(Medsafe, 2022a)
[Chapter 4 Vaccines and vaccinations]
[Appendix 2]

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

COVID-19

Published: 14 December 2022

Adverse events following immunisation with COVID-19 vaccines: Safety Report #46 – 30 November 2022

Medsafe advises people NOT to make any decisions about vaccination based on information contained in this report. If you have questions or concerns about receiving a vaccine, please speak to a health care professional.

What you need to know – up to and including 30 November 2022

Note that counts may change due to receipt of additional information.

For the Comirnaty (Pfizer) vaccine

768
New AEFI reports since last update
(630 non-serious and 138 serious)

0
New safety signals (potential safety issues) have been identified

11,888,254
Total doses administered
(cumulative)

61,141
Total AEFI reports that were non-serious

3,688
Total AEFI reports that were serious

64,829
Total AEFI reports that were received
(cumulative)

- **The protective benefits of vaccination against COVID-19 far outweigh the potential risks of vaccination.**
- The Ministry of Health, the National Immunisation Programme, Medsafe, the Centre for Adverse Reactions Monitoring and manufacturers continue to closely monitor the safety of COVID-19 vaccines. We'll respond to any safety issues right away and will inform New Zealanders about any risks that arise in New Zealand.
- For more information about Covid Vaccine Immunisation Programme, please go to Unite against COVID-19 or call Healthline 0800 611 116 to talk to someone about your concerns.
- **Comirnaty:** There were 630 non-serious and 138 serious reports since the last update. Sadly, we have 7 further notifications of death to report. Any possibility of a causal link is investigated as part of our routine investigations and no new safety concerns with the Comirnaty vaccine were raised by these 7 reports. For information about reported deaths, please refer to the summary of reported deaths.
- **Vaxzevria:** The vaccine was used from 26 November 2021 until September 2022. Therefore, there is no new safety data for the Vaxzevria vaccine. As of the last report (#45) there were 298 non-serious and 21 serious reports for the Vaxzevria vaccine. There have been no notifications of death.
- **Comirnaty:** Up to 30 November 2022 a total of 11,888,254 doses of Comirnaty have been administered and 64,829 AEFIs were reported. This means that more than 11.82 million doses of Comirnaty were administered that did not result in a report of an adverse event. On average for every 10,000 people who are vaccinated 55 people report an AEFI. It is also important to keep in mind that a report can be submitted for any cause and is not necessarily associated with the vaccine.
- **Vaxzevria:** As of the last report (#45), a total of 9,087 doses of Vaxzevria vaccine were administered and 319 AEFIs were reported. This means that more than 8,750 doses of Vaxzevria vaccine were administered that did not result in a report of an adverse event. On average for every 10,000 people who are vaccinated 351 people report an AEFI. It is also important to keep in mind that a report can be submitted for any cause and is not necessarily associated with the vaccine.
- **Nuvaxovid:** The Nuvaxovid COVID-19 vaccine became available in New Zealand on 18 March 2022. Up to 30 November 2022, 7,025 doses of the vaccine had been administered and 84 AEFI reports were submitted.
- **Nuvaxovid Safety Alert:** Medsafe has issued an alert communication about reports of myocarditis and pericarditis following immunisation with Nuvaxovid.

Introduction

The national roll-out of COVID-19 vaccines commenced on 20 February 2021 with Pfizer-BioNTech (Comirnaty). The AstraZeneca vaccine (also known as Vaxzevria) became available on 26 November 2021, and Nuvaxovid on 18 March 2022. The Vaxzevria vaccine stopped being used in September 2022.

This page provides information on the number of adverse events following immunisation (AEFI) reports received for COVID-19 vaccines.

An AEFI is an untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

All medicines can cause side effects, the known side effects for COVID-19 vaccines are listed in the data sheets and consumer medicine information (CMI).

Search for a data sheet or CMI

Suspected AEFI to COVID-19 vaccines are reported to the Centre for Adverse Reactions Monitoring (CARM). The Ministry of Health (through Medsafe) contracts the collection of this information to CARM, based at the University of Otago in Dunedin. Medsafe is closely monitoring the AEFI reported from the use of the COVID-19 vaccine. Find out more about vaccine safety monitoring.

