

133 Molesworth Street PO Box 5013 Wellington 6140 New Zealand T+64 4 496 2000 W www.medsafe.govt.nz

5 June 2024

ASE

By email: fyi-request-26670-533950da@requests.fyi.org.nz

Ref: H2024041059

Tēnā koe ASE

## Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 8 May 2024 for:

- "1- Are/were the same manufacturing processes used to manufacture Comirnaty® and BNT162b2? Has The Ministry of Health confirmed such information with the manufacturer/supplier?
- 2- What information is held by The Ministry of Health regarding similarities and differences between the manufacturing processes of BNT162b2 and Comirnaty®?
- 3- Are there any quantifiable differences between BNT162b2 and Comirnaty®, eg regarding the use or presence of SV40 sequences, the presence of DNA, the integrity of synthetic mRNA, the use of methyl-pseudouridine, or any other quantifiable differences?"

BNT162b2 is now named Tozinameran,.It is the active ingredient in the original Pfizer COVID-19 Comirnaty vaccine. You can search in the Medsafe database for details of approved medicines here: <a href="https://www.medsafe.govt.nz/regulatory/DbSearch.asp">www.medsafe.govt.nz/regulatory/DbSearch.asp</a>

Regarding any changes to Comirnaty since its approval, the specific changes to the methods of manufacture of Comirnaty are proprietary to Pfizer; however, broadly speaking common changes to vaccine manufacture include improvements in the efficiency of the manufacturing process through the implementation of state-of-the-art equipment and technologies, upgrades to facilities and processes, replacement of consumables, extensions or reductions in the time taken for certain steps to be performed, refinements to product controls based on increased manufacturing experience, and so on.

, 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: <a href="mailto:oiagr@health.govt.nz">oiagr@health.govt.nz</a>.

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: <a href="mailto:info@ombudsman.parliament.nz">info@ombudsman.parliament.nz</a> 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: <a href="www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests">www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests</a>.

Nāku noa, nā

Chris James Group Manager Medsafe