MEDSAFE
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12 February 2025

ASE

By email: fyi-request-26670-533950da@requests.fyi.org.nz
Ref: H2025059109

Tēnā koe

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 26 December 2024 for:

> *"Did the manufacturing processes used to obtain any kind of regulatory approval for any "COVID-19 vaccines" and covid "vaccine candidates" significantly and materially change since the applications for approval were first submitted?*
>
> *As more reports have been indicating that manufacturing methods did significantly change subsequent to applications for approval being made, what actions has the Ministry of Health taken to investigate such claims? eg, has the Ministry of Health directly questioned the suppliers, applicants, and other stakeholders about this?"*

As per your previous response ref: H2024041059, 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.

The Medsafe website describes changed medicine notifications: https://www.medsafe.govt.nz/.

Various aspects of medicine manufacturing change over time, for all products, including COVID vaccines. These are evaluated by Medsafe in the same way that new medicine applications are. Please see the following link for more information on the evaluation process: medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp.

I trust this information fulfils your request. 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