

ASE  
[fyi-request-21539-83e09f32@requests.fyi.org.nz](mailto:fyi-request-21539-83e09f32@requests.fyi.org.nz)

Tēnā koe ASE,

**Your request for Official information, reference: HNZ00011844**

Thank you for your email of 20 February 2023 requesting the following information under the Official Information Act 1982 (the Act):

*“Please advise where I can find batch-level release assessment (and underlying test/assessment data) of COVID-19 “vaccines” imported into and/or used in New Zealand”*

Please see our response to your request below:

Health New Zealand are responsible for the release of all batches of the Comirnaty (Pfizer/BioNTech) COVID-19 vaccine, and receive copies of Certificates of Analysis for all batches received in New Zealand.

Approved medicines supplied to New Zealand, including vaccines such as the Comirnaty (Pfizer/BioNTech) vaccine, must be manufactured under Good Manufacturing Practice (GMP). This includes Quality Control (QC) testing sites. When making a medicine application, sponsor companies need to provide evidence that manufacturing sites are certified by a recognised regulator. More information on this process is available here:

- [www.medsafe.govt.nz/Medicines/manufacturing.asp](http://www.medsafe.govt.nz/Medicines/manufacturing.asp)

The product testing for sterile vaccines, such as Comirnaty, include tests for sterility and tests for particulate contamination. Only batches that have undergone and passed full testing may be released for distribution in New Zealand.

In addition to testing undertaken by the manufacturer of Comirnaty, Condition #2 on the provisional consent (approval) granted for Comirnaty in New Zealand, requires results of independent test certification must be made available to Medsafe on request. Please note that we cannot supply this information as the information is confidential to the pharmaceutical company. For more information you may refer to the gazette notices for all Comirnaty vaccines here:

- <https://www.medsafe.govt.nz/COVID-19/status-of-applications.asp>

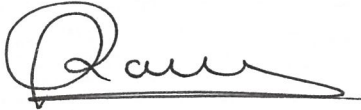
**How to get in touch**

If you have any questions, you can contact us at [hnzOIA@health.govt.nz](mailto:hnzOIA@health.govt.nz).

If you are not happy with this response, you have the right to make a complaint to the Ombudsman. Information about how to do this is available at [www.ombudsman.parliament.nz](http://www.ombudsman.parliament.nz) or by phoning 0800 802 602.

As this information may be of interest to other members of the public, Te Whatu Ora may proactively release a copy of this response on our website. All requester data, including your name and contact details, will be removed prior to release. The released response will be made available on our website.

Nāku iti noa, nā



Astrid Koornneef  
**Interim Director, Prevention**  
**National Public Health Service**  
**Te Whatu Ora – Health New Zealand**