

22 July 2021

Mary Devlin

By email: fyi-request-16083-b0e7d04e@requests.fyi.org.nz
Ref: H202108555

Dear Mary

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 14 July 2021 for information regarding adverse events following immunisation with COVID-19 vaccines.

Information in response to each part of your request is as follows.

- “1. The weekly spreadsheet is a listing of AEFIs (Adverse Events Following Immunization) received from responders. As stated, an AEFI is considered serious if it results in a death. Where and how are these 16 deaths, each of which is considered to be a serious AEFI, represented in the most recent weekly AEFI spreadsheet?
a. Which line numbers in the AEFI spreadsheet correspond to the deaths reported?
2. Could you please add a date of death field to the AEFI spreadsheet to indicate that a death reaction has occurred?”*

While deaths are classified and reported as a serious AEFI, they are not listed alongside that specific individual in the weekly spreadsheets as this information could compromise the privacy of the deceased persons. Due to the low number of deaths occurring following immunisation, the data may become identifiable to an individual.

- “3. How are miscarriages or spontaneous abortions as they are medically referred to, to be represented in the weekly AEFI spreadsheet published going forward?
4. How have miscarriages or spontaneous abortions as they are medically referred to been represented in the weekly AEFI spreadsheet to date?
5. The latest AEFI spreadsheet as at this date includes an abortion following abdominal pain. Is this a miscarriage or spontaneous abortion? Please clarify this entry?”*

Miscarriages and spontaneous abortions are defined by which stage of the pregnancy they occur. As this information is not always provided in an AEFI report they are both represented in the weekly AEFI spreadsheet under the code “Abortion (10000210).” Therefore, the entry mentioned in your request is referring to miscarriage or spontaneous abortion. Please also note that the reactions in the spreadsheet are not listed in order of when they occurred (i.e., it cannot be assumed that the abdominal pains occurred before the abortion in this instance).

Miscarriages and spontaneous abortions will continue to be represented as such going forward.

- “6. The latest AEFI spreadsheet as of 19 June includes 274 reports of abdominal pain, 146 of these were for women under 50 years of age. Did any of these women also suffer a spontaneous abortion or miscarriage?”*

This information is publicly available in the spreadsheet, with spontaneous abortions or miscarriages are coded as "Abortion (10000210)." Any reports of spontaneous abortions or miscarriage can be found under this code. If abortion is not listed as a potential adverse reaction that means that the individual did not report this happening.

"7. How many reports that include a miscarriage, abortion, spontaneous abortions, or otherwise refer to the loss of an unborn baby have been entered into CARM in relation to a person receiving the COVID-19 vaccine?"

This information is publicly available in the spreadsheet. For your reference there is one report of abortion occurring post-vaccine as of the most recent report (26 June 2021, www.medsafe.govt.nz/COVID-19/safety-report-17.asp#death).

"8. In the weekly AEFI spreadsheet going forward please include all reports of a miscarriage, abortion, spontaneous abortions, or otherwise refer to the loss of an unborn baby and identify them accordingly, where they are or have been entered into CARM in relation to a person receiving the COVID-19 vaccine?"

All reports have been and will continue to be included in the spreadsheet and coded to reflect the information provided by those affected.

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.

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.

Yours sincerely



Chris James
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Medsafe