133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

1 April 2022

Chuck Schooner

By email: fyi-request-18836-6171ac7e@requests.fyi.org.nz
Ref: H202203980

Dear Chuck

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 10 March 2022 for information about the Pfizer Comirnaty COVID-19 vaccine. I will respond to each part of your request in turn.

> *Can you please provide the Pfizer Cumulative Analysis Report 5.3.6 that was provided by Pfizer in accordance with their application given this information is now publicly available so that we can see how the application compared to the data.*

The Ministry has previously advised you (H202117069 and H202117155 refers) of the genesis of the *Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021* document (hereafter the Cumulative Analysis Report) that was prepared in the United States to meet a specific legal purpose in that country. The Ministry's earlier response referred you to a comprehensive response that outlined its relevance to New Zealand and was published at www.health.govt.nz/system/files/documents/information-release/h202117570_response_0.pdf. Additionally, information related to Pfizer's application for provisional consent has previously been released under the Act (H202106950) and has been published at: www.health.govt.nz/system/files/documents/information-release/h202106950_response.pdf. This part of your request is refused under section 18(d) on the grounds that the information sought is publicly available.

> *Please provide any and all persons responsible for approving this vaccine and final recommendation reporting.*

Considering recent violent protests in Wellington against vaccination, and the potential harassment of Ministry employees, I am withholding the names of those people involved in the recommendation to grant provisional consent for the Comirnaty vaccine under section 6(d) of the Act. I can confirm, however, that as the Group Manager Medsafe, under delegated authority outlined above (H202106950), I granted provisional consent for the Comirnaty vaccine to be used in New Zealand.

> *Why did Medsafe approve a vaccine that showed 4.6% of the people that took the vaccine developed the virus that it was supposed to fight against? Is that now why we are seeing the virus in so many people? A side effect of the vaccine is Covid itself?!*

These parts of your request appear to be confusing coincidental events with causal events. The Pfizer Comirnaty vaccine does not contain the SARS-CoV-2 virus and does not infect patients

with COVID-19. Information about the transmissibility of the Omicron variant is also available at: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-health-advice-public/about-covid-19/covid-19-about-omicron-variant.

Information about the reasons for Medsafe's approval of the Comirnaty vaccine is publicly available at: www.health.govt.nz/news-media/news-items/medsafe-renews-covid-19-vaccine-provisional-approval while the Gazette notice is available at: www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette-Oct-2021.pdf.

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 website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
Group Manager
Medsafe