

1 November 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022014029

Dear 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 Manatū Haoura (the Ministry of Health) on 4 October 2022 regarding information on COVID-19 vaccinations. Each part of your request is responded to below:

Is there a specific threshold of reported deaths, disablements, and other harms beyond which Medsafe would withdraw its approval for medicine in general as well as for the COVID-19 vaccines? (e.g. is there a relevant policy in place)? If so, what is that threshold/what is the policy?

Medsafe's approval of a medicine (including vaccines) is based on the benefit risk profile, both before approval is granted and in use. Therefore, there is no number that triggers a withdrawal of approval for medicine. Further information can be found in the Medsafe websites below:

- COVID-19 Vaccine Evaluation and Approval Process: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp
- Medsafe's Evaluation and Approval Process: www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp
- COVID-19 Vaccine Safety Monitoring Process: www.medsafe.govt.nz/COVID-19/monitoring-process.asp
- How Does Medsafe Monitor Vaccine Safety: www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Vaccine-safety.asp

Does Medsafe currently hold information about under-reporting of adverse events to CARM for vaccinations in general, and for the COVID-19 vaccinations in particular? If so, what information are those estimates based on?

Medsafe does not hold the information requested and there is no requirement under the Official Information Act 1982 (the Act) for agencies to create new information, provide an opinion or compile information that is not part of the usual reporting process. Your request for this information is therefore refused under section 18(g) of the Act.

Did Medsafe receive information about the autopsies carried out by the coroner or anyone else for the 171 deaths reported post-COVID-19 vaccination? If so, I request a copy of this information.

Medsafe is unable to provide you information about the autopsies carried out by the Coroner to protect the privacy of a natural persons, including deceased natural persons. As such, your request is withheld under section 9(2)(a) of the Act. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Does Medsafe hold information in which it has asked the coroner or anyone else to undertake autopsies in relation to the 171 deaths reported post-COVID-19 vaccination? If so, how many autopsies were requested and to what protocols?

Medsafe does not request autopsies as this function aligns with the role of Coroners, an independent judicial officer. As such, your request is refused under section 18(g). The process for recording and investigating deaths is outlined on the Coroner's website here: <https://coronialservices.justice.govt.nz/about/what-a-corer-does/>

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.

Yours sincerely



Chris James
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Medsafe