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

8 February 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202117828

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 the Ministry of Health (the Ministry) on 20 December 2021 (10.35am, 11.19am, 11.28am, 11.43am and 11.55am) and on 21 December 2021 (3.27pm).

As all the requests were related to COVID-19 vaccines and vaccination, under section 16 of the Act the Ministry has consolidated them into one response to ease the administrative burden. Rather than repeat them verbatim, they are attached as Appendix 1 to this letter.

Several of your requests are related to the publication of the *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). The Ministry received several requests related to the publication of the Cumulative Analysis Report in the United States. A comprehensive response that outlines the genesis of this document, and its relevance to New Zealand has been published at: www.health.govt.nz/system/files/documents/information-release/h202117570_response_0.pdf. Therefore, these parts of your request are refused under section 18(d) of the Act on the grounds that the information requested is publicly available.

You have also sought similar information that was provided by Pfizer to Medsafe as a part of its application for provisional consent for the Comirnaty COVID-19 vaccine under the Medicines Act 1981, and subsequent information provided in meeting the conditions of that approval. You also sought similar information related to the paediatric dose of the Pfizer Comirnaty vaccine. The information you have requested under these parts of your request are withheld in full under section 9(2)(b)(ii) of the Act, to protect information where the making available of the information would likely unreasonably prejudice the commercial position of the person who supplied the information. Although the Ministry appreciates the high degree of public interest in its vaccination programme and the Pfizer vaccine, this does not outweigh the need to protect the commercial sensitivity of the information in the agreement. There is, however, a large amount of information publicly available about the vaccine, including at: www.medsafe.govt.nz/COVID-19/medicine-approval-process.asp. Clinical studies on the safety and efficacy of the Comirnaty vaccine have been published in a range of peer-reviewed medical journals, including *The New England Journal of Medicine,* for example: www.nejm.org/doi/full/10.1056/nejmoa2034577.

In several of your requests, you have asked the Ministry or Medsafe to comment on information and data you have provided as well as remarks and research attributed to researchers, institutions, and universities overseas. While the Act allows New Zealanders and people and organisations resident in New Zealand to request official information from Ministers and government agencies, there is no requirement under the Act for agencies to create new information, compile information they do not hold, or provide or prove an opinion. The Act does

not support requests where an opinion, comment or statement is put to the Ministry for response, couched as a request for information. Therefore, these parts of your requests are refused under section 18(g) on the grounds that the information is not held by the Ministry.

In several of your requests, you have suggested that Medsafe and/or the Ministry is undertaking a "trial" and there is an acceptable level of adverse events. These assertions are incorrect, and the Ministry rejects their premise as it is undertaking the distribution of an approved vaccine. Medsafe has given the Comirnaty vaccine provisional consent and determined that the benefits of vaccination with the Pfizer vaccine continue to greatly outweigh the risk of both COVID-19 infection and the side effects of vaccination. More information about the vaccine evaluation and approval process can be found here: medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.

Several of your requests relate to adverse effects following immunisation (AEFI). Medsafe has in place a robust process for monitoring the safety and efficacy of medicines, including vaccines. AEFI are reported to the Centre for Adverse Reactions Monitoring (CARM) at the University of Otago, which undertakes collection and analysis of individual reports of AEFI in New Zealand under contract to the Ministry. While reporting of AEFI (or any adverse event involving any medication) is voluntary, both Medsafe and CARM encourage their reporting and New Zealand historically has a high level of adverse event reporting. The form to report an AEFI with a COVID-19 vaccine is publicly available (https://report.vaccine.covid19.govt.nz/s/) and anyone – doctor, nurse, pharmacist, vaccinator, government agency, health consumer or a family member – can make a report.

While an AEFI can occur after vaccination, that does not mean it was caused by vaccination, which is why they are investigated by CARM. Reported adverse events for the COVID-19 vaccine are evaluated according to whether they are serious or non-serious according to certain criteria, such as if the person required hospitalisation. All reports are verified to check that:

- the person had a COVID-19 vaccine
- there is an identifiable person in the report
- an adverse event following immunisation (AEFI) has been reported
- there is a reporter who can be contacted for more information.

