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23 June 2023

s 9(2)(a)

Ref: H2023025351

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 Haoura (the Ministry of Health) on 15 May 2023 for information regarding the Medicines Adverse Reactions Committee (MARC).

On 12 June 2023, the due date for responding to your request was extended pursuant to section 15(A)(1)(b) of the Act. It is important to note that while the Act allows people to ask for information from Ministers, government agencies and Crown entities, there is no obligation under the Act for agencies to create information in order to respond to a request. In preference to refusing parts of your request which seek an explanation or an opinion, we are referring you to relevant resources pursuant to section 13 of the Act.

Each part of your request is responded to below.

> *1. The Medicines Adverse Reactions Committee MARC held an out of session meeting on 20th of January 2021: Please provide evidence of how Medsafes concerns were addressed by the manufacturer and evidence of how the missing information was addressed to Medsafe by the manufacturer.*
>
> *2.2 Matters Referred to the MARC by Medsafe*
> *2.2.1 Comirnaty/Tozinameran/BNT162b6, concentrated suspension for injection, 30 µg/0.3 mL, 0.45 mL multi-dose vial – Risk Management Plan*
> *Background*
> *This paper summarises the Risk Management Plan (version 0.1) for Comirnaty/Tozinameran/BNT162b2, a COVID-19 mRNA vaccine jointly developed by BioNTech and Pfizer.*
>
> *Comirnaty (COVID-19 mRNA) Vaccine contains messenger RNA (mRNA) encoding the viral spike (S) protein of SARS-CoV-2. Formulation in lipid nanoparticles (LNPs) enables delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19 disease.*
>
> *The proposed indication is active immunisation to prevent COVID-19 disease caused by SARS-CoV-2 virus, in individuals 16 years of age and older.*

Medsafe considers that the safety specification for this product is currently inadequate and does not accurately reflect the important known risks, important potential risks or missing information. The RMP should be updated to include the additional risks and state how the missing information will be addressed. The additional studies appear to generally address the information gaps, but the company should state specifically how they will provide information on the NZ concerns raised above. In addition the provision of the results of these studies and provision of safety updates should be made a condition of approval.

The Committee was asked to advise whether any changes to the suggested questions on the RMP were required.

The Comirnaty RMP you reference in your request is an older version. The most recently updated RMP that Medsafe has published a summary of is version 8 (7 February 2023). This version includes evidence of Pfizer addressing safety and risk concerns and identifying how these risks can be minimized. You can view the RMP here: www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf.

2. The Medicines Adverse Reactions Committee MARC held an out of session meeting on 15th December 2021:

Please explain why as per section 2.1.1 attached, The statement "The Committee acknowledged the challenges involved with triaging large volumes of patients with common non-specific symptoms such as heart palpitations." was made in context of COVID-19 vaccination Adverse events following immunisation.

Manatū Hauora is unable to provide further information regarding this as the comment was made about the clinical practices of General Practitioners and Emergency Department physicians.

Confirm what measures were taken by Medsafe and MARC after acknowledging this reaction from a safety signal point of view.

This information is publicly available at the following address: www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-reminder.htm. This part of your request is therefore refused under section 18(d) of the Act.

2.0 Pharmacovigilance issues
2.1 Matters Referred to the MARC by Medsafe
2.1.1 Discussion of recent myocarditis reports following COVID-19 vaccination with Comirnaty
Background
The Committee held an out of session meeting to discuss three myocarditis reports following vaccination with Comirnaty that were notified to CARM since November 2021 and highlighted to Medsafe and the COVID-19 Vaccine and Immunisation Programme. The investigation of the reports is ongoing. No comments were sought on the likelihood of causality for these reports as this is within the remit of other expert advisory groups. The Committee was asked to discuss any action that should be taken by the Committee or Medsafe to improve the benefit-risk profile with regard to potential vaccine-associated myocarditis and pericarditis.

Discussion
The Committee agreed that safety-netting advice about myocarditis and pericarditis should be routinely given at the time of vaccination. This is to ensure that patients are aware that they should seek medical attention if they experience symptoms indicative of myocarditis or pericarditis and mitigate the risks of delayed treatment.

The Committee acknowledged the challenges involved with triaging large volumes of patients with common non-specific symptoms such as heart palpitations. The Committee emphasised the importance of ensuring healthcare practitioners are familiar with the support and guidance available to them, such as the joint Australian and New Zealand document 'Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines'.

The Committee supported a further alert communication from Medsafe for healthcare professionals, vaccinators and consumers on myocarditis and pericarditis following vaccination with Comirnaty, including the importance of early recognition and treatment and a reminder to remain vigilant after booster doses and with children.

The Committee will contact the COVID-19 Immunisation Programme to support routine safety-netting advice regarding myocarditis and pericarditis at the time of vaccination and promoting healthcare practitioner access to the vaccination guidance and resources available to them.

