

4 November 2021

By email: [REDACTED]
Ref: H202113975

Dear [REDACTED]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 11 October 2021 for information related to COVID-19 vaccination. Please find a response to each part of your request below:

Up to and including 18 September 2021 a total of 68 deaths were reported to CARM after the administration of the Comirnaty vaccine. Also, up to 30 June within 21 days of the administration of either one or two vaccines a total of 749 people died. From this information can the relevant agencies please provide:

- How many of these recorded deaths received compensation for the deaths and what amounts?*
- With these compensation payouts can you provide copies of the non-disclosure agreements?*
- A total payout to date for these deaths?*

On 14 October 2021, these parts of your request were transferred to the Accident Compensation Corporation (ACC) in accordance with section 14(b)(i) of the Act. You can expect a response from ACC in due course.

Any and all correspondence from internal meetings and how these are to be communicated to with the media outlets.

Material arising from internal meetings is not generally proactively shared with media. All official information, including correspondence and meeting minutes can be requested by any person, including media outlets, and will be provided subject to the provisions of the Act. However, the Ministry of Health (the Ministry) did release this media statement on 30 August 2021 on the one vaccine-related death recorded to date: www.health.govt.nz/news-media/media-releases/clinicians-reminded-be-aware-myocarditis-and-pericarditis-symptoms.

Can you please provide for the last ten years all other vaccine related deaths (can be combined in one) and charted next to the deaths against the Pfizer vaccine.

Reports of fatal outcomes for other vaccines is publicly available at: www.medsafe.govt.nz/publications/OIA/19Sept19ADRReportsWithDeath.pdf. Please note, there has only been one death possibly related to vaccination with Comirnaty in New Zealand, and this is explained on the weekly Adverse Effects Following Immunisation (AEFI) report. This case has been referred to the coroner for determination. All the other deaths are either under investigation or unrelated to vaccination with Comirnaty. In the observed versus expected analysis, there has been no increase in deaths since the introduction of Comirnaty vaccination supporting the conclusion that deaths are not related to vaccination.

Can Medsafe also confirm how there was justification to approve this vaccine when it did in July 2021 when there were statistics on government websites of the 1,000's of deaths recorded in overseas countries?

In response to this part of your request it is important to note that the Act allows people to ask for official information. It does not require the Ministry confirm or prove an opinion. This part of your request asks the Ministry to confirm a justification. As such, this part of your request is refused under section 18(g) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by any other agency subject to the Act.

What is the drop-dead date for Pfizer to complete outstanding conditions?

On 28 October 2021 Medsafe renewed its provisional approval of the Pfizer Comirnaty vaccine until 3 November 2023. Pfizer New Zealand has met all obligations required to date by the conditions of the provisional approval granted in February 2021, including provision of additional data about the clinical trials and vaccine monitoring. Medsafe will continue to receive and assess data from Pfizer about the administration of the vaccine and may grant full approval during this period once Pfizer has submitted a relevant application and information. There is more information at: www.health.govt.nz/news-media/news-items/medsafe-renews-covid-19-vaccine-provisional-approval while the Gazette notice is available at: www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette-Oct-2021.pdf.

How many deaths are required before Medsafe will revoke vaccine?

It appears this part of your request is misinterpreting coincidental events with causal events. Vaccine approval is based on benefits versus risks analysis. As the deaths referred to earlier in your request are not related to vaccination (apart from one suspected case), they do not impact the benefit risk of the vaccine. Further information on the Medsafe approval process can be found at:

- www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medicines-Safety-and-Pharmacovigilance.asp
- www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp
- www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Vaccine-safety.asp
- www.medsafe.govt.nz/COVID-19/monitoring-process.asp

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 Ministry of Health website at: www.health.govt.nz/about-ministry/information-releases.

Yours sincerely



Chris James
Group Manager
Medsafe

Please note since the signing of this OIA request there are now eight conditions attached to the renewal of the Pfizer vaccine. There were previously 58 conditions. 50 of them were met by the deadlines so when it was renewed there are only eight conditions attached now. This can all be found in the Gazette notice: www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette-Oct-2021.pdf