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18 March 2024

Erika Whittome

By email: fyi-request-25124-c3ff613b@requests.fyi.org.nz
Ref: H2024037361

Tēnā koe Erika

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 – Manatū Hauora (the Ministry) on 7 March 2024 as a follow up to information provided to you on 30 January 2024 under reference H2023033891. You requested:

> *"I am still waiting on the complete information requested for these conditions, especially a items 3,4,5 and very importantly the reports. Eg where are any sub clinical reports on myocarditis and pericarditis?"*

The Ministry would like to add some further context to your earlier response around this topic.

In regards to item 3 you asked for copies of any reports on the duration of efficacy and the requirement for booster doses within five working days of them being produced. We referred you to the data sheets for the vaccine as they had been updated to reflect the need for booster vaccines. The Ministry did not receive any reports fulfilling this obligation. However, the Ministry did receive a request to change the datasheet, hence this is why we referred you to them. Medsafe does note that the efficacy of these vaccines changes rapidly in any case due to the strain changes and how many doses the individual has had and whether they have had COVID-19 previously.

In regards to item 4 you asked to provide any reports on efficacy including asymptomatic infection in the vaccinated group, vaccine failure, immunogenicity, efficacy in population subgroups and results from post marketing studies, within five working days of them being produced. Again, the Ministry did not receive any reports in the sense of a review of information, but any changes were processed through a changed Medicine notification.

In regards to item 5 you for the final Clinical Study Reports for Study C4591001 and Study BNT162-01 to be provided within five working days of being produced. The Ministry has nothing further to add to the answer we provided you in response H2023033891 as this requirement was removed by Medsafe as it was no longer considered clinically relevant due to changes in disease landscape and evolving variants.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

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
Group Manager
Medsafe