3. The MARC 185th Committee meeting minutes section 5.2 make mention of a report given to MARC summarising Medsafe's assessment of Risk management plan for COVID-19 vaccine. Please supply a copy of the report referred to in the minutes.

The updated summary of the company's risk management plan is publicly available on Medsafe's website: www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf. This part of your request is therefore refused under section 18(d) of the Act.

4. The MARC 186th Committee meeting minutes section 4.2, Medsafe made a presentation to MARC on work done around myocarditis with Comirnaty vaccine and vaccine induced thrombotic thrombocytopenia with Covid-19 vaccination. Please supply a copy of this presentation or a copy of the work done by Medsafe in order to make the presentation.

5. The MARC 187th Committee meeting minutes section 4.3, Update on myocarditis and pericarditis with Comirnaty. Details of overview of case reports in NZ and possible mechanisms for COVID-19 vaccine induced myocarditis ….
Please provide a copy of the overview presented by Medsafe.

Responses to previous requests under the Act made to Manatū Hauora capture this information and are publicly available. This section of your request is therefore refused under section 18(d) of the Act. You can view a response capturing this information here: www.health.govt.nz/system/files/documents/information-release/h202201068_-_response.pdf.

Other previous responses capturing similar information can also be found by searching keywords related to your request here: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests

6. The MARC 188th Committee meeting minutes,
a. section 3.2.3, Please provide evidence that Medsafe received up to date safety information from the manufacturer.

Please refer to the response provided under question 3.

b. section 5.1, as per minutes please provide details of update on COVID-19 vaccine safety signals given by Medsafe.

7. The MARC 189th Committee meeting minutes, section 5.1. As per minutes please provide details of update on COVID-19 vaccine safety signals given by Medsafe.

8. The MARC 190th Committee meeting minutes, section 5.1. As per minutes please provide details of update on COVID-19 vaccine safety signals given by Medsafe.

A summary of safety signals in Medsafe's safety reports is publicly available at the following address: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp. This part of your request is therefore refused under section 18(d) of the Act.

9. Please answer or provide reference to the following questions:
a. Historically, how many deaths , or other adverse reactions following World Health Organisation, International Health Regulations 2005 guidelines, would trigger the suspension of any medicine until it was definitively proven that medicine was safe for use?
b. Is the accepted threshold lower for experimental and or emergency use medicines where deaths or adverse reactions have occurred?
c. Does New Zealand Ministry of Health have its own threshold that differs from WHO or other internationally accepted limits of tolerance for death or injury from a medicine?
d. Does the Director General of Health in New Zealand have the ability to overrule safety signal decisions or recommendations from CARM, Medsafe, MARC or the CV-ISMB?
e. If the Director General of Health in New Zealand does have the ability to overrule New Zealand medicine regulators and safety committees, is the Director General then directly accountable for any harm that may result as a consequence of the Director doing so?

Explanations of approval processes and regulatory systems are publicly available at the following links:

- www.medsafe.govt.nz/Medicines/medicines-landing.asp (Medicines)
- www.medsafe.govt.nz/COVID-19/covid-landing.asp (COVID-19).

10. Please confirm who is ultimately responsible for completing due diligence on any vaccine supplier to the New Zealand Health sector?

I have interpreted your question to be asking about the supply contract, which is the responsibility of Pharmac. In determining which vaccines should be funded by the New Zealand government, Pharmac considers a range of factors including effectiveness, safety, value for money, and alternative products and suppliers. You can find a breakdown of Pharmac's role in assessing new medicines and suppliers (alongside the roles of other health agencies in this process) here: https://pharmac.govt.nz/about/what-we-do/our-place-in-the-health-system/

11. Please provide evidence of due diligence being completed prior to The New Zealand Government including Ministry of Health agreeing to entering into a supply agreement with Pfizer for the Comirnaty COVID-19 vaccine?

12. Please confirm whether or not those responsible for completing due diligence were aware that Pfizer has been successfully Prosecuted and fined in excess of US $4 Billion for a multitude of offences related to fraudulent activities. In 2009 Pfizer was fined US $2.3 billion the largest single fine imposed in US History, again for fraudulent mis representation of medical products that had questionable safety records. This is a matter of Public record with the United States Justice Department.

On 9 June 2023, the above parts of your request were transferred to the Ministry of Business, Innovation Employment (MBIE) pursuant to section 14(b)(ii) of the Act. You can expect a response from MBIE in due course.

13. If the Pfizer fraud cases were known about, were they considered a serious safety signal for the experimental, emergency use authorised Comirnaty vaccine product that has been administered to the majority of the New Zealand population?

The 2009 Pfizer Drug Breach in the US was related to marketing activities and not the manufacture of medicines. Regulators around the world have inspected Pfizer's medicine manufacturing plants and continue to approve Pfizer manufactured medicines.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on oiagr@health.govt.nz.

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
Group Manager
Medsafe