MANATŪ HAUORA
MINISTRY OF HEALTH

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13 April 2023

[redacted]

[redacted] [redacted]
Ref: H2023021445

Tēnā koe [redacted]

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 7 March 2023 for information regarding Australia's Therapeutic Goods Administration (TGA). You requested:

> *1. Can I please have a copy of the full response from the TGA including the date the information was requested and the date of the TGA response.*

Manatū Hauora emailed Australia's TGA on 31 October 2022 requesting any data or other information they could share on adverse reactions to complementary medicines in Australia. The Adverse Event and Medicine Defect Section (SEMDS) division of TGA receive, monitor, and investigate safety signals for Complementary Medicines (CMs) in Australia including adverse event reports. The SEMDS division provided Manatū Hauora with adverse event data on the 9th of November 2022.

Information shared by international regulators frequently contains information that has been provided to those regulators on a confidential basis. In order to maintain the effective operation of their own regulatory regimes, international regulators only share this information with agencies of other governments under formal confidentiality arrangements. As domestic, post-market safety actions may depend on information provided under these arrangements (and there is no power for a New Zealand regulator to require production of the necessary data if held by a foreign agency), there is a strong public interest in maintaining the confidence of material provided by overseas regulators. Release of correspondence between Manatū Hauora and TGA may hinder information sharing in the future, particularly where the information is shared on a confidential basis and would prejudice information entrusted to the Government of New Zealand. Please refer to publicly available responses such as the response you have mentioned in your original request (H2022018873 refers) for more information.

Consequently, the full response from the TGA has been withheld in full on the grounds of section 6(b)(i) of the Act, as its release would prejudice information entrusted to the Government of New Zealand on a basis of confidence by any international organisation.

> *2. Can I have copies of adverse reactions data from Australia and other international countries that the Ministry of Health held on 26 October 2022 relating to Natural Health Products?*

TAG publishes searchable adverse reaction information at: www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen.

As discussed above, product safety information is shared with international regulators and is usually done under formal confidentiality agreements. Until 26 October 2022, Manatū Hauora did not have permission to release information on adverse reactions data from other jurisdictions due to these confidentiality agreements. Manatū Hauora obtained the agreement of the relevant jurisdiction to publish a limited subset of information.

The adverse reactions data from Australia was provided to Manatū Hauora and the proactively released email can be found here: www.health.govt.nz/system/files/documents/information-release/h2022018873_response.pdf.

Any other international data that Manatū Hauora holds is withheld in full under section 6(b)(i) of the Act, as its release would prejudice information entrusted to the Government of New Zealand on a basis of confidence by any international organisation.

> *3. Can I have copies of recall data from Australia and other international countries that the Ministry of Health held on 26 October 2022 relating to Natural Health Products?*

The TGA maintains a recall actions database, which you can find at: www.tga.gov.au/recall-actions-database.

The release of recall data from Australia and other international countries must occur with agreement of the other jurisdiction. Any data Manatū Hauora may hold is withheld in full under section 6(b)(i) of the Act.

> *4. Can you please provide me with the recall notices for those two products?*

Recall notices are publicly available. I have therefore not included the notices under section 18(d) of the Act. You can find information on therapeutic product recalls is published on the Medsafe website here: www.medsafe.govt.nz/hot/Recalls/recallsearch.asp. You can identify and search in the time period 1 January 2015 to 31 December 2017 to see all recalls in this time period.

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

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Te Pou Rautaki | Strategy, Policy & Legislation