MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

22 November 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022016370

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 Hauora (the Ministry of Health) on 6 November 2022. Please find a response to each part of your request below.

> *1. Seeing as the Pfizer Phase 3 clinical trial was still in progress when NZ was subjected to mandates, and that the whole world is now in the phase 4 trial of postmarking and surveillance, how is Medsafe participating in this phase?*

Pfizer has consent to distribute the COVID-19 Comirnaty vaccine and it is administered in the same way as other medicines in New Zealand. It is incorrect to suggest that the vaccine rollout in New Zealand was a clinical trial.

> *2. What procedures and protocols have been set up in NZ to report accurately on this phase?*

This part of your request is refused under section 18(e) of the Act, as the information requested does not exist. New Zealand is not conducting a clinical trial for the COVID-19 Comirnaty vaccine. Medsafe's processes for monitoring the safety of all medicines and vaccines in use in New Zealand are publicly available on the Medsafe website: www.medsafe.govt.nz/COVID-19/safety-monitoring.asp.

> *3. In NZ, are the number of injections being recorded against the onset of a new disease e.g. cancers or autoimmune conditions, worsening of a disease, or death of a person who received the injection? If not, why not?*

We have interpreted this part of your request as asking whether Medsafe or Manatū Hauora engages in a comparative exercise between COVID-19 vaccinations and new diseases or medical conditions in a general sense. Medsafe and Manatū Hauora do not report in this way and doing so would be of no value without establishing a causal link between COVID-19 vaccinations and other conditions. Therefore, this part of your request is refused under section 18(g) of the Act, as the information requested is not held by Manatū Hauora or any other agency subject to the Act.

Adverse events following an immunisation with any vaccine can be reported to the Centre for Adverse Reactions Monitoring (CARM) by anyone. For COVID-19 vaccines, a summary of these reports is published here: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

4. As we're in the phase 4 trials, any death of a person who took the injection should be investigated. Are all deaths, whether 1, 2, 3, or any number of weeks, following the injection being investigated? If not, why not?

New Zealand is not conducting a clinical trial for the COVID-19 Comirnaty vaccine; therefore this part of your request is also refused under section 18(e) of the Act, as the information requested does not exist.

As stated above, Medsafe's safety monitoring processes are published on the Medsafe website and a summary of reports to CARM regarding COVID-19 vaccines are also published on the Medsafe website.

5. Are autopsies for the spike-protein being carried out in all persons who have died at any time after uptake of the injection? If not, why not?

Referrals for autopsies are not made by Medsafe or Manatū Hauora. This decision is made by the family of the deceased person with support from the healthcare workers involved in the patient's care. When autopsy results are available, Manatū Hauora requests the findings of the post-mortem which are then used to review the relationship between vaccination and the cause of death as determined from the post-mortem. Manatū Hauora does not determine the cause of death. For more information, you may wish to contact the Coronial Services team at Ministry of Justice by email at: coronial.information@justice.govt.nz or by calling 04 466 2789 or 04 466 2786.

6. Why haven't ALL the side effects of the injection ever been reported in the media?

Information concerning the known side-effects of the Pfizer COVID-19 vaccine can be found here: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.

Manatū Hauora cannot comment on what media outlets choose to report about COVID-19 vaccinations, as they are separate entities that are responsible for the material they produce. If you have concerns about a media entity, we suggest you contact the New Zealand Media Council. You can find more information about the New Zealand Media Council's complaint procedure here:
www.mediacouncil.org.nz/complaints/.

7. Clause 57 of the document of "Provisional Consent to the distribution of a new medicine", dated 3 Feb 2021, stated that Medsafe would provide monthly reports as well as safety reviews that are conducted or they become aware of. Where have these monthly reports and safety reviews been posted for public awareness?

The New Zealand Gazette lists the obligations placed on the sponsor (Pfizer) by Medsafe. It does not create an obligation for Medsafe to produce monthly safety reports. As stated earlier in this response, you can find the safety reports created by Medsafe here:
www.medsafe.govt.nz/COVID-19/vaccine-report-overview.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 Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
Group Manager
Medsafe