Medsafe and CARM thank everyone who has contributed to the monitoring of COVID-19 vaccines. Please continue to report any adverse events following immunisation.

Adverse events following immunisation (AEFI) reported

The information below includes:

- AEFI reports by prioritised ethnicity and vaccine dose
- AEFI reports by age band and vaccine dose
- the top 10 most frequently reported AEFIs by vaccine dose
- reported AEFIs by reporter type.

Table 1: AEFI reports received by prioritised ethnicity and vaccine dose, for Comirnaty up to and including 30 November 2022

Ethnicity[a]	Comirnaty				
	Dose 1	Dose 2	Dose 3	Dose 4	Total
Māori	2,745	2,182	960	72	5,959
Pacific Peoples	824	780	318	22	1,944
Asian	2,819	2,348	1,392	53	6,612
European or other	21,161	18,152	9,502	824	43,639
Unknown[b]	347	221	80	5	653
Total	**27,896**	**23,683**	**12,252**	**976**	**64,807[c]**

Notes:

a. The prioritised ethnicity classification system allocates each person to a single ethnic group, based on the ethnic groups they identify with. Where people identify with more than one group, they are assigned in this order of priority: Māori, Pacific Peoples, Asian, and European/Other. So, if a person identifies as being Māori and New Zealand European, the person is counted as Māori. See Ethnicity Data Protocols for further information.

b. There were 347 Comirnaty and 5 Vaxzevria AEFI reports where the person's ethnicity was not reported. Counts may change due to receipt of additional information. Ethnicity is not required for an AEFI report to be considered valid. See 'Valid report' in the Definitions section below.

c. The Comirnaty total is different from the cumulative total above because this table only includes reports following dose 1, 2, 3 and 4. The table also excludes 22 AEFI reports received for infants who did not receive the vaccine.

Table 2: AEFI reports received by age band and vaccine dose for Comirnaty up to and including 30 November 2022

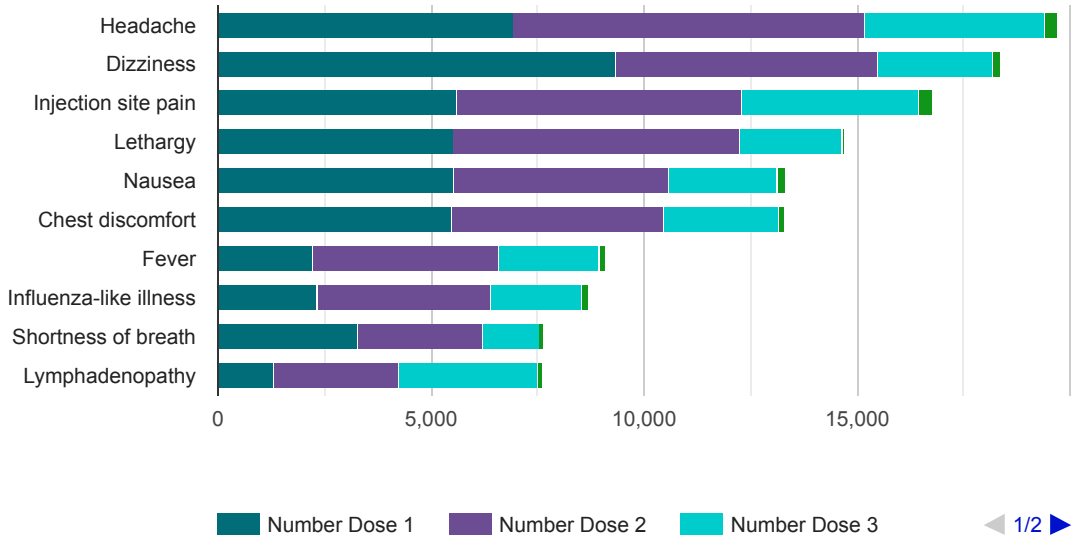
Age	Comirnaty				
	Dose 1	Dose 2	Dose 3	Dose 4	Total
5 - 11 years	630	205	0	0	835
12 - 19 years	2,843	1,778	294	1	4,916
20 - 29 years	5,363	4,113	2,194	20	11,690
30 - 39 years	6,037	5,159	2,785	46	14,027
40 - 49 years	4,772	4,521	2,484	94	11,871
50 - 59 years	4,052	3,841	2,204	201	10,298
60 - 69 years	2,448	2,348	1,355	303	6,454
70 - 79 years	1,177	1,195	665	226	3,263
80+ years	495	491	261	85	1,332
Unknown[a]	79	32	10	0	121
Total	**27,896**	**23,683**	**12,252**	**976**	**64,807[b]**

