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2 July 2021

D Webster

By email: fyi-request-15530-4b21a994@requests.fyi.org.nz
Ref: H202106617

Dear D Webster

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 31 May 2021 for:

> *"I am requesting for each case included in the COVID-19 vaccine safety reports issued by Medsafe to date and ongoing such as at https://www.medsafe.govt.nz/COVID-19/safety-report-7.asp.*
> *a) CARM #, the case number or unique id used in the system or some other reference number used in the system for this/each case,*
> *b) Reporter details (member of the public, health professional, other)*
> *c) Event narrative; the description of what happened as entered by the reporter into CARM*
> *d) Reaction Type; for example blood clot, stroke, headache, dizziness,*
> *e) Age; the age or age group of the person the adverse reaction report is about if known,*
> *f) Gender; the gender of the person if known,*
> *g) Ethnicity; the ethnicity of the person if known,*
> *h) Date of vaccination reported in CARM if known,*
> *i) Date adverse event reported in CARM,*
> *j) AEFI Details (Adverse event description); the full description of the adverse event or reaction as entered in CARM by the reporter of the event,*
> *k) Outcome; Any patient or reaction outcome recorded in the system,*
> *l) Adverse Reaction Review; such as details as to why the adverse reaction entered into CARM was determined to be unrelated to the vaccination, as stated regarding the stroke and blood clots reported to date.*
> *m) Other Information; Any other information pertaining to the adverse reaction entered and held in CARM not covered by the above list."*

All medicines can cause adverse drug reactions. These reactions can range from minor discomfort to serious harm. Reporting suspected adverse drug reactions enables Medsafe to quickly identify and respond to emerging medicine safety issues. As New Zealand's Medicines and Medical Devices Safety Authority, Medsafe wants to encourage health professionals and members of the public to report any adverse reactions with the goal of improving the safety of medicine use. To encourage everyone to report adverse reactions, both Medsafe and Centre for Adverse Reactions Monitoring (CARM) undertake that patient details will remain confidential.

However, given the public interest in the use of vaccines to combat the COVID-19 pandemic, as you have noted, Medsafe has begun publishing regular reports on adverse reactions following vaccination (AEFI). To preserve the privacy of the people providing information the data has been aggregated.

When anyone completes the online form to report a COVID-19 vaccine AEFI as seen here: https://report.vaccine.covid19.govt.nz/s/ they accept a privacy statement that expressly outlines the purposes for which the information provided might be used under the Privacy Act 2020 and the Health Information Privacy Code 2020 (the Code).

While you have said that you do not want any personal information, the Ministry considers providing information for each AEFI in the granular detail you have requested would breach both the Privacy Act and the Code. The Ministry is concerned the release of this level of information would both breach the obligation of confidentiality offered to reporters of AEFI and discourage others from reporting them.

The Ministry is therefore refusing your request under section 18(c) of the Act on the grounds that the release of the information would be contrary to a specified enactment, namely the Privacy Act and the Code. It is also withholding the information under section 9(2)(ba) of the Act to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information and damage the public interest.

However while we cannot release the information you have requested in granular detail, you can find the following information including the AEFI case number, gender and the ten-year age group of each case publicly available at the following link: www.medsafe.govt.nz/COVID-19/safety-report-14.asp. There is a downloadable excel spreadsheet under *Latest listing of all cases received* at the bottom of the page.

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