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17 January 2022

Paul Roberts

By email: fyi-request-17848-b607e5d0@requests.fyi.org.nz

Ref: H202117154

Tēnā koe Paul

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 (the Ministry) on 6 December 2021 for:

"...please provide the date the Ministry/Medsafe received such documentation from Pfizer showing the Cumulative Analysis of Post-authorization Adverse Event Reports, the same or similar to what was released in the above referenced document?"

The Ministry and Medsafe have received several requests for information related to the Cumulative Analysis Report and its publication in the United States. A comprehensive response that explains its genesis and relevance in New Zealand, and addresses your questions has been published at: www.health.govt.nz/system/files/documents/information-release/h202117570 response 0.pdf

As the published response notes, the Cumulative Analysis Report was created to meet a specific legal process in the <u>United States</u>. As it has no relevance to New Zealand's statutory processes, it was not provided by Pfizer. However, as the response also notes as a part of the provisional consent for the Comirnaty COVID-19 vaccine granted in <u>New Zealand</u> under the Medicines Act 1981, Pfizer has provided the same data, albeit in a form that meets the company's legal obligations in New Zealand. Therefore, your request is refused in part under section 18(e) of the Act because the information requested does not exist, and in part under section 18(d) because a response to the matters you have raised is publicly available.

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 Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Jan Torres

Acting Manager OIA Services
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