133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

28 September 2023

Catherine Jamieson

By email: fyi-request-23680-1b4b2b14@requests.fyi.org.nz
Ref: H2023031399

Tēnā koe Catherine

Partial transfer of 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 2 September 2023 for information regarding the product composition of Comirnaty vaccines. Some of the information you have requested is held by Te Whatu Ora - Health New Zealand, specifically:

> *"2. If so what was(were) the date(s) any product of altered composition was imported into NZ, and date(s) first used on consumers?*
>
> *3. By composition category please supply batch numbers, the sites those batches were distributed to for administration and on what dates."*

For this reason, I have decided to transfer parts 2 and 3 of your request to Te Whatu Ora under section 14(b)(i) of the Act. You can expect a response to these parts from their agency in due course. Please accept our apologies for the delay in partially transferring 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 or by calling 0800 802 602.

Nāku noa, na

Jan Torres
Manager, OIA Services
Government and Executive Services | Te Pou Whakatere Kāwanatanga

COPY OF OIA REQUEST

Catherine Jamieson fyi-request-23680-1b4b2b14@requests.fyi.org.nz Sat 2/09/2023 10:51 am

Dear OIA Requests,

Most of my request does not relate to 'details regarding quantitative formulations', can be answered without referring to any detail and therefore not likely to unreasonably prejudice a commercial position.

As per August 2019 Ombudsman Commercial Information report mentioned in an annotation to this request string, a mere assertion of prejudice is not sufficient and agencies need to be able to explain how release of the information at issue would be likely unreasonably to prejudice a commercial position.

An excerpt from page 19:-

'If an agency is a regulator, it may hold commercially sensitive information about the quality of a product or the practices of an organisation. There are strong public interest arguments in allowing access to information that will help protect the public from unsafe products or practices.'

If there was more than one product composition for COMIRNATY® and Pfizer BioNTech Covid-19 products distributed and administered for the 12+ age group prior to 21 December 2022 approval of the bivalent products, there is a strong public interest argument in allowing access to the requested information. What follows below is an excerpt example of such transparency from the United States:-

https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fweb.archive.org%2Fweb%2F20211030000557%2Fhttps%3A%2F%2Fwww.fda.gov%2Fmedia%2F153716%2Fdownload&data=05%7C01%7Coiagr%40health.govt.nz%7C1a09e58e7c034b6190c708dbab3de496%7C23cec7246d204bd19fe9dc4447edd1fa%7C0%7C0%7C638292054549717225%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=v%2BUVCV6rO7h8L7Viwldq0Y94sSILZHeYenNiHj5z0x8%3D&reserved=0

'Pfizer-BioNTech COVID-19 vaccines for individuals 12 years of age and older contain 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered:

- potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose OR

- tromethamine, tromethamine hydrochloride, and sucrose '

For simplicity most questions in my initial request are relabelled below. Q1 can be answered with a yes or no answer. Q2 and Q3 ask solely for dates and a separation of batch numbers into categories that can be differentiated from one another using a heading that provides no detail with regard to quantitative formulation. Q4 can be answered without reference to details regarding quantitative formulations.

1. 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?

2.If so what was(were) the date(s) any product of altered composition was imported into NZ, and date(s) first used on consumers?

3. By composition category please supply batch numbers, the sites those batches were distributed to for administration and on what dates.

4 Please also supply any reports, emails or other correspondence pertaining expectation or otherwise that New Zealand authorities would receive advice of any altered product composition including, but not limited to, to Tozinameran.

Please also confirm the name and/or job title and agency of the person referring to themselves as 'I' in the 31 August response who considers that the public interest of a response does not outweigh the need to withhold at this time.

Yours faithfully,

Catherine Jamieson