Appendix 2

MEDSAFE
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24 November 2021

Tess McCawe

By email: fyi-request-17452-eee1fd70@requests.fyi.org.nz
Ref: H202115491

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 4 November 2021 for:

> *"all documentation relevant to the process and criteria used to determine that AE9128 is not of special interest."*

Adverse events of special interest (AESIs) are pre-specified medically significant events that have the potential to be causally associated with the vaccine and must be carefully monitored. AESI can be serious or non-serious and can include:

- Events of interest due to their association with COVID-19 infection.
- Events of interest for vaccines in general (e.g., to the specific vaccine type or adjuvants).

The list of AESIs for the Comirnaty vaccine takes into consideration the lists of AESIs from expert groups such as the Brighton Collaboration, manufacturers and other regulatory authorities. The AESI list changes based on the evolving safety profile of vaccines. It is important to note that although these adverse events may occur after being vaccinated with a COVID-19 vaccine in New Zealand, they are rare and may not necessarily be related to the vaccine. Medsafe and CARM review the reports to determine whether the vaccine may have played a role in the occurrence of these events. More information on AESIs is available in the safety reports published at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

As stated in the response to your previous request, the final report number for adverse event AE009128 is AEFI-A-033854. This report included the following AEFIs:

- Abdominal pain (10000081)
- Chest discomfort (10008469)
- Dizziness (10013573)
- Dry throat (10013789)
- Headache (10019211)
- Hypoaesthesia (10020937)
- Palpitations (10033557)
- Paraesthesia (10033775)
- Tremor (10044565)

As none of these events are included in the list of AESIs, they were not classified as AESIs. This does not mean that the events were not experienced as significant, rather that they are consistent with common side effects to vaccination with any vaccine.

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
Group Manager
Medsafe