

Chris McCashin
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Tēnā koe Chris,

Your Official Information Act request, reference H2022010003:

Thank you for your email of 11 August 2022 requesting information relating to COVID 19 Vaccine Independent Safety Monitoring Board (CV-ISMB) memos. You stated:

MOH has recently dropped a number of Memo's completed by CV-ISMB on 2nd August. I have reviewed the Memo's and I have the following queries, follow ups.

On 6 October 2022 Te Whatu Ora (Health New Zealand) partially responded to your request. The remaining parts of your response are quoted and responded to below:

12 August 2021 - Memo

Please provide the "expert opinion" completed by Ralph Stewart cardiologist

Professor Ralph Stewart verbally provided his opinion to the Board, rather than in the form of a memo. An abbreviation of this can be found in the minutes of the meeting, which has been provided to you as Document 2 attached to this letter.

This memo mentions the benefits continue to outweigh the risks - please provide the benefit / risk assessment that was used to support the statement from the board?

As explained in the first release of information to you, the Board applies these principles when considering the safety data for COVID-19 vaccines:

www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp

There is no specific document outlining benefit/risk assessment. The principles are embedded throughout the Board's analysis, which is captured both within the memo and the minutes of the meeting and have been provided to you as Document 2.

4 October 2021 - Memo

Please provide the communications that went out to Clinicians, Cardiologists and Pathologists as per point 12 of this memo

Two letters have been identified in scope of this part of your request. These are itemised in Appendix 1 and copies of the documents are enclosed. These are being released to you in full.

11 October 2021 - Memo

Vaccination in Pregnancy - Please provide all of the data associated with pregnancies, congenital abnormalities and the ongoing work associated? Is it not a bit late to review abnormalities when they could have been avoided without vaccine?

Two documents have been identified as being within the scope of this part of your request. These are itemised in Appendix 1 and copies of the documents are enclosed. Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Medsafe has also published the following communication regarding vaccination in pregnancy:

www.medsafe.govt.nz/safety/Alerts/covid-19-vaccination-in-pregnancy.asp.

13 December 2021 - Memo

Please provide the memo of the call with UK Medicines on Friday 9 December 2021 discussing fatal cases of myocarditis in UK? Surely people dying globally requires the vaccine to be stopped? There was no doubt at this stage that people are dying all over the world?

This information is being withheld in full under section 6(b)(i) of the Act, as its release would prejudice information entrusted to the Government of New Zealand from another Government or agency.

Please provide the update by Medsafe to the board including slides of myocarditis in New Zealand.

The communication again mentions benefits outweigh the risks - please provide the risk / benefit analysis that was used to support this statement?

This information can be found in the CV-ISMB minutes which have been provided to you as Document 8. Please see the comments above regarding benefit and risk analysis.

25 February 2022 - Memo

Please provide the memos presented to the board for booster doses for 5 - 11 year olds?

Children aged 5 to 11 are not eligible to receive a booster dose of Comirnaty. As such, there are no memorandums related to this. Therefore, this part of your request is refused under section 18(e) of the Act as the information requested does not exist.

Please provide what "written information" was requested from the Pathologist - Please provide the terms of service for the pathologist ie what additional information are they providing to the CV-ISMB and the cost associated.

This part of your request has been refused under section 18(e) of the Act, as the information requested does not exist. No written information has been requested from the pathologist.

8 March 2022 - Memo

Please provide the study used to evaluate the effect of the Pfizer vaccine on thrombotic events

Information in response to this part of your request has been withheld under section 9(2)(f)(iv) of the Act to maintain the constitutional conventions that protect the confidentiality of advice tendered by Ministers and officials.

Coroner said death did not need to be investigated by them - please provide the communications to the CV-ISMB from the coroner with justification as to why coroner did not want to investigate

This part of your request has been withheld under section 9(2)(ba)(i) of the Act to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source.

Again, benefits outweigh the risks - please provide the risk benefit analysis that the CV-ISMB relied on

As signalled above, the Board applies these principles when evaluating the safety data of COVID-19 vaccinations, which is embedded throughout the minutes of each meeting:

www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp

The minutes from this meeting have been provided to you as Document 11.

