

10 May 2023

Erika Whittome

By email: [fyi-request-22655-496ef40a@requests.fyi.org.nz](mailto:fyi-request-22655-496ef40a@requests.fyi.org.nz)  
Ref: H2023024581

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 2 May 2023 for information regarding a report on pregnancy and lactation. You asked:

*“There is a report from the Comirnaty manufacturer, Pfizer called PREGNANCY AND LACTATION CUMULATIVE REVIEW, BNT162b2, Cumulative Review from Pharmacovigilance Database, approved on 21 Apr 2021 (FDA-CBER-2021-5683-0779745).*

[125742\\_S2\\_M1\\_pll-cumulative-review.pdf \(phmpt.org\)](#)

*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.*

*Please also confirm whether information, data or reports have been received from Pfizer or any other entity on the effects of any of the Pfizer Covid 19 vaccines on male fertility. If so please confirm to which agency and on what date.”*

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. Male fertility is not a topic of interest as it has not been identified as a safety signal. All reports received by the company including if there were any on these topics are summarised in these reviews.

I trust this information fulfils your request. 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**