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11 January 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202117570

Dear 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 10 December 2021 for:

> *"Please provide information to show:*
> *1) When Pfizer or its agents first provided to any representative of the NZ government a copy of the CUMULATIVE-ANALYSIS-OF-POST-AUTHORIZATION-ADVERSE-EVENT-REPORTS-OF-PF-07302048-BNT162B2-RECEIVED-THROUGH-28-FEB-2021 that was recently released through the US courts,*
> *2) when each of you first became aware of this document*
> *3) when this document was first considered by Medsafe and each of the advisory committees to Medsafe and the result of each such assessment*
> *4) when Medsafe and/ or MinHealth communicated with CARM about the adverse effects identified in this document and the contents of any such communications*
> *5) when Medsafe and/ or MinHealth communicated with any other advisors or influencers including Nicky Turner, Prof Baker, Siouxie Wiles, any Coroner, NZMedical Council, NZ Nurses Council any DHB, Medical Officer or others about the adverse effects identified in this document and the contents of any such communications*
> *6) information to show any changes to protocols or advice are have been made or are being considered as a result this or any similar report about the wide array of adverse effects that may be attributable to the Spike Protein and/ or to the PfizerVax*
> *7) Any media or other public statements or changes to public communications as a result of this report.*
> *8) Any information to show why in NZ deaths are reported as Covid death if they are WITH Covid (whether or not there is causation), but different much more stringent criteria are applied for reporting post PfizerVax deaths and what exactly these criteria are- especially when a death is from a disorder that Pfizer itself identified may be a result of the PfizerVax."*

In response to your first seven questions, it is worth noting the genesis of the document you have provided. The Ministry 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.

The Ministry understands that based on this and other information, in August 2021, the FDA fully approved the use of Comirnaty in the United States. There is more information about this at: www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

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 the Ministry or Medsafe as the BLA process does not exist in New Zealand. As it was not provided, neither the Ministry nor Medsafe provided it to the other people or agencies you have listed in your questions and there were no changes in protocols or advice or media statements because of its production. Therefore questions 1 to 7 of your request are refused under section 18(e) of the Act on the grounds that the information requested does not exist.

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, albeit in a form that meets the company's legal obligations in New Zealand. 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 the conditions 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 to continue 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.

Likewise, Medsafe has in place a robust process for monitoring the safety and efficacy of medicines, including vaccines. Adverse events following immunisation (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. Both Medsafe and CARM encourage the reporting of adverse events and New Zealand historically has a high level of 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. That is why AEFI 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 the investigation of a new side effect of the COVID-19 vaccine is found, 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 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.

Turning to your final question, you have questioned the classification of deaths from COVID-19 as opposed to those following immunisation with a COVID-19 vaccine, suggesting the former is more stringent than the latter. This question rests on a fundamental 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.

For your information, 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

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, will 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