MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

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s 9(2)(a)

Ref: H2024036455

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your requests under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 21 February 2024. For ease of reference, your requests have been consolidated and will each be addressed under this response letter:

> *I understand there are approximately 190 reports of death to CARM (and SMARS) following the Pfizer covid-19 vaccine. Please advise how many of these reports of death involved an autopsy?*

This part of your request is refused under section 18(g)(i) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

> *Please advise the number of serious adverse event reports Medsafe notified to VAERS since 1 January 2021 in respect of the Pfizer covid-19 vaccines.*

Medsafe has not notified the Vaccine Adverse Event Reporting System (VAERS) of any serious adverse event reports relating to the Comirnaty vaccine since 1 January 2021.

> *How many deaths reported to Medsafe following covid-19 vaccination were filed by doctors, pharmacists and/or vaccinators. How many death reports were from an individual member of the public? Please provide a figure for each group identified in this question.*

We have interpreted this part of your request to be for the Pfizer COVID-19 Comirnaty vaccine. A list of how many deaths were reported following vaccination is provided in Table One. Where there are duplicate reports, we are only providing one of the reporter types. Please note the database does not have a category for vaccinators; however, some pharmacists may be vaccinators.

Table One: Number of deaths reported to Medsafe following vaccination with Comirnaty

Reporter	Deaths
Consumer	85
Doctor	52
Pharmacist	5

In the absence of a post-mortem following a reported death (or a coroner's report), please advise how Medsafe determines whether there is a causal connection with covid-19 vaccination. Does Medsafe seek further information from the person's family, their GP or elsewhere as part of their investigation and determination on causation. Please provide all guidelines, protocols, minutes, emails and reports including all Teams, Signal and WhatsApp communication discussing reports of death temporally connected to covid-19 vaccination.

Medsafe does not determine cause of death. Information about the process followed is publicly available in accordance with section 18(d) of the Act. You can find information here:

- COVID-19 Safety Monitoring: www.medsafe.govt.nz/COVID-19/safety-monitoring.asp
- Independent Safety Monitoring Board Minutes and Reports: www.tewhatuora.govt.nz/for-the-health-sector/vaccine-information/vaccine-service-delivery/covid-19-vaccine-delivery/vaccine-strategy-planning-and-insights/who-were-working-with/#covid-19-vaccine-independent-safety-monitoring-board-cv-ismb

Please advise the total number of myocarditis and pericarditis reports/events in CARM or SMARS from 1 January 2021 to 31 December 2023 relating to the Pfizer covid-19 vaccines. Please provide the exact figure from your own search of SMARS rather than the search link; Please provide a breakdown of the ages and gender of all myocarditis reports from 1 January 2021 to 31 December 2023

Please note that while the Act allows New Zealanders to ask for information from Ministers and government agencies, there is no requirement for agencies to create new information or compile information they do not hold. In preference to refusing your request under section 18(g)(i) of the Act, you may wish to refer to the following publicly available information:

- The Suspected Medicines Adverse Reaction Search: www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp.
- The number of reports per age band can be found in the safety reports here: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

You state there have been 6,323 reports of serious adverse events. Please confirm the time period in which these reports were received.

The time period for the 6,323 reports of serious adverse events is from the start of vaccination to mid-July 2023 for all forms of the Comirnaty vaccine. The Ministry apologises for any confusion with dates between different OIA responses. Please note the data provided is current at the time of the response. The decision was made to provide a total number as splitting by time periods gives inaccurate numbers due to changes in the way the data was coded during this time.

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