

Virginia Crawford

By email: fyi-request-15059-x@xxx
Ref: H202103948

Dear Virginia Crawford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 3 April 2021 for:

"The Comirnaty vaccine is being rolled out to far more than "a limited number of patients" and there appears to be no restriction in doing so.

The Ministry of Health and other members of the Government (including the Prime Minister) are constantly reassuring the public that the vaccine is "safe and effective".

It would appear that on both counts, the Ministry is in breach of the Medicines Act.

Could you please explain by what authority the Ministry is able to do this?"

I refer you to the Comirnaty data sheet that was approved by Medsafe as part of the provisional consent process, which you can find on the Medsafe website at:

www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf

The data sheet includes: *"COMIRNATY has provisional consent (see section 5.1) for the indication: Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older. The use of this vaccine should be in accordance with official recommendations.*

I also refer you to the Medsafe website for information on the evaluation and approval process www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp for COVID-19 vaccines.

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



Chris James
Group Manager
Medsafe