MINISTRY OF HEALTH
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2 June 2022

s 9(2)(a)

By email s 9(2)(a)
Ref H202205780

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 1 May 2022 for information regarding myocarditis and pericarditis in relation the to the COVID-19 vaccine. You asked for:

> *"Any correspondence sent to doctors by you pointing out that doctors as part of their professional obligations around informed consent ought to be advising their patients about the risk of myocarditis and pericarditis in relation to covid vaccines"*

While the Ministry has not corresponded formally with individual health practitioners regarding the issue you have raised, from the time myocarditis and pericarditis were identified as a potential side effect of the Pfizer COVID-19 Vaccine (Comirnaty) the Ministry has worked hard to engage across the healthcare sector. As part of this engagement, a letter regarding myocarditis and pericarditis following vaccination of the Comirnaty (Pfizer) COVID-19 vaccine was sent out from the Ministry to the district health board Chief Executives, as well as other organisations including Royal New Zealand General Practitioners (RNZGP), to be distributed to the entirety of their networks on 15 December 2021. A copy of this letter is attached to this response and is released in full.

You may be interested to know, Medsafe prepares safety communications to inform consumers and healthcare professionals about safety issues with therapeutic products: ie medicines, including vaccines and medical devices.

There are two types of safety communication. The 'monitoring communication' is issued at an early stage of a safety concern being identified. This communication generally contains little additional information. Rather, it is a warning that a safety concern is under investigation. The monitoring communication issued on 9 June 2021 was a warning that cases of myocarditis and pericarditis had been reported in association with the Pfizer-BioNTech COVID-19 (Comirnaty) vaccine. Further, it encouraged reporting of people experiencing myocarditis- and pericarditis-like symptoms to the Centre for Adverse Reactions Monitoring (CARM) so that the safety concern could be investigated further.

An 'alert communication' is published if a significant safety issue is identified. The alert communication issued on 21 July 2021 was published to alert healthcare professionals and consumers that myocarditis and pericarditis had been determined to be a rare side effect of Comirnaty. An alert communication does not mean a medicine or medical device is unsafe to be used.

The alert communication also provided information on what symptoms to look out for, and what to do if these are identified. You can read more about Medsafe safety communications and recent communications here: https://www.medsafe.govt.nz/safety/SafetyCommunications.asp

Medsafe 'safety communications' are sent to authorised prescribers and organisations such as the Royal New Zealand College of General Practitioners and the Pharmaceutical Society of New Zealand so they can let their members know.

Further information about myocarditis and pericarditis can be found on the following links below:

- Medsafe's safety communication: www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-alert.htm.
- Ministry's media release regarding myocarditis and pericarditis: www.health.govt.nz/news-media/media-releases/clinicians-reminded-be-aware-myocarditis-and-pericarditis-symptoms.
- COVID-19: Pfizer vaccine side effects and reactions on the Ministry's website: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-pfizer-vaccine-side-effects-and-reactions.

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 of Health website at: www.health.govt.nz/about-ministry/information-releases.

Nāku noa, nā

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15 December 2021

Tēnā koe

Urgent update on COVID-19 Vaccine-associated Myocarditis and Pericarditis

In response to recent reports of myocarditis/pericarditis following vaccination with Pfizer Comirnaty vaccine, the COVID-19 Vaccine Immunisation Programme (the Programme) is working to strengthen our system-level approach to ensure the best possible outcomes for our population should they experience this adverse event. This letter is to request you to support us by leading a response in your region, in partnership with primary care, urgent care, pharmacy, and other community organisations and providers. We need to ensure that consumers are well informed of this rare side effect and know when to seek help. We also want to ensure that the health system is poised to diagnose and clinically manage consumers with this condition appropriately.

Myocarditis and pericarditis have been established as very rare but serious adverse events associated with the Comirnaty vaccine. Although people with these conditions are usually diagnosed, investigated and managed effectively within our health system, the Programme's vaccination safety surveillance analysis, conducted in conjunction with Medsafe, highlights the need to reiterate the importance of timely assessment and management to prevent the serious consequences of myocarditis/pericarditis.

