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Catherine Jamieson

By email: fyi-request-24365-023b0239@requests.fyi.org.nz
Ref: H2023032271

Tēnā koe Catherine

Response to your request for official information

Thank you for your requests under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) as a follow up to information provided to you in a previous response (H2023031262 refers). On 8 October 2023 You requested:

> *1. How many reports of deaths have been reported to CARM where Covid 19 vaccines are an associated product?*

I have interpreted your question to mean when COVID-19 vaccines were not the suspected medicine but may have been administered to a person. Medicines that are not considered to have caused a reaction are often not reported, in addition given the high COVID-19 vaccination rate almost everyone who dies will have had a COVID-19 vaccine at some point. Therefore, this part of your request is refused as the information does not exist.

> *2. Why have the events reported through SMARS decreased from that reported earlier in the year?*

While the Act allows New Zealanders to ask for information from Ministers and government agencies, there is no requirement for agencies to create new information, compile information they do not hold or provide or prove an opinion. The Act does not support requests where an opinion, comment, argument, or hypothetical statement is put to the Ministry for response, couched as a request for information. This part of your request is therefore refused under section 18(g)(i) of the Act on the grounds that it is not held by Manatū Hauora.

> *3. What is the rationale for not including reports at https://www.medsafe.govt.nz/safety/reports-and-promotion/ADRStatistics/Comirnaty2023.asp*
> *where death was the only reported reaction?*
> *If a cause of death is established are those reports then included in the line listing?*
> *Was this approach applied to the line listings published with the Covid-19 Safety Reports?*
> *If it was applied to some and not others please identify which had this approach applied.*

The line listing displays reports as they would be displayed in the SMARS database as explained here: www.medsafe.govt.nz/Projects/B1/ADRSearch.asp#Understanding. Since death is an outcome where there are no other reactions reported, these are considered invalid reports but are still included in overall statistics.

4. What is the rationale for removing the term death in the line listing?

The death term has been removed to protect privacy.

5. What is the rationale for not including bivalent product adverse reactions in this line listing? Are these reports held in a different database?
If so what is that database and where are its contents reported?

AEFI for the bivalent vaccine can be found here: www.medsafe.govt.nz/safety/reports-and-promotion/ADR-reporting-statistics.asp.

6. What is the reason for the format change in the 'Report ID' column of the line listing? Is this number in the last (approx) 1000 lines of the line listing the report identification number?
Has the number provided to a reporter at the point of making an adverse event changed or is that number still an AEFI number?

All numbers displayed in the column headed 'Report ID' are the report identification number as per the header of the column. Depending on how a report is made and if contact information is provided reporters will be given a report ID.

7. 'The MedDRA numeric codes ...were only included in the COVID-19 vaccine downloads due to a feature of the database being used at the time.'

The MedDRA numeric codes have disappeared from the line listing format. The words 'at the time' infer this database is not being used any longer. The new database is not live yet so what database is being used if the previous one isn't being used any longer?

All reports sent to CARM are held in a secure database.

8. Please provide reporting and data governance requirements covering adverse events that CARM and Medsafe must or does adhere to, including any domestic or international legislation and convention.

Please provide copies of current policies and procedure documents covering the collection, storage and use of adverse event data not limited to Covid-19. Please specify if and where the Covid 19 data processes deviate from normal.

Medsafe follows ICH and MedDRA guidelines which are publicly available here:

- www.ich.org/page/ich-guidelines
- www.meddra.org/how-to-use/support-documentation/english

9. Please explain the justification for denying previous requests for assessment (AEFI-A) numbers of reports where death has been reported, on grounds that it breaches privacy. The use of an AEFI-A number anonymises the report to the extent that it is not even possible for the reporter to identify with ease and certainty the report they made due to them being supplied an AEFI number at the time of reporting that bears no resemblance to the assessment number. I request you reconsider your position and supply AEFI-A numbers, for all reports they have been allocated to, to date where death has been reported.

