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MINISTRY OF HEALTH

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Athina Andonatou

By email: fyi-request-21620-144e8e55@requests.fyi.org.nz
Ref: H2023020698

Tēnā koe Athina

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 21 February 2023 for information regarding the Therapeutic Products Bill. The first part of your two-part request is as follows:

> *"1) Please send me the peer reviewed scientific papers that have been used to inform the proposed changes to the Therapeutics Products Bill. The link you shared https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime has the cabinet meeting minutes or regulatory impact statements which is not what I've asked for."*

In responding to this part of your request, it will be helpful if I provide you with background information about the development of the Therapeutic Products Bill. New Zealand's government, industry and practitioners have recognised for a number of years that our regulatory regime for medicines and medical devices was becoming increasingly out of date, not fit for purpose, inflexible and out of step with comparator countries. The Therapeutic Products Bill 2022 (the 2022 Bill) was preceded by other initiatives to produce a regulatory regime that was both fit for purpose and future-proof. Prior to the development of the 2022 Bill, the latest of these initiatives involved the development of the Therapeutic Products Bill 2018 (the 2018 Bill), a draft of which was released for consultation in 2018.

A significant change between the 2018 Bill and the 2022 Bill involved the inclusion of natural health products (NHPs) in the 2022 Bill. As with the regulatory regime for medicines and medical devices, the need to reform New Zealand's regulation of NHPs has been acknowledged for over a decade. Current regulatory arrangements make it difficult for New Zealand's NHP industry to export and innovate. They also do not provide an appropriate level of assurance that products imported and supplied in New Zealand are safe for consumers or made to the appropriate quality standards.

In response to these issues, a Natural Health Products Bill was introduced into Parliament in September 2011. It progressed to the Committee of the Whole House before lapsing in November 2017. Subsequent to the release of the 2018 Bill, the Government decided to

include NHPs within the scope of a new Therapeutic Products Bill. This decision recognised that NHPs and other therapeutic products require similar regulatory schemes.

The information above shows that the provisions of the 2022 Bill, including those that apply to NHPs, have been under active development for well over a decade. The development process has been spread over multiple phases and has included input from industry and consumer stakeholders, government officials and independent scientific advisors, as well as from overseas experience and expertise. It is reasonable to assume that the many individuals and organisations involved based their contributions on a variety of sources, including peer reviewed scientific papers.

The significance of this information for your request is that providing you with "*the peer reviewed scientific papers that have been used to inform the proposed changes to the Therapeutics Products Bill"* would involve a very substantial amount of research and collation. Accordingly, this part of your request is refused under section 18(f) of the Act. This section provides that a request may be refused if "the information requested cannot be made available without substantial collation or research."

The second part of your request is as follows:

> *"2) Please also provide me with how many people have died or been hospitalised due to taking supplements or natural remedies in the last 10 years and the name of the supplement or natural remedy that caused it." The reply you provided to this question gave me links to www.health.govt.nz/system/files/documents/information-release/h2022018873_response.pdf. These are just general websites, I'm asking for the exact evidence that is being used to inform the proposed changes to the Therapeutics Products Bill, rather than general links."*

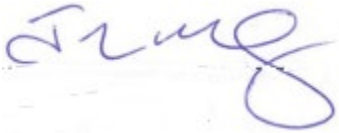
Manatū Hauora has already provided you with a previously released response under the Act. This included reports of cases of suspected adverse reactions associated with dietary supplements and herbal medicines received by the Centre for Adverse Reaction Monitoring (CARM) from 2013-2021. You can access the CARM reports directly through this link: www.medsafe.govt.nz/publications/OIA/20Dec2018ADRsCompMed.pdf.

I note that some information in this table which would have been relevant to your request has been redacted under section 9 of Act, to protect the privacy of natural persons, including that of deceased natural persons.

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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