

11/02/2021

Virginia Crawford

By email: fyi-request-14492-f5b3ebf2@requests.fyi.org.nz

Ref: H202100619

Dear Virginia Crawford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 1 February 2021 for follow up information relating to your previous request for regarding COVID vaccines.

You asked the following:

"These vaccines are all still being trialed [sic] and some of these trials will not be completed until 2023.

Does this mean that Medsafe will recommend that these vaccines be used "under emergency", as is happening in most of the world? Surely they cannot be fully licensed in New Zealand while they are still being trialed [sic]?"

It is not unusual for companies to apply for medicines to be approved before the completion of all clinical trials. Medsafe's evaluation and approval process for COVID-19 vaccines is described here: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp

One vaccine (Comirnaty) has been provisionally approved for use in New Zealand to address an urgent clinical need. Available online are:

- Minutes of the Medicines Advisory Committee that considered the application by Pfizer New Zealand Ltd: www.medsafe.govt.nz/committees/maac/Recommendation109-2February2021.htm
- Gazette notice authorising the sale, supply and use of the vaccine: www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette.pdf
- Data sheet for health professionals: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf
- Consumer information: www.medsafe.govt.nz/Consumers/CMI/c/comirnaty.pdf

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, appearing to read 'Chris James', with a stylized flourish at the end.

Chris James
Group Manager
Medsafe