

25 October 2023

Catherine Jamieson

By email: [fyi-request-23989-dbd4b6b3@requests.fyi.org.nz](mailto:fyi-request-23989-dbd4b6b3@requests.fyi.org.nz)  
Ref: H2023032268

Tēnā koe Catherine

### **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 9 October 2023 for information regarding Medsafe's safety reports and suspected medicine adverse reaction search (SMARS) online database system. You requested:

*"OIA response H2023021744 identifies a significant difference between the serious adverse event reports received and those publicly reported through Medsafe Safety Reports and SMARS. Please supply any reports, emails or other correspondence pertaining to the difference between reports of adverse events following immunisation with Covid vaccines received and those reported in Medsafe Safety Report #46. How many adverse event reports following immunisation have been received to date for Covid vaccines, both total reports and those that fall under the Medsafe definition of serious?"*

As you were advised in your previous response (H2023031262 refers), the difference in data was due to the COVID-19 vaccine reports not being fully integrated into the normal the Centre for Adverse Reactions Monitoring (CARM) database. Since the databases have not yet been joined a line listing for COVID19 vaccine reports was published [www.medsafe.govt.nz/safety/reports-and-promotion/ADRreporting-statistics.asp](http://www.medsafe.govt.nz/safety/reports-and-promotion/ADRreporting-statistics.asp).

Data reported to the Centre for Adverse Reactions Monitoring is published here: [www.medsafe.govt.nz/safety/reports-and-promotion/ADRStatistics/Comirnaty2023.asp](http://www.medsafe.govt.nz/safety/reports-and-promotion/ADRStatistics/Comirnaty2023.asp).

Medsafe stands by its original decision and has nothing further to add.

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.

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



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