

18 March 2021

Virginia Crawford

By email: [fyi-request-14712-e9d7938f@requests.fyi.org.nz](mailto:fyi-request-14712-e9d7938f@requests.fyi.org.nz)  
Ref: H2021001468

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 February 2021 for information relating to the COVID-19 vaccine. You provided the following background information to your request:

*“The FDA has stated the following:*

*All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:*

*This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older; and*

*The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.*

[www.fda.gov/media/144412/download](http://www.fda.gov/media/144412/download)

*Could you please confirm that a similar protocol will be instituted in New Zealand, i.e. that all recipients of the vaccine will be given a leaflet or other documentation to indicate that this vaccine has been given temporary approval only in New Zealand and is not yet fully licensed for use in this country.*

This information is not held by Medsafe, which is a business unit of the Ministry of Health (the Ministry). The information you are seeking would require Medsafe to form an opinion or create information to answer your request. The Act does not support these types of request. Therefore, this part of your request is refused under section 18(g) as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

However, legal information about this vaccine is publicly available at:

- The minutes of the Medicines Assessment Advisory Committee, established under the Medicines Act 1981, that considered the application by Pfizer New Zealand Ltd: [www.medsafe.govt.nz/committees/maac/Recommendation109-2February2021.htm](http://www.medsafe.govt.nz/committees/maac/Recommendation109-2February2021.htm)
- The New Zealand Gazette notice authorising the sale, supply and use of the vaccine: <https://gazette.govt.nz/notice/id/2021-go338> [The Gazette is the official authoritative journal of the New Zealand Government].
- The data sheet, required by the Medicines Regulations 1984, for health professionals: [www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf](http://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf)
- Consumer information: [www.medsafe.govt.nz/Consumers/CMI/c/comirnaty.pdf](http://www.medsafe.govt.nz/Consumers/CMI/c/comirnaty.pdf)
- Letter to Health Professionals: [www.medsafe.govt.nz/safety/DHCPLetters/ComirnatyFeb2021.pdf](http://www.medsafe.govt.nz/safety/DHCPLetters/ComirnatyFeb2021.pdf)  
[www.medsafe.govt.nz/COVID-19/status-of-applications.asp](http://www.medsafe.govt.nz/COVID-19/status-of-applications.asp)

Further to the information above, I specifically draw your attention to the Consent Form and the related *What to Expect* pamphlet that have been prepared for people receiving the Pfizer Comiranty vaccine. This information has been previously publicly released and is available at: [www.health.govt.nz/system/files/documents/information-release/h202101370\\_12\\_march\\_2020\\_covid\\_vaccine\\_information\\_to\\_recipients.pdf](http://www.health.govt.nz/system/files/documents/information-release/h202101370_12_march_2020_covid_vaccine_information_to_recipients.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](mailto: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](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests)

Yours sincerely



Nick Allan  
**Manager OIA Services**  
**Office of the Director-General**