

22 April 2024

Erika Whittome

By email: [fyi-request-26209-d888de09@requests.fyi.org.nz](mailto:fyi-request-26209-d888de09@requests.fyi.org.nz)  
Ref: H2024038268

Tēnā koe Erika

### 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 24 March 2024 for information relating to the Comirnaty (Pfizer) COVID-19 vaccine. Please find a response to each part of your request below.

*The New Zealand gazette has many obligations published February 2021  
Would you please supply the information in this obligation #54 for the provisionally approved product, Comirnaty. I will copy and paste the condition:  
54. Provide any reports on efficacy including asymptomatic infection in the vaccinated group, vaccine failure, immunogenicity, efficacy in population subgroups and results from post-marketing studies, within five working days of these being produced*

Information relating to this part of your request is refused in full under section 18(g)(i) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

Please note, any changes to contraindications and/or warnings and precautions regarding use in pregnancy, lactation, or particular population/patient subgroups', are by changed medicine notification process.

*When did the Medsafe quit using Salesforce to store adverse event reports?*

The COVID-19 vaccination database was a temporary database built to manage the increase in reporting through the COVID-19 vaccine rollout and link to the Covid Immunisation Register (CIR). As it was a temporary database, it had limited scope and restricted capabilities for recording non-essential information for pharmacovigilance.

The data is stored in the Adverse Reaction Source of Truth (ADRSOT) and Salesforce domain houses the database, which also stores data.

*Did the ministry of health join or apply to join ICH? (*  
<https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ich.org%2F&data=05%7C02%7Coiagr%40health.govt.nz%7Ca639abb590c44a03055d08dc4b67077c%7C23cec7246d204bd19fe9dc4447edd1fa%7C0%7C0%7C638468153084373165%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6Ij1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=rNxi3zgwX%2BrARLEe7wUbUVO0Trt7L5EI04n%7C>

[2FsKMKGqQ%3D&reserved=0](#) If so, please share the minutes for this decision to join?

The Ministry did not join or apply to join the International Council for Harmonisation (ICH). The Ministry does not need to join ICH to use its guidelines.

*Please share the procurement documents for agreeing to deploy an E2B system for immunization and safety data?*

*Please supply the RFP for this procurement of a new system to store immunization and safety/pharmacovigilance*

*How much were the annual licensing fees for Salesforce for medsafe or the ministry of health for this safety monitor report from safesforce?*

*Please share the annual software licensing costs for this new E2B system.*

*Please share which vendor has supplied it?*

Information relating to these parts of your request is withheld in full under section 9(2)(b)(ii) of the Act, where its release would likely unreasonably prejudice the commercial position of the person who supplied the information. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

*Is this E2B data housed on NZ soil in NZ data centers? If not, where please?*

The E2B data is available in the cloud base system.

*How is the functionality of the E2B data format for “clinical safety data management” appropriate for the New Zealand population who are not in a clinical setting at all?*

This is standard for data as it has no impact on individuals’ healthcare.

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](mailto: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](mailto: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](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests).

Nāku noa, nā



Chris James  
**Group Manager**  
**Medsafe**