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3 October 2023

Catherine Jamieson

By email: fyi-request-23989-dbd4b6b3@requests.fyi.org.nz
Ref: H2023031262

Tēnā koe Catherine

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 August 2023 for information regarding adverse events following immunisation (AEFI). You requested:

> *What does the date shown in the date column when a detailed search is done in SMARS for Covid 19 Vaccines represent?*

This is the date the report was made.

> *What is the number shown in the report column when a detailed search is done in SMARS for Covid 19 Vaccines? http://icmra.info/drupal/news/20july2020/summary*

This is the report identification number.

> *For each of these report numbers please supply corresponding*
> *i) assessment numbers (AEFI-A) numbers*
> *ii) assessment codes*

On 6 September 2023, you were contact by Manatū Hauora to clarify what you meant by 'assessment codes'. On 11 September 2023, you replied:

> *"The assessment codes I am referring to are those used in the 'Preferred Term' column of the line listing file in the Safety Reports. My apologies for the confusion if that is not the term commonly used to refer to them."*

These codes are the MedDRA numeric codes relating to the medical term displayed which have never been visible in the SMARS database and were only included in the COVID-19 vaccine downloads due to a feature of the database being used at the time. A new database is now being bult which will still utilise MedDRA. You can find out more about MedDRA here: https://www.meddra.org/

> *Please identify the reports associated with deaths of the consumer.*

These are never identified in SMARS and were not identified in the COVID-19 vaccine safety reports for privacy. This is explained in the caveat text for SMARS.

> *OIA response H2023021744 identifies a significant difference between the serious adverse event reports received and those publicly reported through Medsafe Safety Reports and SMARS. Please supply any reports, emails or other correspondence pertaining to the difference between reports of adverse events following immunisation with Covid vaccines received and those reported in Medsafe Safety Report #46.*

The difference was due to the COVID-19 vaccine reports not being fully integrated into the normal CARM database. Since the databases have not yet been joined a line listing for COVID-19 vaccine reports was published www.medsafe.govt.nz/safety/reports-and-promotion/ADR-reporting-statistics.asp

> *How many adverse event reports following immunisation have been received to date for Covid vaccines, both total reports and those that fall under the Medsafe definition of Serious.*

Data reported to the Centre for Adverse Reactions Monitoring is published here: www.medsafe.govt.nz/safety/reports-and-promotion/ADRStatistics/Comirnaty2023.asp.

> *Please also supply any reports, emails or other correspondence pertaining to any discussion, since the issue of Medsafe Safety Report #46, of safety signals.*

On 6 September 2023, you were contacted by Manatū Hauora in accordance with section 18B of the Act in order to refine this part of your request. This part of your request captured all Medsafe correspondence following the Safety Report #46. On 11 September 2023, you provided a refined request for:

> *'Post safety report 46 to present day, please provide all meeting minutes detailing any new safety signals related to Covid 19 vaccines, also email and memorandum issued post 16 December 2022 in respect to those safety signals.'*

There have been no new safety signals since the publication of Safety Report #46. Therefore, this part of your request is refused under section 18(g)(i) of the Act as the information is not held by Manatū Hauora and there are no grounds for believing it is held by any other agency subject to the Act.

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