Notes:

a. There were 121 Comirnaty AEFI reports where the person's age was not reported. Counts may change due to receipt of additional information. Age is not required for an AEFI report to be considered valid. See 'Valid report' in the Definitions section below.

b. The Comirnaty total is different from the cumulative total above because this table only includes reports following dose 1, 2, 3 and 4. The table also excludes 22 AEFI reports received for infants who did not receive the vaccine.

Figure 1: Top 10 most frequently reported AEFIs for the Comirnaty vaccine, by dose, up to and including 30 November 2022



Show table

Table 3: Top 10 most frequently reported AEFIs for the Comirnaty vaccine, by dose, up to and including 30 November 2022

Reaction	Number doses 1-4	Number dose 1	Number dose 2	Number dose 3	Number dose 4
Headache	19,679	6,914	8,252	4,224	289

Reaction	Number doses 1-4	Number dose 1	Number dose 2	Number dose 3	Number dose 4
Dizziness	18,375	9,324	6,153	2,712	186
Injection site pain	16,758	5,583	6,701	4,150	324
Lethargy	14,662	5,508	6,726	2,423	5
Nausea	13,309	5,500	5,063	2,549	197
Chest discomfort	13,289	5,476	4,971	2,711	131
Fever	9,089	2,188	4,387	2,370	144
Influenza-like illness	8,670	2,304	4,093	2,102	171
Shortness of breath	7,625	3,262	2,935	1,344	84
Lymphadenopathy	7,588	1,310	2,912	3,258	108

Hide table

For information on Vaxzevria, please refer to the last safety report (#45).

Download a list of the top 50 most frequently reported AEFIs (any dose) (Excel 12 KB).

Table 4: Reported AEFIs by reporter type (any vaccine) up to and including 30 November 2022

Reporter type	Number of reports[a]
Public Patient	27,021
CIR Vaccinator	15,193
Nurse	8,706
Other	6,583
General Practitioner	8,695
Public: On behalf of a patient	2,252
Pharmacist	387
Not specified	115

a. The total number here differs from the total reported cases elsewhere because a single case can contain multiple reports from different sources.

Please note that one adverse event report, which represents one person, may report on more than one symptom. Reports are sent to CARM if the reporter suspects that the vaccine may have caused the event. This does not necessarily mean that the vaccine did cause the event.

The number of reports can be influenced by how many people are being vaccinated, media attention, the nature of the events (eg, how painful the vaccination was), and other factors which vary over time. Not everyone who has an adverse reaction reports it, and some people may report AEFIs after each vaccination. The information here shows the number of reports not the number of people who experienced an AEFI.

The information is limited by the information provided in the report and may change over time due to quality control procedures and/or receipt of additional information. Non-valid reports are not included in the data.

Summary of reported deaths

Up to and including 30 November 2022, a total of 184 deaths were reported to CARM after the administration of the Comirnaty vaccine. Following medical assessments by CARM and Medsafe it has been determined that:

- 163 of these deaths are unlikely related to the COVID-19 vaccine
- 15 deaths could not be assessed due to insufficient information
- 2 cases are still under investigation
- 2 deaths were determined by the Coroner to be due to myocarditis following first dose Covid-19 (Pfizer) vaccination
- 1 death was likely due to vaccine induced myocarditis (awaiting Coroner's determination)

- for 1 death a link to the vaccine could not be excluded, myocarditis was found at the time of death (this death is awaiting Coroner's determination).

