

11 January 2023

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022018695

Dear s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 15 December 2022, for information about the COVID-19 Comirnaty (Pfizer) Vaccine. Please find a response to each part of your request below.

Copies of all reports provided to Medsafe/MOH that satisfy the requirements of conditions 56 and 57 in the Gazette Notice at: <https://www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette.pdf>

- 56. Provide Periodic Safety Update Reports according to the same schedule as required by the EMA.
- 57. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.

Information relating to this part of your request is withheld in full under the following sections of the Act:

- Section 9(2)(b)(ii) – where its release would likely unreasonably prejudice the commercial position of the person who supplied the information; and
- Section 9(2)(ba)(i) – to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source.

Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Copies of any documents that outline/state that outline what authorised use of the Comirnaty vaccine for a 13-year-old is on 1 October 2022, which when breached would result in the use being described as "off-label use."

I refer you to the publicly available data sheets for the COVID-19 vaccines:

- Comirnaty (Pfizer) Vaccine: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.
- Vaxzevira previously known as COVID-19 Vaccine AstraZeneca: www.medsafe.govt.nz/profs/Datasheet/c/Covid19VaccineAstraZenecainj.pdf.
- NUVAXOVID also known as the Novavax COVID-19 vaccine: www.medsafe.govt.nz/profs/Datasheet/n/Nuvaxovidinj.pdf.
- Janssen: www.medsafe.govt.nz/profs/Datasheet/c/COVID19VaccineJansseninj.pdf.

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 Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Chris James', with a stylized flourish at the end.

Chris James
Group Manager
Medsafe