MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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10 May 2024

Catherine Jamieson

By email: fyi-request-26390-12b27cf1@requests.fyi.org.nz
Ref: H2024039361

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 10 April 2024. You requested:

> *"Has the Director General of Health, either past or present, been notified by the Accident Compensation Corporation under Section 284(2) of the Injury Prevention, Rehabilitation, and Compensation Act 2001 of any events, or series of events, it believes represent a degree of 'risk of harm' to the public with regard to Covid 19 vaccines or preventative medicines? Please provide any materials relating to that notification if it exists."*

You refer to section 284(2) of the Injury Prevention, Rehabilitation, and Compensation Act 2001: www.legislation.govt.nz/act/public/2001/0049/4.0/DLM103407.html. which states:

> If the Corporation believes, there is a risk of harm to the public, the Corporation must report the risk, and any other relevant information, to the authority responsible for patient safety in relation to the treatment that caused the personal injury.

Medsafe receives information from ACC on its risk of harm reporting under the legislation you have quoted above. This responsibility is delegated to Medsafe by the Director-General of Health. The information received from ACC covers adverse reactions to medicines and medical devices. Any information which constitutes a valid adverse reaction report for the Centre for Adverse Reactions Monitoring (CARM) database is entered into the database and reviewed with the totality of the information in that database.

By making the CARM database accessible, individuals can gain insights into medicine safety and potential risks associated with the products. However, it is pertinent to note that the information that is accessible from the database is limited due to privacy considerations. A summary of information for all adverse reactions in the CARM database is published here: www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp. This incorporates the information Medsafe receives from ACC.

Prior to the health and disability reforms, there was a process where ACC would notify the Director-General of Health of treatment injury decision which may present a risk of harm to the public. For example, surgical mesh was reported to the Ministry, but this process has since transferred to Health New Zealand – Te Whatu Ora.

Copies of notifications received by Medsafe from ACC are withheld under section 9(2)(a) of the Act, to protect personal privacy. By safeguarding privacy, it encourages individuals to provide accurate and detailed reports, which in turn enhances the quality and reliability of the data collected. ACC has also published a response to an official information request regarding COVID-19 vaccination injury analysis, which may be of interest to you: www.acc.co.nz/assets/oia-responses/IPA4784-Covid-Vaccination-Claims-Refresh-Nov21-FINAL.pdf

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