MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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7 October 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2020012229

Dear 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 Hauora (Ministry of Health) on 8 September 2022 for information relating to myocarditis and pericarditis. You specifically requested:

> *"The medicine sponsor now considers that myocarditis and pericarditis may be rare side effects of Nuvaxovid."*
>
> *Can I have copies of all Medsafe's risk assessments of all SARS-CoV-2 vaccines regarding myocarditis and pericarditis as potential adverse events?*

Please refer to the summary of risk management plans (RMPs) for Comirnaty and Nuvaxovid on Medsafe's website here: www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf and www.medsafe.govt.nz/COVID-19/Nuvaxovid-RMP.pdf.

The RMP is created by the vaccine manufacturer and is submitted to medicine regulators as part of the vaccine approval and safety monitoring process. The RMP details vaccine risks, how these risks can be minimised, and how more information will be obtained about risks and uncertainties (missing information). Missing information refers to information on the safety of the medicinal product that is currently missed or unknown. Over time, the RMP is updated as more information becomes available.

Myocarditis and pericarditis as potential adverse events to Covid vaccination have also regularly been discussed with the Independent Safety Monitoring Board (ISMB). Documents from these meetings have already been released under the Act, under the reference H202201068. Please refer to the documents in this response for additional information regarding myocarditis and pericarditis. www.health.govt.nz/system/files/documents/information-release/h202201068_-_response.pdf

> *Can I also have copies of all risk assessments relating to SARS-CoV-2 vaccines regarding myocarditis and pericarditis provided to Medsafe by the respective vaccine sponsors?"*

This part of your request is refused under section 9(2)(ba)(ii) of the Act, to protect information that is subject to an obligation of confidence and making it available would likely damage the public interest.

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.

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 website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Catherine Marnane
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Medsafe