By chance, some people will experience new illnesses or die from a pre-existing condition shortly after vaccination, especially if they are elderly. Therefore, part of our review process includes comparing natural death rates to observed death rates following vaccination, to determine if there are any specific trends or patterns that might indicate a vaccine safety concern. See below for more information about these observed-versus-expected analyses.

To date, the observed number of deaths reported after vaccination is actually less than the expected number of natural deaths.

There have been no deaths reported for the Vaxzevria or Nuvaxovid vaccines.

Table 5: Mortalities by age group up to and including 30 November 2022 reported to CARM, Comirnaty vaccine

Age	Mortalities[a]
10 - 29 years	9
30 - 59 years	36
60 - 79 years	85
80+ years	54

a. Counts may change due to receipt of additional information, for example, identification of duplicate reports.

Observed-versus-expected analyses – Comirnaty vaccine

It is important to note that no conclusions should be made from these observed-versus-expected analyses in isolation. Other investigations looking at pre-existing risk factors are always required.

The analyses below show that the number of deaths recorded in the mortality register for people vaccinated with the Comirnaty vaccine is lower than expected based on the average number of deaths in previous years over the same number of days (natural death rate).

For these observed-versus-expected analyses, we compare the vaccinated population to natural (expected) rates (taken from past data). The comparison is done by dividing the observed rate of death in the vaccinated population by the expected rate to give the relative risk (RR).

Observed / Expected Rate = Relative Risk (RR)

The methods used to calculate the relative risk also provide a confidence interval (CI). The confidence interval is a range of values that we are fairly sure our true value lies in. We are using a 95 percent confidence interval (95% CI), which is the range that will include the true value 95 percent of the time. If both the relative risk AND the lower end of the confidence interval are greater than one (>1.0), this is statistically significant and could indicate an increased risk of death in the vaccinated population. This will be highlighted in the table when applicable.

We are monitoring people for 21 days after vaccination. This monitoring period was chosen because people can receive their second dose a minimum of 21 days after the first dose. Age-specific natural (expected) death rates were obtained for the period 2008–2019. One reason for the number of deaths in the vaccinated group appearing to be lower could be that healthcare professional of extremely frail patients give the advice not to get vaccinated.

These analyses do not consider causality and instead, report on all deaths that have occurred in the monitoring period (observed deaths). This results in a much higher number than those reported to CARM where the reporter (eg, family member or health care provider) might have had a suspicion the vaccine could have played a role. The number of observed deaths also includes deaths from other causes, such as deaths due to accidents, medical conditions, other medicines or medical treatments.

Please note that the mortality collections operate many weeks in arrears. This means that these observed-versus-expected analyses will also be in arrears – for example, the tables below are for the period up to 30 September 2022.

Table 6: Observed-versus-expected deaths[a] by age group from any cause, up to 21 days after Comirnaty dose 1, 19 February 2021 to 30 September 2022

Age	Dose 1 – number administered	Expected deaths[b] in monitoring period	Observed deaths[c] in monitoring period	Relative risk[c] (95% confidence interval)
0 to 9	182,072	6.38	0	- [d]
10 to 19	585,511	10.96	12	1.09[e] [0.57 – 1.91]
20 to 29	652,325	22.65	24	1.06[f] [0.68 – 1.58]
30 to 39	678,350	31.21	14	0.45 [0.25 – 0.75]
40 to 49	593,720	57.61	24	0.42 [0.27 – 0.62]
50 to 59	608,884	135.88	65	0.48 [0.37 – 0.61]
60 to 69	517,264	269.69	129	0.48 [0.40 – 0.57]
70 to 79	349,627	492.44	240	0.49 [0.43 – 0.55]
80+	182,898	1,084.32	606	0.56 [0.52 – 0.61]
Total	4,350,651	2,111.13	1,114	0.53 [0.50 – 0.56]

a. Expected and observed deaths among people who have received dose 1 of the Comirnaty vaccine during the specified period, by age group. Inclusion criteria were: monitoring time of 21 days after receiving dose 1, all genders, all ethnicities, aged 5 years and older. The data was collected from the Mortality database.

