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17 June 2024

s 9(2)(a)

Ref: H2024041985

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 22 May 2024 for information regarding the Pfizer COVID-19 Comirnaty vaccine. Each part of your request is responded to below:

> *"A SMARS search for the Comirnaty original covid vaccine for the period January 2021 to 31 December 2023 lists the following suspected adverse event reports:*
> *Cardiac arrest 34*
> *Cardiac failure 67*
> *Cardiomyopathy 20*
> *Myocardial infarction 108*
> *Myocarditis 480*
> *Pericarditis 634*
>
> *1. Please provide a breakdown by age groups for the 480 myocarditis reports/events, the 634 pericarditis reports, the 108 myocardial infarction reports, the 20 cardiomyopathy reports, the 67 cardiac failure reports and the 34 cardiac arrest reports following the Comirnaty original covid vaccine. Also please supply a breakdown of gender for each of these adverse event report categories.*
> *2. Please supply the number of myocarditis reports/events for 12 years and under age group and for 13 years to 30 year age group following the Comirnaty original covid vaccine, or the closest possible age banding.*
> *3.Please supply the number of pericarditis reports/events for the 12 years and under age group and for 13 years to 30 year age group following the Comirnaty original covid vaccine, or the closest possible age banding."*
> *4. Please supply a breakdown of the median time from the date of vaccination to the onset of the suspected reaction of myocarditis and pericarditis*

The information you have requested is attached to this letter as Appendix 1. Appendix 1 contains tables that provide a breakdown of age groups and adverse events. Please note that not all reports have age or sex reported. Please also note that not all a report of an event does not mean that it was clinically verified or related to vaccination. For example, in the review of myocarditis and pericarditis published here https://www.medsafe.govt.nz/COVID-19/safety-report-45.asp there were 931 reports of myocarditis or pericarditis of which 500 provided evidence of a clinical diagnosis. This report also provides information on age for those reports with evidence of a clinical diagnosis.

5. *Please advise whether there has been any follow up by Medsafe in respect of the myocarditis and pericarditis reports to determine how the person is progressing?*

Medsafe is the medicines regulator, not a health care provider. Therefore, Medsafe is not involved in providing healthcare and does not routinely follow up cases reported to CARM. However, reporters can update their CARM report if they wish to do so.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe

Appendix 1: Adverse event reports following vaccination with Comirnaty by age group and gender

Cardiac arrest

Age group	Number of adverse events reported
≤44	6
45-64	11
65 to 74	6
75+	10

Gender	Number of adverse events reported
Female	19
Male	24

Cardiac failure

Age group	Number of adverse events reported
≤44	12
45-64	22
65 to 74	12
75+	20

Gender	Number of adverse events reported
Female	32
Male	35

Cardiomyopathy

Age group	Number of adverse events reported
≤44	5
45-64	10
65+	5

Gender	Number of adverse events reported
Female	8
Male	12

Myocardial infarction

Age group	Number of adverse events reported
≤44	19
45-64	33
65 to 74	21
75+	31

Gender	Number of adverse events reported
Female	28
Male	81

Myocarditis*

Age group	Number of adverse events reported
0-17	39
18 -44	275
45-64	106
65 to 74	30
75+	23

Gender	Number of adverse events reported
Female	210
Male	268

*****Median onset time of 3 days

Pericarditis**

Age group	Number of adverse events reported
0-17	35
18-44	409
45-64	132
65 to 74	35
75+	13

Gender	Number of adverse events reported
Female	262
Male	368

**Median onset time of 4 days