

6 May 2022

Chuck Schooner

By email: fyi-request-18890-e9dc77bb@requests.fyi.org.nz
Ref: H202203979

Tēnā koe Chuck

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) received by the Ministry of Health (the Ministry) on 15 March 2022 for information relating to the COVID-19 Vaccine Independent Safety Monitoring Board (CV-ISMB). You specifically requested:

“Please provide all of the data / studies / minutes / discussions that the CV-ISMB used to determine that there is no evidence to support a link between menstrual disorders and Comirnaty administration.

How did the CV-ISMB determine that all of these menstrual disorders locally had no link to the gene therapy?”

The topic of menstrual disorders and Comirnaty administration was discussed by the CV-ISMB on 24 June 2021 and 27 October 2021. The CV-ISMB reviewed the available evidence, including Adverse Event Following Immunisation (AEFI) reports submitted to the Centre for Adverse Reactions Monitoring (CARM); a memo discussing menstrual disorders/ unexpected vaginal bleeding; and also, the international published literature and post-marketing safety reports provided by the sponsor (Pfizer). Based on the available information, the CV-ISMB determined there was no evidence to support a link between menstrual disorders and Comirnaty. It was, however, recommended that Medsafe continue to monitor this issue.

Following this discussion, Medsafe published a monitoring communication. You can read about this here: www.medsafe.govt.nz/safety/Alerts/comirnaty-menstrual-disorders.asp.

An update on the topic was also published in Medsafe’s Safety Report #36, which may be of interest to you: www.medsafe.govt.nz/COVID-19/safety-report-36.asp.

Information within scope of this request is itemised in Appendix 1 of this letter and copies of the documents are enclosed. The table in Appendix 1 outlines the grounds under which I have decided to withhold information. Where information is withheld under section 9 of the Act, 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.

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 of Health website at: www.health.govt.nz/about-ministry/information-releases.

Nāku noa, nā

A handwritten signature in blue ink, appearing to read 'Astrid Koornneef', written over a horizontal line.

Astrid Koornneef

Director
National Immunisation Programme

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	22 June 2021	Comirnaty vaccine and menstrual disorders/ unexpected vaginal bleeding	Released with some information withheld under the following sections of the Act:
2	27 October 2021	Comirnaty vaccine and menstrual disorders/ unexpected vaginal bleeding – update	<ul style="list-style-type: none"> • 9(2)(a) to protect the privacy of natural persons; • 9(2)(ba)(i) to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source; and • 9(2)(g)(ii) maintain the effective conduct of public affairs through the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment.
3	22 June and 27 October 2021	CV-ISMB meeting minutes	<p>A copy of these documents is refused under section 18(d) of the Act, as the information will soon be made publicly available here:</p> <p>www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-strategy-planning-insights/covid-19-who-were-working.</p>