

11 June 2021

Ross Francis

By email: fyi-request-15522-2faa30b9@requests.fyi.org.nz

Ref: H202106608

Dear Ross Francis

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 27 May 2021 regarding reactions to the COVID-19 vaccine in New Zealand.

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

"1. What are the 10 severest reactions to the COVID-19 vaccine (excluding death) in New Zealand?"

Please note severity is considered an opinion. It can apply to any event including a headache. Medsafe therefore does not systematically collect information on reaction severity to the COVID-19 vaccine. With it being an opinion, some people may provide this in their adverse events following immunisation (AEFI) reports, however it is unclear if severity information is provided by everyone and in the same way. There are also no internationally accepted criteria to define severity. We are therefore unable to provide you with such information. As such, this part of your request is refused under section 18(e) as the information requested does not exist.

Medsafe however does publish some information on serious AEFI reports as an overview which are included in the Weekly COVID-19 Vaccine Reports. These reports can be accessed here: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

An AEFI is considered serious if it is:

- A medically important event or reaction
- Requires hospitalisation or prolongs an existing hospitalisation
- Causes persistent or significant disability or incapacity
- Is life threatening
- Causes a congenital anomaly/birth defect
- Results in death

Please note it is possible for different people to have experienced the same event but for the report to be serious for one person and non-serious for another person.

To find additional information on the top 10 AEFI reactions in New Zealand please see here: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-safety-and-approval/covid-19-vaccine-side-effects-and-reactions.

“2. How many reports have there been of each of the 10 severest reactions to the COVID-19 vaccine (excluding death) in New Zealand?”

As aforementioned, the Ministry does not collect data based on severe reactions therefore this part of your request is refused under 18(e) of the Act as the information requested does not exist.

“3. Does CARM keep records of each individual severe reaction to the vaccine? If so, where is such information published?”

Reports to the Centre for Adverse Reactions Monitoring (CARM) are kept in a database. Information is publicly published and accessed here: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

“4. Are vaccine recipients provided with any information about the 10 severest reactions before they are vaccinated?”

Known adverse reactions are recorded in the data sheet. This can be publicly accessed and searched here: www.medsafe.govt.nz/Medicines/infoSearch.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.

Yours sincerely



Chris James
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Medsafe