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28 June 2021

Virginia Crawford

By email: fyi-request-15189-85a329eb@requests.fyi.org.nz
Ref: H202107138

Tēnā koe Virginia

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 14 June 2021 for information relating to missing information on the Risk Management Plan.

You specifically requested:

> *"Please supply in full any further information you have regarding the "missing information" or any other similar matters arising from the Risk Management Plan, in accordance with the latest MARC committee meeting minutes."*

The 'missing information' refers to information on the safety of the medicinal product that is currently missing and needs to be collected. These areas are named in the Risk Management Plan (RMP) published on the Medsafe website here: www.medsafe.govt.nz/COVID-19/status-of-applications.asp. The RMP also describes the studies that are planned to address these areas of missing information.

Medsafe has not yet received any results from these studies and holds no new safety information on the areas of missing information. The New Zealand Data Sheet for Comirnaty will be updated as new information becomes available.

Therefore, your request for this information is refused 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.

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.

Nāku noa, nā

Chris James
Group Manager
Medsafe