

Greg Keen

By email: fyi-request-14993-582ee030@requests.fyi.org.nz

Ref: H202103598

Dear Greg Keen

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 25 March 2021 for:

“What is the limited number of patients who can receive treatment with this medicine while it is under the status of 'provisionally approved'?”

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:

<https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf>. The data sheet provides:

“COMIRNATY has provisional consent (see section 5.1) for the indication below:

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 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



Derek Fitzgerald
Acting Group Manager
Medsafe