Te Whatu Ora
Health New Zealand

22 December 2022

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Tēnā koe Chris

Your Official Information Act request, reference: HNZ00005831

Thank you for your request of 4 November 2022, which has been considered under the Official Information Act 1982 (the Act). I will quote and respond to each part of your request below.

> *You state there were no Covid memorandums prior to 7 May 2021. So please provide me the scope of works with the CV-ISMB, how much they were paid by that date, deliverables associated with CV-ISMB - what did they do if they didn't produce one memo in the first five months of them being paid?*

Established in February 2021, the COVID-19 Vaccine Independent Safety Monitoring Board (CV-ISMB) provides advice to the Centre for Adverse Reactions Monitoring (CARM), Medsafe, the National Immunisation Programme and Ministry of Health on the safety of the COVID-19 vaccine(s).

The CV-ISMB scope of work is clearly outlined in the Terms of Reference which are included as part of the interim report available here: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-strategy-planning-insights/covid-19-who-were-working#:~:text=Established%20in%20February%202021%2C%20the,-19%20vaccine(s).

The Board:

- assesses potential links between reported adverse events following immunisation (AEFI) and COVID-19 vaccines
- reviews all serious and significant AEFI for the COVID-19 vaccines that are presented for expert opinion (this includes all fatal reports)
- advises Medsafe and the Ministry of Health in relation to the balance of benefits and risks for potential safety concerns under investigation and whether further action is needed
- ensures equity is a key consideration for the collection, monitoring and reporting of adverse events.

Throughout 2021 the Board held regular meetings every 3-4 weeks. The Board can also call additional meetings if an urgent issue arises internationally or if there is a report of a serious unexpected event.

In addition the minutes of the Board's meetings provide an overview of their meetings, these are published here: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-strategy-planning-insights/covid-19-who-were-working#:~:text=Established%20in%20February%202021%2C%20the,-19%20vaccine(s).

From the date of establishment of the CV-ISMB in February 2021, up until 7 May 2021, payments totalling $1,175.88 were made to members of the CV-ISMB.

Medsafes own data confirms that TTS has occurred from the Pfizer vaccine - how can you say this isn't a side effect from the Pfizer vaccine when there are over 60 side effects registered on your own data that this is a side effect?

Thrombosis with thrombocytopenia (TTS) is not a side effect of the Pfizer COVID-19 vaccine and this is clearly articulated in the previous documentation provided to you. We have not had any reports of TTS in New Zealand.

Table 10: Adverse events of special interest (AESI) up to and including 31 August 2022

AESI Category	AESI	Comirnaty total[a]	Vaxzevria total[a]	Background rate (hospitalisations per year)[b]
Immune system disorders	Guillain-Barré Syndrome	34	0	273
	Thrombocytopenia	38	<6	4,325
	Thrombosis with thrombocytopenia syndrome (TTS)	n/a[c]	0	
	Anaphylaxis[d]	127	<6	1,102

The above table outlines the number of reported Adverse Events of Special Interest (AESI), up to and including 31 August 2022. This shows that there have been no reports of TTS with the Pfizer COVID-19 vaccine.

Taken from the Medsafe Safety Report www.medsafe.govt.nz/COVID-19/safety-report-45.asp.

Please provide data as requested on the anaphalaxis - how many cases of anaphalaxis were not recorded when measuring against the Brighton Collaboration

Up to 1 November 2022, we have received 469 reports of anaphylaxis for the COVID-19 vaccines.

The use of the Brighton criteria helps to differentiate between true anaphylaxis and other non-anaphylactic reactions. Some cases reported to CARM as anaphylaxis were not anaphylaxis, for example less severe allergic reactions and anxiety related symptoms. All reports of anaphylaxis have been reviewed by medical assessors at CARM. Please see the CV-ISMB minutes for the full rationale for implementing the use of the Brighton criteria.

Were people prior to vaccination warned of all the safety signals?

A safety signal is an indication that there may be a safety problem related to a medicine or vaccine. They do not represent confirmed side-effects to a medicine.

For someone to be able to give informed consent, they need to be able to understand the expected benefits, and potential side-effects, of all possible treatments including doing nothing. Since a signal is not a side-effect a person is not better informed if they are told about signals which in the majority of cases are not found to be side-effects.

A safety communication was issued - are these safety communications relayed to people prior to vaccination? If not, why not?

