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16 January 2023

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022018890

Tēnā koe s 9(2)(a)

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 21 December 2022. Please find a response to each part of your request below:

> *Is the Minister aware of Pfizer's own document "5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021" dmoanon.com/pdfs/5.3.6-pfizer-Adverse-Event-Reports.pdf*

Manatū Hauora understands that the report, *Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021,* (hereafter referred to as the Cumulative Analysis Report) was prepared by Pfizer as a part of its application to the Food and Drug Administration (FDA) in the United States for its Biologics License Application (BLA) for the Comirnaty COVID-19 vaccine. The BLA process followed the FDA earlier granting Emergency Use Authorization (EUA) for the use of the vaccine in December 2020. There is more information about the BLA process at: www.fda.gov/vaccines-blood- biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber.

As the Cumulative Analysis Report was prepared by Pfizer for a specific legal purpose for the FDA in the United States, Pfizer did not provide it to either Manatū Hauora or Medsafe as the BLA process does not exist in New Zealand.

However, I can advise that as a part of the provisional consent for the Comirnaty COVID-19 granted in New Zealand under the Medicines Act 1981, Pfizer has provided the same data, albeitin a form that meets the company's legal obligations in New Zealand.

> *Are all doctors, medical professionals and the general population aware of the 9 pages of adverse effects stated in Pfizer's own document "5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021" dmoanon.com/pdfs/5.3.6-pfizer-Adverse-Event-Reports.pdf and if not why not?*

The conclusions of the Cumulative Analysis Report are consistent with the information and data provided by Pfizer to Medsafe as a part of its provisional consent obligations in New Zealand. As Pfizer had met all theconditions required under the initial consent granted in February 2021, the provisional consent was renewed for a further two years on 28 October 2021. The renewed consent requires Pfizer tocontinue to provide data and analysis about the global administration

of the vaccine. There is more information at: www.health.govt.nz/news-media/news-items/medsafe-renews-covid-19- vaccine-provisional-approval.

> *Please provide all documents, meeting minutes, emails, and any other correspondence between the Ministry of Health, The Prime Minister and Medsafe where this document has been discussed.*

This part of your request is refused under section 18(e) of the Act, as the information requested does not exist.

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
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Medsafe