MINISTRY OF HEALTH
MANATŪ HAUORA

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

11 April 2022

Erika Whittome

By email: fyi-request-19065-8e5b24eb@requests.fyi.org.nz
Ref: H202205202

Tēnā koe Erika

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 6 April 2022 about the approval of the Pfizer Comirnaty COVID-19 vaccine. Specifically, you asked:

> *"1. Please provide the minutes for when Pfizer "post marketing" data was reviewed with "intense scrutiny" by Medsafe or the appropriate government authority (EPA or otherwise).*
> *2. Please provide the minutes for when Medsafe wrote their own safety data sheet for the Pfizer "Comirnaty" medicine.*
> *3. The Pfizer post marketing report is 38 pages long and lists 1,290 adverse events below copied from Appendix 1. Please provide the meeting minutes for when Medsafe redacted the "Comirnaty" adverse events reported by Pfizer and reduced the list to the following 4 rows in one table on Medsafe's safety data sheet in https://medsafe.govt.nz/Profs/datasheet/c/comirnatyinj.pdf.*
> *MEDSAFE Table 2:Adverse reactions from COMIRNATY post marketing experience*
> *System Organ Class Adverse Drug Reaction*
> *1. Immune system disorders :*
> *Anaphylaxis*
> *Hypersensitivity reactions (e.g. rash, pruritis, urticaria, angioedema)*
> *2. Cardiac disorders :*
> *Myocarditis*
> *Pericarditis*
> *Gastrointestinal disorders*
> *Diarrhoea*
> *Vomiting*
> *3. Musculoskeletal and connective tissue disorders:*
> *Pain in extremity (arm)*
> *4. General disorders and administration site conditions:*
> *Extensive swelling of vaccinated limbs*
> *PFIZER APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST*
> *FDA-CBER-2021-5683-0000083*
> *BNT162b2*
> *5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports (https://scanmail.trustwave.com/?c=15517&d=zOrM4ugvJChaX3p5jNhYDX_EFcqUHiWhwWlN5NBIWA&u=https%3a%2f%2fphmpt%2eorg%2fwp-content%2fuploads%2f2021%2f11%2f5%2e3%2e6-postmarketing-experience%2epdf)*

Your questions appear linked to the publication in the United States 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). The Ministry received several requests about the genesis of the Cumulative Analysis Report and has published three responses about it. These responses emphasise that the Cumulative Analysis Report was prepared in the United States to meet a specific legal purpose in that country. The responses

also emphasise that while adverse events following immunisation (AEFI) occur after vaccination that does not mean they were caused by vaccination. They then go on to outline how Medsafe and the Centre for Adverse Reactions Monitoring (CARM) at the University of Otago investigate and assess events to establish whether there is any link between AEFI and vaccination.

Three published responses are available under the 12 January 2022 publication date for *Information on Pfizer Cumulative Analysis Report* at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests. Several other responses have been published on FYI website. Your request is therefore refused under section 18(d) of the Act on the grounds that the information sought is publicly available.

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.

Nāku noa, nā

Jan Torres
Acting Manager, OIA Services
Office of the Director-General