It is not uncommon that a report is received about the same event from both the vaccinator and the consumer, so there are checks to ensure an event is not reported twice.

Significant reports are medically assessed by CARM according to the World Health Organization guidance and if required, follow up is conducted to seek further information. Significant reports are also reviewed by the COVID-19 Vaccine Independent Safety Monitoring Board (CV-ISMB), which provides expert advice on a potential link to the vaccine. All potential safety signals investigated in New Zealand for the COVID-19 vaccine are presented and discussed with the CV-ISMB, with Medsafe providing an update on these in its regular safety report available at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

If an investigation finds a new side effect this is communicated through an alert communication and an update to the data sheet and Consumer Medicine Information Sheet (CMIS), for example, with Medsafe's report about myocarditis, available at: www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-alert.htm. This alert, for example, was widely publicised in the media and was accordingly added to the datasheet. A further alert was issued in December 2021 and is available at: https://medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-reminder.htm and www.health.govt.nz/news-media/media-releases/statement-covid-19-vaccine-independent-safety-monitoring-board.

Your references to AEFI involving deaths are based on a misunderstanding of the difference in certifying deaths (from whatever cause) and the reporting of AEFI. As noted above, while

anyone can report an AEFI and the process is voluntary, the certification of a death is a mandatory and statutory process. Unless a death is referred to the coroner for determination under the Coroners Act 2006, the medical or nurse practitioner responsible for the care of the deceased person is required under the Burial and Cremation Act 1964 to certify the cause of death. It is for this reason the process outlined above involving CARM, CV-ISMB and Medsafe is undertaken to assess whether an AEFI is linked to vaccination (i.e., is a side effect). Death is not a side effect to vaccination but a possible outcome of a side effect, therefore the CV-ISMB, CARM and Medsafe do not determine the cause of death but whether there is a plausible link between vaccination and a side effect that may have resulted in death. Guidance for certifying deaths from or with COVID-19 has been on the COVID-19 'Information for health practitioners' section of the Ministry's website since early in the COVID-19 pandemic at:

- www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-information-health-professionals/recording-covid-19
- www.health.govt.nz/our-work/regulation-health-and-disability-system/burial-and-cremation-act-1964/completing-death-documents/covid-19-deaths

To date, two deaths have been identified as linked to vaccination and are under the jurisdiction of the coroner. The coroner is an independent judicial officer working in the Coroner's Court with administrative support from the Ministry of Justice. As the courts are specifically excluded from the Act under section 2(6)(a), under section 18(c), the Ministry is refusing to provide any further information about these cases as to do so would constitute a contempt of court. There is more information at: www.health.govt.nz/news-media/media-releases/statement-covid-19-vaccine-independent-safety-monitoring-board.

Turning to the use of the Comirnaty vaccine among children and young people, as noted above, information provided by Pfizer related to its use is withheld in full under section 9(2)(b)(ii). However, Medsafe and the Ministry have published information on its use at:

- www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-health-advice/covid-19-vaccine-and-children-information-parents-and-caregivers
- www.medsafe.govt.nz/COVID-19/status-of-applications.asp#Comirnaty5

The Immunisation Handbook (chapter 5) (especially sections 5.2.1, 5.2.2 and 5.2.4) outlines the risks to children of COVID-19 and their role in transmitting the virus, as well the importance of vaccination in reducing transmission and serious illness. The Handbook is fully referenced with a wide range of peer-reviewed scientific research and is available at: www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19. Additionally, a range of peer-reviewed scientific research about the COVID-19 virus and vaccines has been published on *PubMed* by the National Center for Biotechnology Information at the National Institutes of Health in the United States at: https://pubmed.ncbi.nlm.nih.gov.

The Ministry has also responded to other requests seeking information about the recommendation to use the vaccine among 5-11 year-olds. It is available at: https://fyi.org.nz/request/17871/response/69604/attach/3/H202117274%20Response%20Binder.pdf.

