

4 October 2024

Erika Whittome

By email: [fyi-request-25124-c3ff613b@requests.fyi.org.nz](mailto:fyi-request-25124-c3ff613b@requests.fyi.org.nz)  
Ref: H2024050978

Tēnā koe Erika

### **Response to your request for official information**

Thank you for your follow up request to the Ministry of Health – Manatū Hauora (the Ministry) on 9 September 2024. You requested:

*“Where is the information on how 8 conditions were originally specified in the Gazette for provisional approval and then those 8 conditions can be discarded?  
Would you kindly share the minutes, memos correspondence etc on how the original 8 conditions can be discarded?”*

On 25 September 2024, you were contacted by the Ministry and were asked to clarify what you were meaning by the 8 conditions specified in the Gazette in order for the Ministry to proceed with your request. On the same day you responded with the following:

*“The provisional approval in the Gazette for the Comirnaty medicine had 8 conditions. You have told me that original conditions are no longer applicable. Changes were processed through a changed Medicine notification. The changes were processed through a changed medicine notification under section 24 of the Medicines Act 1981. Kindly share the information for how those 8 conditions have been abandoned and now processed with a "changed medicine notification". Please include all meeting minutes, memos, correspondence etc to come to the decision to abandon those 8 original conditions.”*

To clarify, the conditions of provisional consent for Comirnaty (Pfizer) COVID-19 vaccine which you referenced in your request were not abandoned. Therefore, this part of your request is refused under section 18(e) of the Act, as the information does not exist. The sponsor company Pfizer New Zealand Limited submitted an application to Medsafe on 20 June 2023 to convert this provisional consent to full consent under section 20 of the Medicines Act 1981. This application was assessed by Medsafe, which included consideration of all data provided by Pfizer to date to address the conditions of provisional consent, and full consent was granted on 15 November 2023. Conditions are not typically applied to full consent under section 20 for medicines, as was the case for Comirnaty.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: [oiagr@health.govt.nz](mailto:oiagr@health.govt.nz).

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 Manatū Hauora 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).

Nāku noa, nā

A handwritten signature in blue ink, appearing to read 'Derek Fitzgerald', is positioned above the printed name.

Derek Fitzgerald  
**Acting Group Manager**  
**Medsafe**