In New Zealand, the true incidence of vaccine-associated myocarditis is unknown as the onset of symptoms occurs in the first few days after vaccination and is potentially under-reported. However, the overall rate of this event in New Zealand is reported to be around 3 per 100,000 vaccinations.

The international literature is helpful in identifying the demographic and clinical characteristics of those who are more likely to have this adverse event. However, the pattern of the reports to the Centre for Adverse Reactions Monitoring (CARM) in New Zealand is slightly different. Our data shows that clinically-validated myocarditis/pericarditis in the 30-days following the vaccine occurs:

- Approximately equally in both males and females
- Over a wide age range, with a median age of diagnosed cases in the mid-30s
- Approximately equally after dose 1 and after dose 2[1].

In this New Zealand data, the most common symptomatology described is:

- Chest heaviness, discomfort, tightness or pain
- Difficulty breathing, shortness of breath
- Feeling dizzy, light-headed or faint
- Racing or fluttering heart, or a feeling of 'skipped beats'

The onset of these symptoms was usually in the first few days following the vaccine but can occur in the weeks later.

Serious complications of this condition are avoidable with timely assessment and treatment. A critical component to preventing the harm of vaccine-associated myocarditis/pericarditis is effective person-centred communication at point of vaccination. We know vaccinators and clinicians are

[1] We do not yet have sufficient data in New Zealand around occurrence after boosters.

excellent in describing the common and mild vaccine side-effects to consumers prior to vaccination as part of the consent conversation. However, informing consumers of the rare and serious potential side-effects (such as anaphylaxis, myocarditis and pericarditis) is also crucial. The few people who will be affected by vaccine-associated myocarditis/pericarditis must know what symptoms they might experience, and when and how to seek medical advice in time to prevent harm. This is important information also for those who present with parents and caregivers.

What we are doing as part of our response

- We are working with Whakarongorau Aotearoa to update the 0800 Helpline screening questions and advice.
- There are several changes underway to strengthen consumer knowledge on the symptoms of myocarditis/pericarditis in the range of vaccination information sheets including when and how to seek help. All website content on this issue will also be reviewed and updated.
- IMAC's webinar on vaccine-associated risks is available now and will be revised to strengthen key messages on myocarditis/pericarditis.
- Safety monitoring of the vaccine continues including active monitoring for some consumers via text message. The health sector will be updated on actions to prevent the serious consequences of untreated or misdiagnosed myocarditis as required.
- The effectiveness of the changes and approach will be evaluated in late January.
- Communication with key stakeholder groups to facilitate them to activate their networks and update their resource material with this information.

What can you do?

- Engage local leadership to work with your Programme and site Clinical and Quality leads to ensure all vaccinators in your region have up-to-date clinical knowledge and have reviewed the resources available on vaccine-associated myocarditis/pericarditis.
- The vaccinating workforce are required to review the IMAC webinar as soon as practical, and ensure they are competent and confident to provide consumers with information on the symptoms of these conditions.
- There is an expectation that this information is provided through the printed collateral and brochures available, as well as verbally, to every consumer.
- All healthcare providers including pharmacies, urgent care, general practice, emergency departments and hospital clinicians should consider the possibility of myocarditis/pericarditis in people presenting with the symptoms above, in particular in the days or first few weeks following the vaccine.
- All healthcare providers should review their local clinical pathways on myocarditis/pericarditis investigation and management and ensure they are accessible and known by clinicians.
- The vaccination pathway provides several touch points to share health education on the risk of vaccine-associated myocarditis/pericarditis. They are designed to all work together to raise consumer awareness about the vaccine and include: pre-vaccination screening, informed decision making, vaccinator check of understanding and consent, aftercare observation, and the range of information sheets. Please ensure you are familiar with the requirements of each stage in the process.
- Consider your local workforce education requirements and inform your IMAC regional advisor on any new or specific training needs. This may lead to opportunities for localised, regional, or national targeted training for at risk groups and tailored to local service provision.

Finally, could we ask you to cascade the requirements across your provider network and confirm in writing that local planning and clinical leadership is in place to guide a local response to prevent the serious consequences of undiagnosed or untreated myocarditis/pericarditis.

Ngā mihi

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