MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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

2 July 2024

Catherine Jamieson

By email: fyi-request-27095-fd8c3ce9@requests.fyi.org.nz
Ref: H2024043265

Tēnā koe Catherine

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 – Manatū Hauora (the Ministry) on 31 May 2024 for:

> *"As provided in H2023033887 for batches FK0892, FK9797, FF2387, FE8163, FK0115, FH4752 and FK9414 please provide the number of adverse events reported to CARM following Covid injection by Pfizer batch for the batches not included in the list above."*

Medsafe does not hold information on any batches outside of those listed. Your request is therefore refused under section 18(e) of the Act, as the document alleged to contain the information requested does not exist.

If it is of use, Medsafe can provide a more detailed spreadsheet of the listed batches and number of adverse events following immunisation (AEFI) reported for each batch. A copy of this is attached. In receiving this spreadsheet, please consider the following caveats:

- Reporting suspicions of an adverse event to a vaccine is voluntary. Therefore, the AEFI reports provided to the Centre for Adverse Reactions Monitoring (CARM) represent a fraction of the total number of AEFI's.
- In order to report an AEFI, a link must be made between an event and the vaccine by the person who experienced the AEFI or the healthcare professional they consulted about the event.
- In order to report an AEFI, the person and/or their healthcare professional must know how to report an AEFI and have the time to report an AEFI.
- Reporting may be influenced by many factors such as media publicity. Therefore, the proportion of events reported is likely to change over time.
- There may be a difference in reporting in different age groups, genders, vaccination sites and ethnicity.
- Reporters may choose to report a diagnosis which would be counted as one event or the symptoms of the condition/diagnosis, which will be many events. The Ministry considers that the two reports would essentially be the same, but for the purposes of this request would have a significant effect on the numbers requested.
- The batch number is as reported, and the Ministry does not know how accurate the recording of batches was.
- The Ministry does not know the size of the batches (and each batch may have been distributed across several countries).

- The Ministry does not know how many doses were obtained from each of the multidose vials.
- The Ministry does not know how much wastage there was from each batch.
- The Ministry does not know if batches were distributed evenly throughout the country, or if there was regional variation which may have coincided with a regional variation in reporting.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

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 Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe