocarditis 2 days after the second dose of COVID-19 vaccine Spikevax. * Deemed uncomplicated at the time of reporting.

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004952) for COVID-19 vaccination. Previously administered products included for an unreported indication: COMIRNATY (5'capped mRNA encoding full length SARS-CoV-2 spike protein). On 18-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Aug-2021, the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Aug-2021, Cardiac telemetry: normal (normal) No arrhythmia. On 21-Aug-2021, Echocardiogram: normal (normal) Normal. On 21-Aug-2021, Troponin T: 660 - 1120 (abnormal) 660 - 1120 ng/L. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b)) to be possibly related. Concomitant medication not provided. Treatment medication not provided. Based on the current available information and temporal association between the use of the product mRNA-1273 and the start date of the serious event of Myocarditis, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 03-Sep-2021: Translation doc received on 08-Sep-2021 contains no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: (4.1(b))) on 03-Sep-2021 and was forwarded to Moderna on 03-Sep-2021.	Contact with healthcare professionals: Physician. The patient reported duration for side effects CHEST PAIN and

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		This regulatory authority case was reported by a consumer and describes the occurrence of PALPITATIONS (Palpitations), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnea), CHEST DISCOMFORT (Chest pressure) and RASH (Rash on face and neck) in a 53-year-old female patient who received mRNA-1273 (Spikevax) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. Concomitant products included PANTOPRAZOLE SODIUM SESQUIHYDRATE (SOMAC) for Esophageal hernia, RAMIPRIL (TRIATEC [RAMIPRIL]) for Hypertension. On 29-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Aug-2021, the patient experienced PALPITATIONS (Palpitations) (seriousness criterion hospitalization) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). On an unknown date, the patient experienced DYSPNOEA (Dyspnea) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest pressure) (seriousness criterion hospitalization), RASH (Rash on face and neck) (seriousness criterion hospitalization) and INTERCHANGE OF VACCINE PRODUCTS (Revaccination with different COVID-19 vaccine). In August 2021, CHEST PAIN (Chest pain) was resolving. At the time of the report, PALPITATIONS (Palpitations), RASH (Rash on face and neck) and INTERCHANGE OF VACCINE PRODUCTS (Revaccination with different COVID-19 vaccine) outcome was unknown and DYSPNOEA (Dyspnea) and CHEST DISCOMFORT (Chest pressure) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Aug-2021, Computerised tomogram: normal (normal) No findings.	PALPITATIONS as approx. 20 minutes. The patient has set /Aug/2021 as Cessation Date for the side effect CHEST PAIN, but has also stated the Outcome as Recovering/Resolving. The patient was hospitalized for 2 days due to the ADRs. No individual report of dose 1.

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		The patient reported duration for side effects chest pain and palpitations as approximately 20 minutes. The patient was hospitalized for two days due to the adverse drug reactions. The patient reported duration for side effects dyspnea and chest pressure as 12-14 days after the incident. The patient administered Nitroglycerin against adverse drug reactions, which relieved some of the chest pressure. The patient reported latency for side effect RASH ON FACE AND NECK as 12-14 days after vaccination. The patient was being treated for the ADRs. Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded. Use of a different vaccine has a causality of "not applicable" by convention. Event terms, onset dates and outcomes captured per SD Authority reporting. Events seriousness per assessment by Authority and per SD narrative stating that the patient was hospitalized for their adverse events so events of rash, dyspnea and chest discomfort upgraded to serious (H) conservatively. Event of Interchange of vaccine products added to clarify that the report states that they took different products.	