Turning to your final request for information about vaccine batches and the number of serious AEFI linked to each one, batch numbers and diluent number details are recorded in the COVID Immunisation Register (CIR). When an AEFI report is made, the AEFI assessment is generated to include the CIR information alongside the information in the AEFI report. The AEFI assessment is used by CARM for the assessment of the adverse event. This means that if there any is reason to believe an adverse event or events may be the result of a specific batch, CARM has the capacity to utilise the batch number for the purpose of its assessment.

Whilst the batch numbers are linked to AEFI in the CARM database, the database does not support the generation of AEFI by batch number report in the manner you have requested. This would require a significant manual collation of information. There is no requirement under the Act for agencies to create new information. Therefore, this part of your request is refused under section 18(g) on the grounds that the information requested is not held.

There are several safeguards built into the provisional consent for the vaccine given by Medsafe. First, the vaccine is manufactured and tested according to the requirements of Good Manufacturing Practice (GMP) and the relevant sites are regularly inspected by regulators (for example, the United States Food and Drug Administration) to ensure the quality meets these requirements. Secondly, as part of Medsafe's evaluation process, the sponsor (Pfizer) must supply evidence of current GMP for manufacturing and testing sites. The sites of manufacture and testing are published at: www.medsafe.govt.nz/regulatory/ProductDetail.asp?ID=21938.

In addition, before being delivered to New Zealand, batches of the Pfizer vaccines are tested by a testing laboratory, independent of Pfizer. This independent testing has regulatory oversight, for example, by way of European Union Official Control Authority Batch Release certification. The Gazette notice that outlines these requirements 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.

Nāku noa, nā

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

Appendix 1

Request 1 – 20 December 2021 – 10.35am

The attached document is the first of many documents to be released by Pfizer/FDA as part of a court mandate by the US Supreme Court. It is a summary of adverse reactions/deaths of the Pfizer vaccine to immunise against Covid19. It is a summary from December 2020 - February 28, 2021. This document was approved for print on April 30,2021.

https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

Please advise if Medsafe is in receipt of this clinical information and if so what was the date of receipt? Please also confirm the actual number of Pfizer vaccinations worldwide as of February 28,2021.

Page 7 outlines the deaths and adverse reactions to the Pfizer vaccine after 3 months on the market. Can Medsafe please forward the equivalent adult data set they received from Pfizer, the FDA or the CDC when the vaccine was under trial for a similar period of time. Please confirm the actual number of vaccinations in the adult Pfizer trial.

Page 8 bar graph outlines the serious adverse effects compared to total adverse effects. Can Medsafe please forward the equivalent data set they received from Pfizer, the FDA or the CDC when the vaccine was under trial for a similar period of time. Please confirm the actual number of vaccinations in the adult Pfizer trial.

Page 8 table 2 outlines the adverse effects > 2% rate of occurence. Can Medsafe please forward the equivalent data set they received from Pfizer, the FDA or the CDC when the vaccine was under trial for a similar period of time.

Pages 14-15 table 6 outlines the lack of efficacy of the vaccine at 3.9%. Can Medsafe please forward the equivalent data set they received from Pfizer, the FDA or the CDC when the vaccine was under trial for a similar period of time. Please confirm the actual number of vaccinations in the adult Pfizer trial.

Pages 30-38 outlines all the potential adverse effects of special interest. Can Medsafe please explain why only a few of those on the list are actually recorded on the Medsafe website?

Request 2 – 20 December 2021 – 11.19am

The summary below records the number of serious adverse effects from vaccines in NZ.

Year	Total Adverse Effect	Serious Adverse Effect	Serious Adverse/Total Adverse Effect %
2016	1385	141	3.6%
2017	1236	137	3.6%
2018	1473	157	3.6%
2019	1531	152	3.6%
2020	1269	133	3.6%
2021 April - Nov 20	37094	1462	3.9%
Average 2016-2020	1379	144	3.6%

With 15 times the number of serious adverse effects from the Pfizer vaccine why hasn't Medsafe set any safety standards after 8 months on the market? Surely just having the vaccine should be recorded as a safety issue given this sheer number of serious adverse effects?

