

16 May 2023

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By email: [fyi-request-22655-496ef40a@requests.fyi.org.nz](mailto:fyi-request-22655-496ef40a@requests.fyi.org.nz)  
Ref: H2023025222

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 Haoura (the Ministry of Health) on 11 May as a follow up to the information provided to you in response to your previous OIA (reference: H2023024581). Each part of your request is responded to below in turn.

*You say Medsafe have received safety documents. "The manufacturer has been providing Medsafe with safety reports."*

*1. You have not specifically confirmed that Medsafe received this particular document dated 21 Apr 2021. I asked about this specific report from 21 Apr 2021.*

You previously requested (H20230245181 refers): *please confirm whether Pfizer or any other entity has provided information consistent with the information and data contained in the above report, to which Manatū Hauora provided you with a response.*

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.

*2. There are no dates supplied in your response. I asked:  
"If so please confirm which agency and on what date."*

As stated in the previous response (H20230245181 refers) male fertility is not a topic of interest as it has not been identified as a safety signal. Therefore, there are no dates or agencies to disclose.

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.

Nāku noa, nā



Chris James  
**Group Manager**  
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