

10 May 2021

Virginia Crawford

By email: fyi-request-15189-85a329eb@requests.fyi.org.nz
Ref: H202104627

Dear Virginia Crawford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 19 April 2021 for missing information in the Risk Management Plan. Information in response to each part of your request is below.

Request 1: Your Risk Management Plan (RMP) mentioned the following "missing information". Use in pregnancy and while breast feeding Use in immunocompromised patients use in frail patients with co-morbidities use in patients with autoimmune or inflammatory disorders interaction with other vaccines. Could you please provide an update on each of the above? Is that information coming solely from Pfizer or are other sources included? What information do you have regarding VAED/VAERD?

Medsafe does not hold this information as it is the responsibility of the vaccine company. Medsafe has not received an update to the risk management plan (RMP) since the public summary was published on its website or since the European Medicine Act (EMA) published the full report.

Please be advised, all information within the scope of your request for 'information regarding VAED/ VAERD' is publicly available on the Medsafe website: www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf or can be found here: www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf

Request 2: Please could you explain the rationale for making it mandatory for front line staff to be injected with a vaccine that is still experimental, when you are STILL insisting that they are being regularly tested?

The Act enables people to request official information from the Director-General and the Ministry of Health (the Ministry). However, the Act only applies to information that is already held by the Ministry. There is no obligation for the Ministry to create information in order to respond to a request. The Ministry is also not obliged to provide an opinion. This part of your request is therefore refused under section 18(g)(i) of the Act, as it is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

Information regarding testing and vaccination of front-line staff is publicly available at:

- www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-information-specific-audiences/covid-19-resources-border-sector
- www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-strategy-and-planning

I trust this information fulfils your request. 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 website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

A handwritten signature in blue ink that reads "Clare Perry". The signature is written in a cursive, flowing style.

Clare Perry
Deputy Director-General
Health System Improvement and Innovation