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24 August 2023

Catherine Jamieson

By email: fyi-request-23680-1b4b2b14@requests.fyi.org.nz
Ref: H2023030117

Tēnā koe Catherine,

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Haoura (the Ministry of Health) on 3 August 2023 for information regarding the Comirnaty (Pfizer) COVID-19 vaccine. Please find a response to each part of your request below:

> *Prior to the December 2022 Medsafe consents granted in respect of bivalents containing Famtozinameran and Riltozinameran, has the product composition of Comirnaty BNT162b2 entering New Zealand (other than that for use in the under 12s) altered at any time from the original product imported into New Zealand in the first delivery in early 2021?*
> *If so what was(were) the date(s) any product of altered composition was imported into NZ, and date(s) first used on consumers. By composition category please supply batch numbers, the sites those batches were distributed to for administration and on what dates. Please also supply any reports, emails or other correspondence pertaining to:*
> *i. any altered product composition; or*

The qualitative formulation for Comirnaty 0.5mg/ml has not changed since its initial approval. Product details of the Comirnaty vaccine can be found on Medsafe's website at: www.medsafe.govt.nz/regulatory/ProductDetail.asp?ID=21938.

> *ii. expectation or otherwise that New Zealand authorities would receive advice of any altered product composition including, but not limited to, to Tozinameran.*

Changes to the formulation of medicines must be notified to Medsafe via a changed medicine notification. I refer you to Medsafe's guidelines, specifically the overview of regulatory processes for new and changed medicines. Section 20 and 24 of the Medicines Act 1981 outlines the requirements for new and altered medicines to be distributed in New Zealand, including the need for the Minister of Health and the Director-General of Health to be advised and provide consent.

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.

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.

Nāku noa, nā

Chris James
Group Manager
Medsafe