

15 October 2024

9(2)(a)

Tēnā koe 9(2)(a)

Your request for official information, reference: HNZ00065851

Thank you for your email of 23 September 2024, asking Health New Zealand | Te Whatu Ora for the following under the Official Information Act 1982 (the Act):

1. I refer to OIA HNZ00027473 dated 19 September 2023. This OIA states "The Vaccine Safety, Surveillance and Research team (VSSR, formerly known as the "Post-Event team") within the National Immunisation Programme, has no written document on a protocol for sharing information with Pfizer. It was an informal agreement that communication about serious adverse events and safety signal would occur via a secured Microsoft Teams channel". Did Pfizer request an informal arrangement to share information via a secured Microsoft Teams channel? Please explain why there was no formal protocol established from 2021 onwards for sharing information concerning serious adverse events following vaccination and safety signals with Pfizer. Did VSSR establish their own internal protocols, memos or guidelines for communications with Pfizer about reports of serious adverse events and/or reports of death following covid-19 vaccination. If so, please provide these documents including any relevant Minutes of Meetings within VSSR.

2. How many times did communications between Pfizer and VSSR take place on Microsoft Teams for each year from 2020 to September 2024 about serious adverse events and/or reports of death following vaccination? Please provide a breakdown of the communications by way of videoconferences and written messages? Please provide a further breakdown based on whether the communication was initiated by Pfizer or initiated by VSSR from 2020 to September 2024?

3. Did VSSR record the Microsoft Teams videoconferences with Pfizer?

4. How many people currently work for VSSR? Please supply the names and the job titles of the team members of VSSR.

Response

The Centre for Adverse Reactions Monitoring (CARM) reporting system is well-established and has been used for nearly 60 years for spontaneous reporting of adverse events to medicines. During this time, companies have always been able to request data on CARM reports relating to their medicines. As such, processes in the way adverse event reports are shared with pharmaceutical companies were already well established prior to COVID-19.

The only change for COVID-19 vaccines was the way in which this information was exchanged due the establishment of the COVID-19 Vaccine Immunisation Programme (the Programme) and the unprecedented nature of the pandemic.

VSSR was part of the Programme and assisted in this process of the pandemic response using the existing guidelines for sharing information. This included the use of a shared Teams channel with Medsafe and Pfizer, which was used to communicate about serious adverse events and safety signals.

The Teams channel was open to posts and messages (contact initiated) from both sides. There were no video conferences. However, please note that Health NZ no longer has access to this Teams channel. Therefore, the part of your request for the number of communications between Pfizer and VSSR is refused under section 18(e) of the Act, as the information does not exist or cannot be found.

Furthermore, note that internal protocols were not established within VSSR and formal protocols with Pfizer were not arranged by VSSR. Medsafe had a pre-established relationship with Pfizer, as is standard for a pharmaceutical company and medicines control agency, and therefore already had their own protocols in place. Health NZ does not hold information on this relationship. However, if it is something you are interested in, we recommend contacting Medsafe directly at askmedsafe@health.govt.nz.

The VSSR team, now Vaccine Safety team, has four members currently. A team lead, a Senior Advisor and two Advisors. Names of the members are withheld under section 9(2)(a) of the Act, to protect their privacy. In making this decision, we considered the public interest in releasing their names and have determined that it does not outweigh the need to protect the privacy of these staff members.

How to get in touch

If you have any questions, you can contact us at h.nzOIA@tewhatuora.govt.nz.

If you are not happy with this response, you have the right to make a complaint to the Ombudsman. Information about how to do this is available at www.ombudsman.parliament.nz or by phoning 0800 802 602.

As this information may be of interest to other members of the public, Health NZ may proactively release a copy of this response on our website. All requester data, including your name and contact details, will be removed prior to release.

Nāku iti noa, nā



Sara Freitag

**Manager, Machinery of Government Support
National Public Health Service**