

14 December 2021

Tess McCawe

By email: fyi-request-17452-eee1fd70@requests.fyi.org.nz
Ref: H202116818

Dear Tess

Response to your request for official information

Thank you for your follow up request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 25 November 2021. You specifically requested:

"I have not been provided with the information I requested. I asked specifically for the decision making criteria for how MoH changed the information related to the reaction I had to the vaccine which was reported by a health professional who was there as "medically significant" and "serious". MoH have changed my record to other categories which were not experienced by me. MoH created a new form with a new number and new information and not provided it. As I lay on the chemist floor, the defibrillator was out and ambulance called because of my heart symptoms. MoH has denied that this happened. The "significant and prolonged shaking" was described as very uncommon but MoH have said it is common. MoH have not provided me with the information requested which is the criteria and process they used to change my medical records.

As MoH's false records will be used to deny me an exemption, I want to know how they explain changing my records."

Copies of the responses to your previous requests, reference numbers H202114758 and H202115491, are enclosed as Appendix 1 and 2.

The adverse event following immunisation (AEFI) report attached as Appendix 3 confirms the details of the report made to the Centre for Adverse Reactions Monitoring (CARM) regarding your adverse event following COVID-19 vaccination. This information was sourced from the COVID-CARM database on 26 November 2021. As you have declined to provide an email address, the Ministry has withheld information that may identify you under section 9(2)(a) of the Act, to protect the privacy of natural persons.

You have the right to ask the Ministry to amend any incorrect information it holds about you. Please contact the Ministry via email at covid-19.privacy@health.govt.nz if you believe any personal information in this report requires correction or if you have any further inquiry regarding information held about you in the COVID-CARM database.

CARM completes a medical assessment of each report to identify and classify reactions for reporting purposes. Information on how CARM assesses these reports is available at:

- www.vaccine-safety-training.org/causality-assessment-of-aefis.html
- www.who.int/publications/i/item/causality-assessment-aefi-user-manual-2019
- <https://apps.who.int/iris/handle/10665/338400>

As explained in the previous response (ref: H202115391), if an event is not classified as an adverse event of special interest (AESI), this does not mean that it is not medically significant. An event may be medically significant without being classified as an AESI. As per your AEFI report attached as Appendix 3, the events you experienced were considered medically significant.

The information included in the attached report is what is taken into account by your healthcare professional when you apply for an exemption. The CARM medical assessment of the event has no relevance and is not part of the exemption process, and an event does not have to be classified as an AESI in order to qualify for an exemption.

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', with a stylized flourish at the end.

Chris James
Group Manager
Medsafe