Appendix 3

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

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

Chris James
Group Manager
Medsafe

Appendix 3

Report information			
AEFI Report ID	AEFI025110	Reporter Type	CIR Vaccinator
Channel	CIR	Received Date/Time	s 9(2)(a)

Consumer information			
Consumer First Name	THERESA	Consumer NHI Number	s 9(2)
Consumer Last Name	MCCAWE	Consumer Date of Birth	s 9(2)(a)
Consumer Ethnicity	s 9(2)(a)	Consumer Gender	s 9(2)

Consumer contact information			
Patient Address	s 9(2)(a)	Patient Phone	-

Vaccination details			
Antigen Name	Pfizer BioNTech COVID-19	Dose Number	1
Time of Antigen Administration	s 9(2)(a)	Vaccination Facility	s 9(2)(a)
Injection Site	Right Deltoid	DHB	s 9(2)(a)

AEFI description	
Occurrence Date/Time	s 9(2)(a)
Reporters Description of AEFI	Patient felt tingling in arms, heart racing and feeling faint. We took her into private area and lay her down with feet up. Rang ambulance and continued to watch breathing and took blood pressure. Blood pressure was high 170/99 second 150/87 and patient had severe and uncontrollable shaking and Dry throat, but no problem swallowing. Ambulance came and have done obs and taken to hospital to observe in case of delayed reaction.
List of terms	Abdominal pain; Chest discomfort; Dizziness; Headache; Numbness

Severity and seriousness			
Severity	Moderate	Seriousness	Serious
Severity details	-	Seriousness Type	-
		Seriousness Detail	Medically Significant

Outcome details			
Outcome	Recovering	Medical attention sought	-
Outcome details	-	Medical attention details	-

Medical history
s 9(2)(a)