4.1(b)	4.1(b)	This case was received via United States FDA VAERS (Reference number: 4.1(b) on 07-Sep-2021 and was forwarded to Moderna on 07-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of KYPHOSCOLIOSIS (Kyphoscoliosis) and EXOMPHALOS (abdominal organs on the outside of her body adhered to the placenta) in a female patient of an unknown age exposed to mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011M20A) , while the mother received the product for COVID-19 vaccination. CO-SUSPECT PRODUCT exposures included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE). MEDICAL HISTORY (Parent): Concomitant reported for mother was PRENATAL VITAMINS. The mother's past medical history included Pregnancy since 28-Apr-2021, Maternal exposure during pregnancy on 16-Feb-2021,	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Paternal exposure before pregnancy on 28-Apr-2021 and Exposure via father on 28-Apr-2021. MEDICAL HISTORY (Patient): Concomitant product exposures included MINERALS NOS, VITAMINS NOS (PRENATAL VITAMINS [MINERALS NOS;VITAMINS NOS]) for an unknown indication. On 16-Feb-2021, the mother received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the mother started TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 28-Apr-2021, the patient was diagnosed with KYPHOSCOLIOSIS (Kyphoscoliosis) (seriousness criterion congenital anomaly). 28-Apr-2021, the patient experienced EXOMPHALOS (abdominal organs on the outside of her body adhered to the placenta) (seriousness criteria medically significant and congenital anomaly). The delivery occurred on an unknown date, which was reported as Abnormal Pregnancy Outcome. For neonate 1, The outcome was reported as Unknown. At the time of the report, KYPHOSCOLIOSIS (Kyphoscoliosis) and EXOMPHALOS (abdominal organs on the outside of her body adhered to the placenta) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Jun-2021, Ultrasound foetal: abnormal (abnormal) abnormal. On 09-Aug-2021, Ultrasound foetal: abnormal (abnormal) abnormal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Transplacental), the reporter did not provide any causality assessments. No treatment medications were reported. It was reported that the patient become pregnant with a baby with limb body wall complex (fatal diagnosis). The baby had abdominal organs on the outside of her body at 18 weeks gestation which are adhered to the placenta. Not only the fetal condition fatal,	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		but continuing the pregnancy poses high risks to the mother. The baby's father received the second dose of the Pfizer vaccine 2 days prior to conception. This case concerns a female fetus subject, with a history of maternal exposure during pregnancy, who experienced the unexpected events Omphalocele and kyphoscoliosis at 18 weeks of gestation . The events occurred approximately 2 months 13 days after the mother received the second dose of mRNA-1273 . The rechallenge is not applicable since we do not have information regarding the first dose. Patient's medical history of paternal exposure before pregnancy with other COVID 19 vaccine is a confounder for the case. The benefit-risk relationship of mRNA-1273 in not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 07-Sep-2021 and was forwarded to Moderna on 07-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FLUTTER (Cardiac flutter) and TUNNEL VISION (Tunnel vision) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. The patient's past medical history included Anxiety and GERD. Concurrent medical conditions included Obsessive-compulsive disorder, Post-traumatic stress disorder, Bipolar disorder, Irritable bowel syndrome, RA, Drug allergy ((N/V)), Drug allergy, Drug allergy, Drug allergy, Latex allergy (rash), Penicillin allergy (Hives), Adhesive tape allergy ((Skin lesions)) and Adhesive tape allergy (rash). Concomitant products included ABATACEPT, ACETAMINOPHEN, APAP, ACETYLSALICYLIC ACID (ASPIRIN (E.C.)), ESTRADIOL (CLIMARA [ESTRADIOL]), CLONAZEPAM, DOCUSATE, ESOMEPRazole, FAMOTIDINE,	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		GABAPENTIN, LAMOTRIGINE, SOLIFENACIN and ZOLPIDEM for an unknown indication. On 19-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient received dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 19-Aug-2021, the patient experienced CARDIAC FLUTTER (Cardiac flutter) (seriousness criterion medically significant), TUNNEL VISION (Tunnel vision) (seriousness criterion medically significant), TACHYCARDIA (Tachycardia), ABDOMINAL PAIN UPPER (Abdominal pain upper), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations), PARAESTHESIA ORAL (Paraesthesia oral) and NAUSEA (Nausea). 19-Aug-2021, the patient experienced BLOOD PRESSURE INCREASED (Blood pressure increased). On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product). The patient was treated with PROMETHAZINE (intravenous) for Adverse event, at a dose of 12.5 mg IV. At the time of the report, CARDIAC FLUTTER (Cardiac flutter), TUNNEL VISION (Tunnel vision), TACHYCARDIA (Tachycardia), ABDOMINAL PAIN UPPER (Abdominal pain upper), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations), PARAESTHESIA ORAL (Paraesthesia oral), BLOOD PRESSURE INCREASED (Blood pressure increased) and NAUSEA (Nausea) had not resolved and INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Aug-2021, Blood pressure management: increased (High) Increased. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Treatment medications included LR 1L and GI cocktail. Patient reported that she developed tachycardia (120's) and mildly elevated BP with SBP in 150's and patient was transferred to ED via EMS. BP elevations had resolved as of first documented assessment at 1530. Patient reported similar reaction to Humira. After first Pfizer Covid19 vaccination, patient had arm and neck pain. developed back pain, sore throat. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Sep-2021 and was forwarded to Moderna on 07-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of PNEUMONIA (Klínísk merki um lagnabólgu) and PYREXIA (Fever) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004730) for COVID-19 immunisation. The patient's past medical history included Alzheimer's disease (advanced alzheimer's disease). Previously administered products included for an unreported indication: COMIRNATY. Concomitant products included FISH OIL, XANTOXYL, ZEAXANTHIN (ACTAVISIO), LOSARTAN POTASSIUM (LOSATRIX), PARACETAMOL (PARATABS), ACETYLSALICYLIC ACID (HJARTAMAGNYL), SIMVASTATIN (SIMVASTATIN +PHARMA), MEMANTINE HYDROCHLORIDE (ZALATINE), SOTALOL, BUPRENORPHINE and CEFUROXIME (FURIX [CEFUROXIME]) for an unknown indication. On 17-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Aug-2021, the patient experienced PNEUMONIA (Klínísk merki um lagnabólgu) (seriousness criteria death and medically significant). On an unknown date,	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		the patient experienced PYREXIA (Fever) (seriousness criterion death). The patient died on 19-Aug-2021. The reported cause of death was most likely cause is bacterial pneumonia. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Aug-2021, Body temperature: 38.2 (normal) 38.2 degree celcius. On an unknown date, Breath sounds abnormal: abnormal (abnormal) abnormal. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment medication provided. The case concerns a 79 -year-old male patient with past medical history of Alzheimer's disease, presented with unexpected events of Pneumonia and pyrexia 1 day after booster dose of vaccine. Patient died 2 days after booster dose, cause of death was most likely Bacterial Pneumonia. The benefit risk relationship of vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 07-Sep-2021. The most recent information was received on 07-Sep-2021 and was forwarded to Moderna on 10-Sep-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (4.1(b)) in a 56-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003183) for Prophylactic vaccination. The patient's past medical history included Hay fever (Patient developed Hay fever due to Grasses). Previously administered products included for Prophylactic vaccination: ComirnatyBNT162b2 (ComirnatyBNT162b2 Dose- 0.3 ml). Past adverse reactions to the above products included No adverse event with ComirnatyBNT162b2.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		Concurrent medical conditions included Penicillin allergy, Grass allergy and Hypertension (Controlled hypertension). Concomitant products included ASA and TICAGRELOR (BRILIQUE) for Prophylaxis. On 28-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Jul-2021, the patient experienced CEREBROVASCULAR ACCIDENT (4.1(b) [REDACTED]) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on sometime in July 2021 due to CEREBROVASCULAR ACCIDENT. At the time of the report, CEREBROVASCULAR ACCIDENT (4.1(b) [REDACTED]) had resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. It was reported that on 03-Jul-2021, patient developed Feeling of slight lightheadedness and the morning of 04-Jul-2021 when the patient woke up, he noticed that his right eye (was twitching) slightly to the right. After an estimated 2 mins. Then patient developed brief nausea. Since the feeling of slight lightheadedness and dizziness did not decline over the day, patient visited the clinic in the afternoon and there, vascular occlusion was determined in the brain stem in a small vessel. No measures were taken to dissolve the clot. Further diagnostic measures were performed without finding a clear cause for this. It was reported that patient was diagnosed with stroke even though he was taking ASA 100 and Brilique 90 mg. The information available on a recent vascular event in the brainstem could be a contributory factor to the current event. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		relationship cannot be excluded. No further information is expected. Most recent FOLLOW-UP information incorporated above includes: On 07-Sep-2021: Translation document received on 10-Sept-2021 and included patient Allergies (grasses, Penicillin) were added, Current condition (Controlled hypertension) added, Clinical course of patient events were added and updated in narrative, New Concomitant drugs were added.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 08-Sep-2021 and was forwarded to Moderna on 08-Sep-2021. This regulatory authority case was reported by a consumer and describes the occurrence of HYPOAESTHESIA (NUMBNESS IN HANDS, LIPS AND NECK), ARTHRALGIA (JOINT TENDERNESS), DIZZINESS (DIZZINESS), PYREXIA (FEVER) and INFLUENZA LIKE ILLNESS (FLU LIKE SYMPTOMS) in a 40-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for Vaccination. Concomitant products included DESLORATADINE (AERIUS [DESLORATADINE]) for Dust allergy. On 06-Aug-2021 at 1:05 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 07-Aug-2021, the patient experienced HYPOAESTHESIA (NUMBNESS IN HANDS, LIPS AND NECK) (seriousness criterion hospitalization), ARTHRALGIA (JOINT TENDERNESS) (seriousness criterion hospitalization), DIZZINESS (DIZZINESS) (seriousness criterion hospitalization), PYREXIA (FEVER) (seriousness criterion hospitalization), INFLUENZA LIKE ILLNESS (FLU LIKE SYMPTOMS) (seriousness criterion hospitalization) and NAUSEA	Contact with healthcare professionals: Physician. Description of adverse reaction progress, diseases and other relevant information: 4.1(b) Dietary supplement: Patients weight: 60 Patients height: 165 Is reaction still ongoing?: Side effect 4.1(b) No Latency: Side effect 4.1(b) Is reaction still ongoing?: Side effect 4.1(b)