There are two types of safety communication; the first is a *Monitoring Communication*, this is issued at an early stage of a safety concern being identified. This communication generally contains little additional information and is a warning that a safety concern is under investigation.

A monitoring communication was issued on 9 June 2021, warning that cases of myocarditis and pericarditis had been reported in association with the Pfizer COVID-19 vaccine. Further, it encouraged reporting of people experiencing myocarditis- and pericarditis-like symptoms to CARM so that the safety concern could be investigated further.

The second kind of safety communication is an *Alert Communication*. This is published if a significant safety issue is identified. These alerts are sent to vaccinators and other health care

professionals directly, who then disseminate this information to consumers. The alerts are also made publicly available on the Medsafe website.

An alert communication was issued by Medsafe on 21 July 2021 to alert healthcare professionals and consumers that myocarditis and pericarditis had been determined to be rare side-effects of the Pfizer COVID-19 vaccine. This included an instruction for vaccinators to inform consumers of the risk of myocarditis and its symptoms. It is important to note that at this date, the printable collateral and website content available to vaccinators and the public provided information on the symptoms of myocarditis.

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/alerts.asp

> *I have read the minutes you don't need to link me through to stuff you have sent - what is the average "under reporting" rate of vaccine injuries for this medication and previous medications*

The rate of under reporting is not relevant as the purpose of reporting to CARM is to detect new side-effects not the frequency of events in a population, there are other methods for ascertaining this.

> *This means nothing - you are studying people after you have injured them - a 400% increase in Myocarditis and likely numerous delayed deaths through cardiac arythmia in children is going to occur going forward in New Zealand and is already happening overseas*
> *Whilst the information is publically available are vaccinators warning of Myocarditis so that New Zealanders get informed consent?*

As stated above, the Medsafe Alert Communication on 21 July 2021 instructed vaccinators to inform consumers of the risk of myocarditis and its symptoms. It is important to note that the printable collateral and website content available to vaccinators and the public provided information on the symptoms of myocarditis.

Information on myocarditis and pericarditis and the evolving situation was also regularly communicated to the vaccinating workforce and wider health sector throughout the second half of 2021 in a fortnightly newsletter 'COVID-19 Vaccine Update'. The Immunisation Advisory Centre (IMAC) presented a webinar on myocarditis to the vaccinating workforce on 20 July and also updated information on their website to included reference to the Medsafe Alert Communication and FAQs around myocarditis. Following a press release by the Ministry in August 2021 advising clinicians and consumers to be aware of the signs and symptoms of myocarditis, IMAC updated their vaccinator training modules to further disseminate emerging evidence on vaccine safety.

Additionally, on 15 December 2021 the Programme sent a letter to all DHB CEOs, along with a request that the letter be distributed to all local providers. This letter included the term "fluttering heart" and noted that all people vaccinated with the Pfizer vaccine should be made aware of the possible symptoms of myocarditis/pericarditis and understand when and how to seek medical advice. The letter stressed that serious complications of this condition are generally avoidable with timely assessment and supportive management.

A critical component to preventing the harm of vaccine-associated myocarditis/pericarditis is effective person-centred communication at the point of vaccination. Subsequently the Ministry coordinated with the DHBs shared support service known as TAS, to have all Senior Responsible Officers (SROs) confirm that their DHBs had "cascaded the letter locally to anyone who might provide a medical service - including pharmacies, emergency departments, urgent care, PHOs, etc".

The National Immunisation Programme continue to advise healthcare providers and consumers of the risk of myocarditis, as part of the informed consent process.

Please provide appendix one

Our decision regarding this Appendix was communicated to you in your previous response H202207158. The appendix is withheld in full under section 9(2)(ba)(ii) to protect information that is subject to an obligation of confidence and making it available would likely damage the public interest.

I have read the safety signals - however are people warned of the safety signals per informed consent process

Please see the answer to question 6 above.

How to get in contact

If you have any questions, you can contact us at hnzoia@health.govt.nz.

If you are not happy with this response, you have the right to make a complaint to the Ombudsman. Information about how to do this is available at www.ombudsman.parliament.nz or by phoning 0800 802 602.

As this information may be of interest to other members of the public, Health NZ may proactively release a copy of this response on Health NZ's website. All requester data, including your name and contact details, will be removed prior to release. The released response will be made available on our website.

Nāku iti noa, nā

Astrid Koornneef
Kaitohu | Director
National Immunisation Programme