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11 March 2024

Catherine Jamieson

By email: fyi-request-25838-0ee78620@requests.fyi.org.nz
Ref: H2024036528

Tēnā koe Catherine

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 22 February 2024 for:

> *1. What mechanism is used to remove reports where death is the only reported reaction and reported terms of death from line listings, both in the Safety reports and at the links supplied in H2023032268 and H2023032271 for the Comirnaty Original/monovalent and bivalent vaccines respectively. (The supplied links in the OIA response numbers do not appear to still work - please supply links to where these can be accessed now.)*
>
> *For each of these line listings please advise if it was a manual or automated process to remove/not include the reports where death is the only reported reaction? If automated please provide the date(s) at which it became automated for each of the locations. If it is manual what department of what agency does this?*

I have interpreted your question to refer to the Suspected Medicine Adverse Reaction Search https://www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp.This database is programmed to remove invalid reports.

I acknowledge your statement that links previously provided under OIA H2023032268 are no longer valid. This information is now available in the SMARS database and at the following link: https://www.medsafe.govt.nz/safety/reports-and-promotion/ADR-reporting-statistics.asp.

> *2. Is the practise categorising death as an outcome and not a reaction and therefore reports being considered invalid where death is the only reported reaction applied with vaccines and medicines other than the Covid vaccines?*

Categorising death as an outcome is standard practice for AEFI across all vaccinations and medicines.

> *3. Have I received an answer specific to the circumstance where death is the only reported reaction in any subsequent report?*
> *What is the treatment when an update is made to an existing report(s) where death is the only reported reaction in the update? Are the initial and any subsequent reports then removed from the line listing?*

If whether a subsequent report, indicating only that the subject has died (no other reactions,) results in all lines in the line listing relating to the patient being deleted is dependant on different circumstances of a case please indicate what these dependant variables could be ie timeframe between reports etc.

Please refer to the information provided to you under OIA H2023032271. The Ministry has nothing further to add.

4. There are AEFI- A numbers that were included in Safety Report 46 that are not included in the line listing posted 28/8/23 under 'Reports and Publications on the Medsafe website. The Ministry of Health has declined my request to be supplied with a suite of all reasons for this on the grounds that there is no statutory obligation to 'create new information, compile information they do not hold or provide or prove an opinion'. Has there been any form of analysis or audit done on why these reports ceased to be published in the line listing, in order to establish accuracy of the file? If so please provide anything referencing the results of that audit or analysis. Are some of them reports where death is the only reported reaction in a subsequent report?

The line listing has been removed as it was only an interim measure until the data could be displayed in the SMARS database. No information has been identified in scope of of this part of your request, therefore it is refused under section 18(g)(i) of the Act as the information is not held.

5. This question was asked and the following response given. Please provide the results or any material arising from Medsafe's further investigation.

Question: '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.'

Answer: 'Manatū Hauora did 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.'

Medsafe has looked into this issue and can advise that the data had been extracted in a different way to previously as the size of the dataset was not appropriate for the excel spreadsheet. The information is now included in the Suspected Medicine Adverse Reactions Search.

6. Please provide an org structure document of CARM as it was for 2021-23 and org structure of whatever replacement structure now sits within Medsafe.

This part of your request is refused under section 18(e) of the Act as the alleged document does not exist. Please note, CARM is run by the New Zealand Pharmacovigilance Centre (NZPhvC) within the University of Otago Medical School. CARM does not sit within Medsafe or the Ministry of Health.

Please note, the Ministry has provided you with a number of responses to similar requests. I suggest you refer to all previous information provided to you before submitting subsequent

requests. Repeated requests for the same information may be considered vexatious and refused under section 18(h) of the Act.

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