

9 February 2023

Chris McCashin

By email: fyi-request-21667-bc817bc1@requests.fyi.org.nz
Ref: H2023019684

Tēnā koe Chris

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 29 January 2023 for information regarding the Medicines Adverse Reactions Committee (MARC). You requested:

“Please provide the following since the start of 2021 including the Out of Session Meeting - 20 January 2021 relating to the Medicines Adverse Reactions Committee (MARC)

Meetings 185 - 192 and to include the following

Ultimately I am looking for all of the information MARC received from CARM and then the work completed by MARC which I believe relate to Sections 2.0 and Sections 3.0 of the minutes.

*2.0 Matters Arising from the New Zealand Pharmacovigilance Centre
CARM Quarterly Reports and fatal reports for which CARM assessed the causality to be at least possible, Reports of Cases of Injuries etc etc, all of the information presented to MARC by CARM*

*3.0 Pharmacovigilance Issues
Matters referred to MARC under Section 36 of the Medicines Act 1981*

I am specifically looking for all of the above relating to the Covid-19 vaccine. Such things arising from the Medsafe Reports include but limited to being the 4 Causal Deaths relating to the Covid-19 vaccine, all of the associated heart issues, pregnancy - suspect there should be a number of things given the safety signals that have been reported by Medsafe.

Can you also please provide the standards for Section 36 of the Medicines Act 1981.

Ultimately want all of the Matters Referred to MARC by Medsafe

Following on from that can you please provide all of the Recommendations and Associated Reporting completed by MARC.

As noted above - I am specifically asking for information relating to the Covid-19 vaccine and not all the other reports referring to the other Medicines.

Can you also please provide the total number of matters referred to MARC by Medsafe associated with the Covid-19 vaccine”

Section 36 of the Medicines Act 1981 publicly available here:
www.legislation.govt.nz/act/public/1981/0118/latest/DLM55444.html.

MARC meetings that have taken place from the start of 2021, where a COVID-19 vaccine was discussed are outlined in table 1 below. The table also provides links to the publicly available meetings minutes which include details of MARC discussions:

Table 1:

| Meeting date | Matter | Information |
|--------------------------------|---|--|
| January 2021 – out of session | Risk Management Plan for Comirnaty COVID-19 vaccine | Minutes publicly available here: www.medsafe.govt.nz/profs/adverse/MinutesOoS-20-jan-2021.htm |
| March 2021 | Ad26.COV2.S (Janssen covid 19 vaccines) Risk Management Plan | Minutes publicly available here: www.medsafe.govt.nz/profs/adverse/Minutes185.htm |
| June 2021 | Vaxzevria Risk Management Plan | Minutes publicly available here: www.medsafe.govt.nz/profs/adverse/Minutes186.htm#5.1 |
| December 2021 | Update of Risk Management Plan for Comirnaty to include vaccination of children 5 - < 12 years of age | Minutes publicly available here: www.medsafe.govt.nz/profs/adverse/Minutes188.htm |
| December 2021 – out of session | Discussion of recent myocarditis reports following COVID-10 vaccination with Comirnaty. | Minutes publicly available here: www.medsafe.govt.nz/profs/adverse/MinutesOOS-15-Dec-2021.htm |
| December 2022 | Comirnaty RMP version 8 | Minutes publicly available here: www.medsafe.govt.nz/profs/adverse/Minutes192.htm |

At some meetings, the MARC were provided oral updates, this includes oral updates of vaccines signals that were taken to the COVID-19 Independent Safety Monitoring Board (CV-ISMB). These meetings are outlined in table 2 overleaf. These issues were not discussed by the MARC, therefore there is no further information to release.

Table 2:

| Meeting | Update |
|----------------|---|
| September 2022 | Inform MARC of safety alert for Nuvaxovid |
| June 2022 | Update on COVID-19 vaccine signals |
| March 2022 | Update on general reporting trends for COVID-19 vaccines |
| Dec 2021 | Update on COVID-19 vaccine signals |
| September 2021 | Update of case reports of myocarditis and pericarditis with Comirnaty in NZ |
| June 2021 | Update on Medsafe work around myocarditis with the Comirnaty vaccine and vaccine – induced thrombotic thrombocytopenia with COVID – 19 vaccines |

The Risk Management Plan for Comirnaty is available on the Medsafe website here: www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf.

The Risk Management Plan for Vaxzevria is available on the Medsafe website here: www.medsafe.govt.nz/COVID-19/AstraZeneca-RMP.pdf.

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
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Medsafe