b. Data for expected death rates was obtained from the AESI background rate (SAFE) study provided by the University of Auckland (however, please note that the publicly available information only shows rates of sudden death not all deaths). The age-specific background rates used are the average from 2008-2019.

c. The observed deaths column (4th column) is a raw data observation, and this is used to calculate the relative risk (5th column).

d. The relative risk has not been calculated for the 0 - 9 years age group because no deaths were observed during the monitoring period.

e. The relative risk of 1.09 does not indicate there is an increased risk of mortality in the 10 - 19 age group because the lower end of the confidence interval is 0.57 (ie, <1.0). The COVID-19 Independent Safety Monitoring Board (CV-ISMB) has reviewed AEFIs in children and found that this group was not disproportionately affected by the vaccine. Medsafe will continue to monitor this closely.

f. The relative risk of 1.06 does not indicate there is an increased risk of mortality in the 20 - 29 year age group because the lower end of the confidence interval is 0.68 (ie, <1.0).

Table 7: Observed-versus-expected deaths[a] by age group from any cause, up to 21 days after Comirnaty dose 2, 19 February 2021 to 30 September 2022

Age	Dose 2 – number administered	Expected deaths[b] in monitoring period	Observed deaths[c] in monitoring period	Relative risk[c] (95% confidence interval)
0 to 9	95,910	3.35	0	- [d]
10 to 19	536,666	10.05	10	1.00 [0.48 – 1.83]
20 to 29	641,337	22.26	7	0.31 [0.13 – 0.65]
30 to 39	670,202	30.84	16	0.52 [0.30 – 0.84]
40 to 49	587,373	56.99	33	0.58 [0.40 – 0.81]
50 to 59	605,059	135.02	85	0.63 [0.50 – 0.78]
60 to 69	516,438	269.19	152	0.56 [0.48 – 0.66]
70 to 79	349,750	492.57	218	0.44 [0.39 – 0.51]
80+	182,669	1,082.94	626	0.58 [0.53 – 0.63]
Total	4,185,404	2,103.21	1,147	0.55 [0.51 – 0.58]

a. Expected and observed deaths among people who have received dose 2 of the Comirnaty vaccine during the specified period, by age group. Inclusion criteria were: monitoring time of 21 days after receiving dose 2, all genders, all ethnicities, aged 5 years and older. The data was collected from the Mortality database.

b. Data for expected death rates was obtained from the AESI background rate (SAFE) study provided by the University of Auckland (however, please note that the publicly available information only shows rates of sudden death not all deaths). The age-specific background rates used are the average from 2008-2019.

c. The observed deaths column is a raw data observation, and this is used to calculate the relative risk (5th column).

d. The relative risk has not been calculated for the 0 - 9 age group because no deaths were observed during the monitoring period.

Table 8: Observed-versus-expected deaths[a] by age group from any cause, up to 21 days after Comirnaty dose 3, 19 February 2021 to 30 September 2022

Age	Dose 3 – number administered	Expected deaths[b] in monitoring period	Observed deaths[c] in monitoring period	Relative risk[c] (95% confidence interval)
10 to 19	83,891	1.56	0	- [d]
20 to 29	343,629	11.91	<6	- [e]
30 to 39	424,042	19.48	8	0.41 [0.18 - 0.81]
40 to 49	427,625	41.46	18	0.43 [0.26 – 0.69]
50 to 59	488,019	108.83	56	0.51 [0.39 – 0.67]
60 to 69	458,863	239.07	111	0.46 [0.38 – 0.56]
70 to 79	330,651	465.50	217	0.47 [0.41 – 0.53]
80+	177,019	1,049.05	558	0.53 [0.49 – 0.58]
Total	2,733,743	1,936.87	972	0.50 [0.47 – 0.53]

a. Expected and observed deaths among people who have received dose 3 (including the 'booster' dose) of the Comirnaty vaccine during the specified period, by age group. Inclusion criteria were: monitoring time of 21 days after receiving dose 3, all genders, all ethnicities, aged 12 years and older. The data was collected from the Mortality database.

