

Virginia Crawford

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Ref: H202100723 and H202102151

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 5 February 2021 for:

“In the interest of informed consent, will each person receiving a vaccine be told that it's an experimental vaccine, or at least that it has been licensed conditionally?”

Without this information, it would be reasonable to assume that the vaccine is 100% safe and effective and since vaccine trials are not scheduled to be completed until 2023, no guarantees can be given until a full licence has been granted in New Zealand.

Please do not refer me to the Medsafe website - I would like to know if every person giving the vaccine will be instructed to inform each vaccinee of the vaccine's actual status.”

This was then followed by another request on 1 March 2021 for:

“Could you please let me know if intended recipients of the current (or future) vaccine(s) are, or will be, informed that at the present time, these vaccines are still EXPERIMENTAL, that there is no guarantee that they won't get infected, or possibly transmit the infection to others.”

As your requests are seeking similar information, the Ministry has made the decision to combine these requests into one response.

In response to your request, Medsafe, New Zealand's independent medicines regulatory authority, gave provisional approval to the Pfizer/BioNTech COVID-19 vaccine (Comirnaty) to be used in New Zealand on 3 February 2021. With the approval of the vaccine, a data sheet for health professionals and consumer information has been published that provides information about the efficacy and safety of the vaccine and any precautions or advice for health professionals and consumers before and after a person is vaccinated. The documents about Comirnaty are publicly available at:

- Data sheet: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf
- Consumer information: www.medsafe.govt.nz/Consumers/cmi/c/comirnaty.pdf

Information about other vaccines will be published when they are approved by Medsafe. More information about New Zealand's vaccination programme is available at:

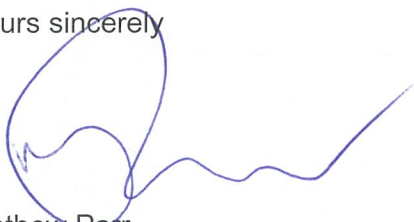
www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines

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



Mathew Parr

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