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Athina Andonatou

By email: fyi-request-19480-9f1b5d52@requests.fyi.org.nz
Ref: H202206977

Tēnā koe Athina

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 (the Ministry) on 26 May 2022 for:

> *"Please provide all sources and evidence used on the CARM reports for the numbers written as the "AESI background hospitalisation rates used to estimate the expected number of events in the general population, which help in vaccine safety surveillance. Counts indicate average of hospitalisation rates for the calendar years 2016-2019".*
>
> *And please provide all documents that support it being used as an accurate predictor. It does not seem to be comparing the same conditions, if it was would it not also be more accurate if the adverse effects of this gene editing therapy were compared to the adverse effects from other injections. Or at least include the totals of the hospitalisation rates over the calendar years 2016-2019 for each of the adverse effects listed, minus those where a CARM report has been filed. This seems to be a more accurate method."*

The purpose of the Adverse Events of Special Interest (AESI) section of the Adverse Events Following Immunization (AEFI) report is to discern if there is a safety signal from COVID-19 vaccines by noting if the number of reports for a condition is higher than expected. The purpose of the AESI section is not to compare vaccines. As stated in the report, the background rates are the mean numbers for the years 2016 to 2019. The data is taken from the National Minimum Data Set (NMDS) and there is more information available on the Ministry's website on the NMDS: www.health.govt.nz/nz-health-statistics/national-collections-and-surveys/collections/national-minimum-dataset-hospital-events.

The safety profile of vaccines cannot be compared as vaccines are used in different populations, with different denominators, for different infections. This means that there is a range of different potential effects of using different technologies and platforms under different conditions of stimulated reporting.

Data comes directly from the database and the codes used are published in the AEFI report. The Ministry cannot subtract Centre for Adverse Reactions Monitoring (CARM) reports for COVID-19 vaccines from historical data as the COVID-19 vaccines were not available 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.

Nāku noa, nā

Chris James
Group Manager
Medsafe