b. Data for expected death rates was obtained from the AESI background rate (SAFE) study provided by the University of Auckland (however, please note that the publicly available information only shows rates of sudden death not all deaths). The age-specific background rates used are the average from 2008-2019.

c. The observed deaths column (4th column) is a raw data observation, and this is used to calculate the relative risk (5th column).

d. The relative risk has not been calculated for the 10 - 19 year olds because no deaths were observed during the monitoring period.

e. The relative risk has not been calculated for the 20 - 29 year olds because fewer than six deaths have occurred in this age group.

For further reading about the methodology used to analyse death rates, see:

- Centers for Disease Control and Prevention (CDC) – Rapid Cycle Analysis (RCA) to monitor the safety of COVID-19 vaccines in near real-time within the Vaccine Safety Datalink. URL: https://www.cdc.gov/vaccinesafety/pdf/VSD-1342-COVID19-RCA-Protocol_FinalV1.1_508.pdf
- Kulldorff M, Davis RL, Kolczak M, et al. A maximised sequential probability ratio test for drug and vaccine safety surveillance. Sequential Analysis 30(1): 58–78. URL: https://www.tandfonline.com/doi/full/10.1080/07474946.2011.539924.

Download the data used to calculate the number of expected deaths in the monitoring period:

Expected mortality data (Excel 23 KB)

Adverse events of special interest

Adverse events of special interest (AESI) are pre-specified medically significant events that have the potential to be causally associated with the vaccine and must be carefully monitored. AESI can be serious or non-serious and can include:

- Events of interest due to their association with COVID-19 infection
- Events of interest for vaccines in general (eg, to the specific vaccine type or adjuvants).

The list of AESIs below takes into consideration the lists of AESIs from expert groups such as the Brighton Collaboration, manufacturers and other regulatory authorities. The AESI list changes based on the evolving safety profile of vaccines. It is

important to note that although these adverse events may occur after being vaccinated with a COVID-19 vaccine in New Zealand, they are rare and may not necessarily be related to the vaccine. Medsafe and CARM review the reports to determine whether the vaccine may have played a role in the occurrence of these events.

Table 9: Adverse events of special interest (AESI) up to and including 30 November 2022

AESI Category	AESI	Comirnaty total[a]	Background rate (hospitalisations per year)[b]
Immune system disorders	Guillain-Barré Syndrome	35	273
	Thrombocytopenia	38	4,325
	Thrombosis with thrombocytopenia syndrome (TTS)	n/a[c]	
	Anaphylaxis[d]	128	1,102
Cardiovascular system	Myocardial infarction (heart attack)	104	16,347
	Myocarditis/pericarditis	974	931
Blood and lymphatic system	Thrombosis	67	2,863
	Embolism	162	4,571
	Deep vein thrombosis (DVT)	130	519
	Vasculitis	78	4,325
	Haemorrhage[e]	168	
Hepato-gastrointestinal and renal system	Acute kidney injury	30	38,631
	Acute liver injury	8	420
	Pancreatitis	15	3,359
	Appendicitis	23	6,048
Nervous system	Aseptic meningitis	<6	744
	Encephalitis	13	409
	Stroke	136	14,776
	Bell's Palsy/facial paralysis	230	694
	Myelitis/myelitis transverse	9	53
Infections and musculoskeletal	Erythema multiforme	21	97
	Arthritis	135	178
	Herpes zoster	412	1,148
Pregnancy, puerperium and perinatal conditions	Abortion (spontaneous abortion /miscarriage)	67	2,680

a. Includes all AESI reports, both serious and non-serious. Counts below 6 are reported as <6 for privacy reasons. Counts may change due to receipt of additional information and subsequent reclassification of cases. The Vaxzevria vaccine was phased out in September 2022 and there is no new safety data. Therefore, Vaxzevria data is not included in this table, for previously published information please refer to the previous safety report (#45)

b. AESI background hospitalisation rates used to estimate the expected number of events in the general population, which help in vaccine safety surveillance. Counts indicate average of hospitalisation rates for the calendar years 2016-2019.

c. The thrombosis with thrombocytopenia syndrome (TTS) AESI occurs only in non-replicating viral vaccines (eg, the Vaxzevria vaccine)

d. Includes anaphylaxis reports meeting levels 1-3 of the Brighton Collaboration case definition.

e. Haemorrhage can manifest in different ways depending on the mechanism and anatomic location. It is difficult to know if the haemorrhage was minor or significant through the hospitalisation background rates.

