

15th February 2023

Steven Cranston

By email: fyi-request-21556-c3d0804c@requests.fyi.org.nz
Ref: H2023019217

Tēnā koe Steven

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 13 January 2023.

On 7 February 2023, you were contacted by Manatū Hauora to clarify part of your request. We asked if you could please clarify what this part of your request was referring to:

“A recent Medsafe report titled - Adverse events following immunization with Covid19 vaccines, has been used by the Ministry of Health to dismiss concerns that Covid vaccines may result in an increased chance of death.”

On the same day you responded with:

“The information I requested is specifically regarding the use of voluntary data to assess vaccine deaths”.

Please find a response to each part of your request below.

A recent Medsafe report titled - Adverse events following immunization with Covid19 vaccines, has been used by the Ministry of Health to dismiss concerns that Covid vaccines may result in an increased chance of death. This report references deaths that are voluntary reported to CARM so can not give an accurate assessment of all vaccine related deaths.

Does the Ministry of Health have any research or documents that includes ALL deaths recorded in the 21 days after receiving a Covid-19 vaccine?

This information you have requested is included in Medsafe’s COVID-19 vaccine safety reports, which are publicly available at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

The observed versus expected (O/E) analysis for the Pfizer COVID-19 Comirnaty vaccine compares the number of deaths recorded in the mortality register for people vaccinated to the natural death rate (average number in previous years) over a 21-day period.

Can the Ministry of Health release all documents or communication related to the limitations of the Medsafe report relying on voluntarily reported deaths data?

Does the Ministry of Health have any documents or communication that demonstrates they acknowledge voluntary reported data is not suitable for making statistically robust conclusions about Covid-19 vaccine related deaths?

As outlined above, the Medsafe safety report includes an O/E analysis of deaths recorded in the mortality register within 21 days after vaccination. In addition, a summary of the deaths reported to the Centre for Adverse Reactions (CARM) for the Pfizer COVID-19 Comirnaty vaccine is also provided. The limitations of the spontaneous reporting system are publicly available at the following links:

- www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Vaccine-safety.asp
- www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medicines-Safety-and-Pharmacovigilance.asp

Can the Ministry of Health provide all communication, emails or documents between the Ministry of Health and other entities or individuals relating to the decision to use voluntary reported deaths as opposed to using data on all deaths?

As noted above, the pharmacovigilance system is explained in the links provided to you. There are no documented decisions in scope of the request. Therefore, this part of your request is refused under section 18(e) of the Act, as the information requested does not exist. The safety monitoring in place for COVID-19 vaccines uses both spontaneous reporting and statistical analysis of the mortality register.

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