

19 December 2023

s 9(2)(a)

By email: s 9(2)(a)  
Ref: H2023033190

Tēnā koe s 9(2)(a)

### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 24 November 2023 for information regarding adverse events following immunisation (AEFI) for COVID-19 vaccines. You requested:

*“Please inform me how many reports of AEFIs were received directly by Medsafe, and what communications Medsafe received or sent about them, both internally, to other government entities, or to government employees who also have external roles, such as Helen Petousis Harris as she collects data and submits to GVDN. Were these reports of AEFIs forwarded to CARM, and if not are they archived securely, and to what end?”*

Medsafe has not directly received any adverse events following immunisation (AEFI) reports. These reports are held in a database which both Medsafe and the Centre for Adverse Reactions Monitoring (CARM) have access to. When the vaccine roll out was established, a new database was created to receive AEFI reports. A webform and a reporting tool within the immunisations register were also developed and these could communicate with the newly created database, where information was populated directly.

In response to your request for Medsafe's internal and external communications regarding these AEFI reports, individuals completing the webform to report an AEFI were informed that there would be no correspondence other than the webform stating that their report had been submitted. Anonymised information is shared with the World Health Organization as per normal processes. Anonymised information on significant cases was shared with the Independent Safety Monitoring Board for their expert advice. The Covid Immunisation programme provided some information to Ministers and DHBs to support local immunisations.

The updated CARM reporting form can be seen here:

<https://pophealth.my.site.com/carmreportnz/s/>. The covid vaccine reporting form is no longer in use since the covid immunisation programme was incorporated into the normal immunisation programme.

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](mailto: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](mailto:info@ombudsman.parliament.nz) or by calling 0800 802 602.

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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](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests).

Nāku noa, nā

A handwritten signature in blue ink, appearing to read 'Chris James', with a stylized flourish at the end.

**Chris James**  
**Group Manager**  
**Medsafe**