

14 June 2021

Virginia Crawford

By email: fyi-request-15493-098f2be0@requests.fyi.org.nz
Ref: H202106063

Dear Virginia Crawford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 18 May for:

"I note that the Australian version of the Cominarty vaccine insert, states the following:

"This vaccine has provisional approval in Australia to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults and adolescents from 16 years of age and older. This approval has been granted on the basis of short term safety and efficacy data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed."

This essential information (or the appropriate New Zealand version of it) has NOT been included in either of the two information leaflets (Data Sheets or CMI's) available in New Zealand.

Without this information, persons vaccinated or to be vaccinated in New Zealand, do NOT have proper INFORMED CONSENT.

Please explain discrepancy"

The provisional status of Pfizer vaccine in New Zealand is publicly available on the Ministry of Health's website www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-safety-and-approval/covid-19-assessing-and-approving-vaccines. Information regarding the approval process can be found on the Medsafe website www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.

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 black ink, appearing to be 'Nick Allan', with a long horizontal stroke extending to the right.

Nick Allan
Manager OIA Services
Office of the Director-General