

9 July 2021

Paul Jones

By email: fyi-request-15670-0c494f13@requests.fyi.org.nz
Ref: H202106858

Dear Paul

Response to your request for official information

Thank you for your follow up request under the Official Information Act 1982 (the Act) on 2 July 2021 relating to the Medsafe Safety Report #14. Information in response to each part of your request is as follows.

"1) Column "Date first reported" contains the Month and Year of the AEFI event. We appreciate you are trying to anonymize the data, however as the Safety reports are issued weekly, we request for this column to show what "Week" of the year it was filed instead of the Month, eg: "Week 23,21" to indicate Week 23 of 2021."

The 'date first reported' is the month, as this aligns with the way Medsafe reports this type of information for other medicines. It is also done this way for privacy reasons.

*"2) Safety Report #14 lists a total of 4521 Total AEFI reports that were received (cumulative). In the XLSM file a total of 4511 events has been provided, ie: there are 10 missing events. We suspect 8 of those missing events are the death reports as we can not find those.
(i) Would you provide the "Preferred Term" number (the code in the parentheses) used for reporting the 8 deaths.
(ii) Confirm what events have been excluded when generating the XLSM file that may explain the 10 missing events."*

Thank you for bringing this to our attention. It seems that some medication error reports have been miscategorised into the listing. These will be removed and updated. Please note the fatal cases are not identified within this spreadsheet as this aligns with the data released for other medicines and maintains privacy. However, where deaths have occurred after vaccination, these have been outlined in the substantive report.

"3) We request a column to be added for Ethnicity as are given in the written reports."

Ethnicity is not provided in this listing as this is to maintain privacy as some ethnic groups are only a small proportion of the population.

"4) Does the CARM system record the date the injection/administration of the dose was made? If so then would you provide a further Column containing the number of days since dose administration until report filing date for each AEFI event."

This information is not provided to maintain privacy. It is also not provided for other medicines.

I trust this information fulfils your request. 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.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Chris James', written in a cursive style.

Chris James
Group Manager
Medsafe