Download a list of all ICD-10 codes used to produce the hospitalisation rates for Table 9.

ICD-10 Codes (Excel, 17 KB)

Further information on Myocarditis and Pericarditis

Please see Safety Report #45 for information on myocarditis and pericarditis.

Summary of safety signals

There have been no new safety signals identified since the last safety report. Medsafe will continue to monitor reports for safety signals through routine pharmacovigilance.

Table 10: Summary of Medsafe's investigations into possible safety signals

Safety signal	Outcome
Comirnaty vaccine	
Blood clots	Continue to monitor. See also the Monitoring communication
Appendicitis	Continue to monitor
Myocarditis/pericarditis	Information has been added to Comirnaty data sheet. See also the Alert communication. Medsafe will continue to monitor this closely.
Herpes zoster	Continue to monitor
Bell's palsy/facial paralysis	Continue to monitor
Menstrual disorder	Continue to monitor. See also the monitoring communication.
Stroke	Continue to monitor
Tinnitus	Continue to monitor
AEFIs in the elderly	Continue to monitor and updated data sheet
Pancreatitis	Continue to monitor
Glomerular diseases	Continue to monitor
Guillain-Barré Syndrome	Continue to monitor
Thrombocytopenia	Continue to monitor
AEFIs in children	Continue to monitor
Erythema multiforme	Continue to monitor
Pregnancy	Continue to monitor. See also the monitoring communication.
Persisting disability	Continue to monitor
Thyroid conditions	Continue to monitor
Vasculitis	Continue to monitor
Vaxzevria vaccine	
Overview of AEFI reports to date	No safety signals identified
Nuvaxovid vaccine	
Myocarditis/pericarditis	Information has been added to the Nuvaxovid data sheet. See the alert communication. Medsafe will continue to monitor this closely.

Definitions

Adverse event following immunisation (AEFI)
An AEFI is an untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Serious adverse event following immunisation

An AEFI is considered serious if it:

- is a medically important event or reaction
- requires hospitalisation or prolongs an existing hospitalisation
- causes persistent or significant disability or incapacity
- is life threatening
- causes a congenital anomaly/birth defect
- results in death.

It is possible for different people to have experienced the same event but for the report to be serious for one person and non-serious for another person.

Adverse events of special interest (AESI)
An AESI is a pre-specified medically significant event that has the potential to be causally associated with the vaccine product based on past experience, the technology used to make the vaccine or the infection the vaccine is used to protect against. AESIs need to be carefully monitored and any potential association to vaccination confirmed by further analysis and studies.

Safety signal
Information on a new or known adverse event that may be caused by the vaccine and requires further investigation. Safety signals can be detected from a wide range of sources such as CARM reports, clinical studies and scientific literature.

Valid report
There are only four requirements for a valid AEFI report:

1. one patient identifier (eg, name, initials, gender, date of birth, age)
2. suspect medicine(s)
3. suspected reaction(s)
4. reporter details.

These four requirements are the minimum requirements. However, including more information in the report helps Medsafe to investigate the reaction more quickly. Reporting is easiest online.

More information

See the data sheets and consumer medicine information for the expected reactions for approved COVID-19 vaccines.

COVID-19 Vaccine Safety Monitoring Process

View Ministry of Health COVID-19 vaccine data

Latest listing of all cases received

The latest listing of AEFIs received is included in the attached spreadsheet. Medsafe advises patients NOT to make any decisions about vaccination based on information contained here.

Download AEFI-line-listing.xlsx (Excel, 4087 KB)