

5 October 2023

Erika Whittome

By email: fyi-request-22655-496ef40a@requests.fyi.org.nz
Ref: H2023031808

Tēnā koe Erika

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 19 September 2023, as a follow up to information previously provided to you (H2023025222 and H2023024581 refers). You requested information relating to the document titled: *PREGNANCY AND LACTATION CUMULATIVE REVIEW, BNT162b2, Cumulative Review from Pharmacovigilance Database*. Specifically, you requested:

“Please confirm whether Pfizer or any other entity has provided information consistent with the information and data contained in the above report to any New Zealand health or government agency. If so please confirm which agency and on what date.”

As you have been previously advised:

The report you refer to titled *PREGNANCY AND LACTATION CUMULATIVE REVIEW, BNT162b2, Cumulative Review from Pharmacovigilance Database*, was produced for the Food and Drug Administration (FDA) only and was not received by Medsafe from Pfizer.

As per the conditions imposed on the provisional approval for Comirnaty vaccines, the manufacturer has been providing Medsafe with safety reports. Effects of medicines on pregnancy and lactation is a topic of interest in these reviews. All reports received by the company including if there were any on these topics are summarised in these reviews.

Medsafe stands by this response and has nothing further to add. Please note, repeated requests for the same information may be considered vexatious and refused under section 18(h) of 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.

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.

Nāku noa, nā



Chris James
Group Manager
Medsafe