The report ID allows people to identify age and gender. In combination with data from other sources, disclosing this information may make individuals identifiable. As such, Manatū Hauora stands by this decision.
On 20 October 2023, you requested:

OIA response H2023031262 refers to caveat text. Can you please confirm that this refers to the following text on the link below:-

'any report where it is considered the patient may be identifiable (eg due to the rareness of the condition).'
https://www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp

The link you have provided is to the caveat text which explains the nature of the data included in SMARS and the whole of this explanation is relevant to understanding the data and it does include the quoted text.

> *Can you please answer the question that remains unanswered in OIA response H2023032008 and confirm whether or not the aggregated material from the Covid 19 Medsafe Safety Reports includes AEFI-A numbers not included in the line listings because they are associated with a report of death or otherwise.*
>
> *I understand reports cannot be removed from the system they can only be made invalid and that criteria for a valid report are:-*
> 1. *one patient identifier (eg, name, initials, gender, date of birth, age)*
> 2. *suspect medicine(s)*
> 3. *suspected reaction(s)*
> 4. *reporter details.*
>
> *What mechanism is used to remove reports of where death is the only reported reaction and reported terms of death from line listings? Is it a manual or automated process? If automated please provide the date at which it became automated.*

The aggregated data in the Safety reports includes all valid reports and in this case due to the unprecedented interest all fatal cases. The SMARS data is published through an automated process and has been since the database was created.

> *If an assessment number is missing from a line listing can there be other reasons for that other than the report being marked invalid or it being associated with a report where death is the only reported reaction?*

Yes, this is explained in the caveat text in the line listing, for the safety reports and SMARS.

> *What is the treatment for an update made to an existing report where death is the only reported reaction in the update? Is this report then removed from the line listing?*

For any report for which further information is provided, the case is updated whether a report is included in the line listing depends on the information in the case.

> *In H2023032008 it is stated that with regard to safety reports 'counts may change due to receipt of additional information. This may mean some reports are determined to be invalid*

or incorrect when further information is made available..the information may change over time, due to quality control procedures and/or receipt of further information'.There are AEFI-A numbers that were included in Safety Report 46 that are not included in the line listing posted 28/8/23. Can you please supply the suite of all reasons these AEFI-A numbers have not been included ie not satisfying the criteria for a valid report, duplicate reports etc.

While the Act allows New Zealanders to ask for information from Ministers and government agencies, there is no requirement for agencies to create new information, compile information they do not hold or provide or prove an opinion. As such, this part of your request is refused under section 18(g)(i) of the Act as the information is not held by the Ministry.

As the vast majority are very early reports it is unlikely they have been omitted post December 2022 due to being invalid - this would be fairly belated wouldn't it? If a further report was made with updated symptoms and given another assessment number rather than an update to intial report, which report would be retained - the earlier with update information or the later including the prior information? Or are they both retained and linked somehow?

Generally, the first ID would be retained, however, this may vary on a case-by-case basis. All cases are retained in the database but if there are duplicate cases, they are joined together under one ID number.

In addition to direct contact with the reporter or patient what are the different specific processes whereby updated information can be received and what systems or procedures are used?

The reporter may make another report or contact Medsafe directly.

Furthermore, allowing for the omitted reports there are 355 more AEFI-A numbers in the line listing posted 28/8/23 than in Safety Report 46 yet there are in the realm of 13,000 less lines in the line listing posted 28/8/23. In addition there are duplicate rows in the line listing posted 28/8/23 and there do not seem to be duplicate rows in report 46. Can you please provide explanation as to what has caused this unusual presentation? Please include any communications, procedure or policy documents or reports that reference the reason for this or provide explanation partial or full.

Manatū Hauora does not hold any information within scope of this part of your request. However, there may have been an issue transferring data between databases. Medsafe will look into this further.

There may be process/procedure documentation that cover answers to some of these questions. I do wonder whether CARM (now moved to within Medsafe I understand?) has been adequately resourced to manage 240k line entries. I understand there has been introduction of new IT systems too within this tumultuous time. Are you able to provide me with the org structure of CARM as it was for 2021-23 and the org structure of whatever replacement structure now sits within Medsafe (if that is correct).

CARM continues to exist independently of Medsafe.

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