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		(NAUSEA). On an unknown date, the patient experienced PRESYNCOPE (PRESYNCOPE), DYSSTASIA (DIFFICULTY IN STANDING), DIARRHOEA (DIARRHEA) and VOMITING (VOMITING). On 11-Aug-2021, HYPOAESTHESIA (NUMBNESS IN HANDS, LIPS AND NECK), ARTHRALGIA (JOINT TENDERNESS), DIZZINESS (DIZZINESS), PYREXIA (FEVER) and INFLUENZA LIKE ILLNESS (FLU LIKE SYMPTOMS) had resolved. At the time of the report, PRESYNCOPE (PRESYNCOPE), DYSSTASIA (DIFFICULTY IN STANDING), DIARRHOEA (DIARRHEA), VOMITING (VOMITING) and NAUSEA (NAUSEA) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Body temperature: 39 (Inconclusive) 39 degree Celsius. Treatment medication was not provided by the reporter. The dizziness did not subside, patient could not stand without help. The patient felt pressure in her neck, had numb hands and lips. The patient could not feel her lips. The patient was admitted to hospital and taken neurological tests. It was denied that it had anything to do with the vaccine. These symptoms went over, but for the next three days the patient has a high fever (39) and flu symptoms. This case refers to a 40-year-old female patient with no known medical history who experienced the unexpected events of Hypoaesthesia, Arthralgia, Dizziness, Pyrexia and Influenza like illness approximately 1 day after the second dose of Spikevax. No causality assessment was provided by the reporter. Rechallenge was not provided. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 08-Sep-2021: Translation document received as live follow up on 13-Sep-2021 contained No New Information.	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 08-Sep-2021 and was forwarded to Moderna on 08-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of ANAPHYLACTIC REACTION (4.1(b)), RESPIRATORY DISTRESS (4.1(b)), HYPOTENSION (4.1(b)), GENERAL PHYSICAL HEALTH DETERIORATION (4.1(b)) and COVID-19 IMMUNISATION (4.1(b)) in a 43-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005241) for COVID-19 vaccination. Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included Adverse event with Comirnaty. Concurrent medical conditions included Allergy (Allergy with symptoms from airways.). Concomitant products included DESLORATADINE (AERIUS [DESLORATADINE]) for Allergy. On 20-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Aug-2021, the patient experienced ANAPHYLACTIC REACTION (4.1(b)) (seriousness criteria hospitalization, medically significant and life threatening), RESPIRATORY DISTRESS (4.1(b)) (seriousness criteria hospitalization, medically significant and life threatening), HYPOTENSION (4.1(b)) (seriousness criteria hospitalization and life threatening), GENERAL PHYSICAL HEALTH DETERIORATION (4.1(b)) (seriousness criteria hospitalization and life threatening) and COVID-19 IMMUNISATION (4.1(b)) (seriousness criteria hospitalization and life threatening). On 22-Aug-2021, ANAPHYLACTIC REACTION (4.1(b)), RESPIRATORY DISTRESS (4.1(b)), HYPOTENSION (4.1(b)), GENERAL PHYSICAL HEALTH	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		DETERIORATION (4.1(b)) and COVID-19 IMMUNISATION (4.1(b)) had resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter considered ANAPHYLACTIC REACTION (4.1(b)), RESPIRATORY DISTRESS (4.1(b)), HYPOTENSION (4.1(b)), GENERAL PHYSICAL HEALTH DETERIORATION (4.1(b)) and COVID-19 IMMUNISATION (4.1(b)) to be possibly related. Treatment medications were not reported. Company comment: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 08-Sep-2021: Translation document was received on 13-SEP-2021 for initial Source document and had no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 08-Sep-2021 and was forwarded to Moderna on 08-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of 4.1(b) (4.1(b)) in a 50-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004670) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. On 28-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced 4.1(b) (4.1(b)) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION	

Case ID	WW Identifier	Narrative (Complete)	MAH Comment
		(REVACCINATION WITH DIFFERENT COVID-19 VACCINE). At the time of the report, 4.1(b) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Aug-2021, Ophthalmological examination: abnormal (abnormal) Ophthalmologist: minor anterior chamber reaction right eye as well as macular edema and papilledema.. In August 2021, Blood test: abnormal (abnormal) Syphilis and HIV negative. Quantiferon negative. No ongoing infection of Herpes viridae, Toxoplasmosis, CMV, EBV or Borrelia.. In August 2021, Chest X-ray: normal (normal) Normal. In August 2021, Lumbar puncture: abnormal (abnormal) Cells 39, interpreted as meningitis.. In August 2021, Magnetic resonance imaging: abnormal (abnormal) Thickening of ocular wall, no other pathology. On 16-Aug-2021, Ophthalmological examination: abnormal (abnormal) Hospital examination: Significant vision reduction (finger counting test right eye). Changes in posterior pole resembling 4.1(b) .. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant information was not provided by reporter. No treatment information was provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 08-Sep-2021: Translation received on 13-SEP-2021 and does not contain any new information.	