

27 July 2023

s 9(2)(a)

Ref: H2023029281

Tēnā koe

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Haoura (the Ministry of Health) on 18 July 2023. Each part of your request is responded to below:

I note that the Covid-19 Vaccine Safety reports ended on 30 November 2022. Are you able to direct me to the reports for 2023 and / or where I find that data

Medsafe will continue to publish safety information for COVID-19 vaccines on our website in line with the information published for all other medicines and vaccines approved for use in New Zealand. However, this will no longer be in the previous format of safety reports for COVID-19 Vaccines. Therefore, your request for the 2023 safety reports is refused under section 18(g)(i) of the Act as the information is not held by Manatū Hauora or any other agency subject to the Act.

Due to the reduced number of COVID-19 vaccines being administered and therefore reduced numbers of adverse events following immunisation (AEFI) being reported, AEFI data from 30 November 2022 that would have previously been published in the COVID-19 safety reports is currently withheld under the following grounds of the Act:

- Section 9(2)(a) to protect the privacy of natural persons;
- Section 9(2)(ba) protect information which is subject to an obligation of confidence, where the making available of the information— would be likely to prejudice the supply of similar information, and it is in the public interest that such information should continue to be supplied; and
- Section 9(2)(c) to avoid prejudice to measures protecting the health or safety of members of the public.

Where information is withheld under section 9 of the Act I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

The final report dated 30 November 2022 noted that there were 184 deaths reported to CARM. Are you able to provide for all of those 184 deaths.

As noted in the safety report, by chance, some people will experience new illnesses or die from a pre-existing condition shortly after vaccination, especially if they are elderly. Out of these 184 deaths, medical assessments by CARM and Medsafe determined at the time of the report's release 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 were 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 (awaiting Coroner's determination).

More information on how Medsafe conducts its review processes is publicly available here: www.medsafe.govt.nz/COVID-19/safety-report-46.asp.

I trust the above response fulfils this part of your request. However, please note if you were seeking copies of individual AEFI reports, this information would be withheld to protect the privacy of natural persons.

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



Derek Fitzgerald
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Medsafe