Please provide the study of thrombotic events as per section 17 - 20.

This part of your request has been withheld under section 9(2)(f)(iv) of the Act to maintain the constitutional conventions that protect the confidentiality of advice tendered by Ministers and officials.

Please provide the minutes as Appendix 2.

The minutes from this meeting have been provided to you as Document 11.

Please link me to where all the CV-ISMB meeting minutes are at

The CV-ISMB minutes that have been made publicly available can be found here:

www.health.govt.nz/system/files/documents/pages/h202200492-documents-redacted.pdf

18 March 2022 - Memo

Please provide Medsafes "regular" updates on Myocarditis, Pericarditis in NZ - please provide all slides, data associated

Manatū Hauora has identified 6 documents within the scope of this part of your request. These are itemised in Appendix 1 and copies of the documents are enclosed.

Please provide all work associated with Post Partum congenital abnormalities, documents associated / work completed by Medsafe?

Again - isn't this a bit late - pregnant woman are warned away from mayonnaise yet they were recommended this gene therapy that the Ministry of Health is still unable to produce or quantify any of the benefits associated with this therapy.

The information you have requested can be found in Documents 5 and 12 which have been provided to you.

I trust the information provided is of assistance. You are advised of your right to also raise any concerns with the Office of the Ombudsman. Information about how to do this is available at: www.ombudsman.parliament.nz or by phoning 0800 802 602.

Nāku iti noa, nā



Rachel Mackay
Acting Interim Director, Prevention
National Public Health Service
Te Whatu Ora - Health New Zealand

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	July 2021	Presentation – Overview of Comirnaty	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • Section 9(2)(a) to protect the privacy of natural persons; and • Section 9(2)(g)(ii) to protect Ministers, members of organisations, officers, and employees from improper pressure or harassment.
2	9 August 2021	CV-ISMB Minutes	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • 9(2)(a); • 9(2)(g)(ii); • 9(2)(g)(i) to maintain the effective conduct of public affairs through the free and frank expression of opinions by or between or to Ministers and officers and employees of any public service agency; and • 18(c)(ii) as releasing the information would constitute a contempt of court.
3	August 2021	Presentation - Comirnaty and myo/pericarditis	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • Section 9(2)(a); and • Section 9(2)(g)(ii)
4	9 September 2021	Presentation – Comirnaty and myo/pericarditis	
5	22 October 2021	Memo – Pregnancy-related AEFI reports in New Zealand following administration of Comirnaty	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • Section 9(2)(a); • Section 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information; and • Section 9(2)(g)(ii)

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6	27 October 2021	Presentation – Updated case reports myocarditis/pericarditis/myopericarditis	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • Section 9(2)(a); and • Section 9(2)(g)(ii)
7	December 2021	Presentation – Myo(peri)carditis overview.	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • Section 9(2)(a); • Section 9(2)(ba)(i) to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source; and • Section 9(2)(g)(ii)
8	8 December 2021	CV-ISMB Minutes	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • Section 9(2)(a); • Section 9(2)(g)(i); • Section 9(2)(g)(ii); and • Section 18(c)(ii)
9	14 January 2022	Letter for pathologists	Released in full.
10	9 February 2022	Presentation – Update on reported cases of myocarditis/pericarditis/myopericarditis	Some information withheld under section 9(2)(g)(ii) of the Act.
11	2 March 2022	CV-ISMB Minutes	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • Section 9(2)(g)(ii); and • Section 18(c)(ii).
12	23 March 2022	Memo – The safety of COVID-19 vaccination during pregnancy	Some information withheld under the following sections of the Act: <ul style="list-style-type: none"> • Section 9(2)(a); • Section 9(2)(g)(ii); • 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.

#	Date	Document details	Decision on release
13	28 February 2022	Letter for coronial investigation	Released in full.
14	September 2022	Presentation – Comirnaty and mechanisms for adverse reactions	