Columbia University in the US has recently reported from their research that adverse effects can be under reported by up to 20 times! This therefore must be an important part of the product safety equation as vaccine safety should be paramount to the continuation of a trial.
Given that advising of adverse effects is voluntary (and therefore under reported) can Medsafe please advise what action they have taken to inform those being vaccinated of their obligation to report any adverse reaction?

Given that Medsafe still hasn't defined their safety parameters, what information does Medsafe rely upon to allow the continuation of the Pfizer vaccine trial?

In particular I request that Medsafe advise what are acceptable levels of serious adverse effects (given that they are grossly under reported)?

We now know the Pfizer vaccine does not stop infection rates or transmission in vaccinated individuals. Can Medsafe please advise what are acceptable levels of infection and transmission in vaccinated individuals for the trial to be considered successful?

We have had 117 reported deaths and a total of 1462 serious adverse reactions as of November 20,2021 from the Pfizer vaccine. As of today's date we have 49 recorded deaths from Covid19. Can Medsafe please advise what information they rely upon to continue with the trial when serious adverse effects are nearly 30 times the recorded deaths (even with under reporting)?

Request 3 – 20 December 2021 – 11.28am

Please forward the data received from Pfizer, the FDA or the CDC that satisfies any of the 28 outstanding special conditions relating to the provisional approval of the Pfizer Covid19 vaccine.

Request 4 – 20 December 2021 – 11.43am

On November 30,2021 I emailed Medsafe with concerns of product safety of the mRNA Pfizer vaccine. In this email I stated as below:

Firstly you need to be aware of medical research from Dr Bryam W Bridle PhD from Canada and a new bio distribution study in Japan which tracked the vaccine and spike proteins when it was injected into the deltoid muscle in the arm. This peer reviewed research has proven that the spike protein does not remain in the arm as previously thought and can travel through the blood vessels to other parts of the body. Within days of vaccination it accumulates in the spleen,the brain,bone marrow, liver, the adrenal glands and worryingly the ovaries. It will bind to platelets and result in clotting, bleeding,heart problems and brain blood clotting.

There are also implications for the blood donation service accepting blood from vaccinated people as their donation may well be contaminated with the spike protein pathogen.Refer below.

https://www.australiannationalreview.com/health/doctor-on-covid-vax-we-screwed-up-we-didnt-realize-the-spike-protein-is-a-toxin-does-this-mean-everyone-vaxinated-is-manufacturing-their-own-spike-protein-toxins-in-their

There is also new research that confirms the number of heart attacks and returning cancers is up many fold with very strong links to the mRNA vaccine uptake.

Given this research can Medsafe please advise what reviews have or are being done in order to provide NZer's better informed consent about the likely long term risks of the mRNA vaccine through the product safety page of their website?

Or alternatively could Medsafe comment on why the vaccine rollout hasn't been halted when damning research of this nature has been highlighted to them?

Request 5 – 20 December 2021 - 11.55am

Given there has been just one death from Covid19 to a child aged 6-11 years old there appears to be very little reason to vaccinate up to 450,000 children as their risk of death is very low.

Can Medsafe forward all clinical evidence for making their decision to give provisional approval for the mRNA vaccine be administered to children aged 6-11 years old?

In particular I request all the clinical details of the Pfizer trial including sample size, time frame, sex of participants, any existing health problems, the number of adverse effects, the number of serious adverse effects and the number of deaths.

Can Medsafe also advise any other data they relied upon to make their decision such as risk calculations and existing health problems in this age group.

Request 6 – 21 December 2021 – 3.27pm

Please advise the batch numbers of the Pfizer vaccine that caused serious adverse effects. I also want to know how many different batches of the Pfizer vaccine have been used in NZ? I do not want personal information. I simply want to know if batch 2556 for example had 50 serious adverse effects reported or that batch 2545 had 1 serious adverse reaction reported.