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13 June 2023

s 9(2)(a) [redacted]

[redacted]
Ref: H2023025335

Tēnā koe s 9(2)(a)

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 13 May as follow up to information previously provided to you regarding the Therapeutic Products Bill (the Bill) (H2023019499 refers). Each part of your request is responded to below.

> *Do you currently have any credible estimates of the cost of administering proposed regulations for NHPs? Yes or no. If you please provide the figures. Please answer this question directly, in plain English, with no links to other material.*

Please refer to the decision made under your previous request for information (H2023019499 refers). Manatū Hauora has nothing further to add regarding this part of your request.

> *Specifically how many of those 16,500 submissions requested that clauses relating to the regulation of NHPs be removed from the Bill? Please answer this question directly in plain English with no links to other material*

The Health Committee returned their report to Parliament on their consideration of the Bill on 13 June 2023. Included on their website is the Departmental Report, which provides in-depth analysis of the submissions to the Health Committee and a summary of those submissions.

Included in the report is a breakdown of the submissions received. Of 16,586 written submissions the Committee received on the Bill, 9,042 submissions (including 4,892 submissions that made a one-line reference to NHPs) stated opposition to the Bill, or elements of the Bill, on the basis of inclusion of NHPs in the Bill.

You can read the full report on the New Zealand Parliament's website. Many further documents regarding the Bill are available on Parliament's Health Committee's website.

> *Q. I am not asking for names. I am asking for data. How many people in New Zealand have been hospitalised or died in the last 10 years due to the use of NHPs? Which products were recalled and why? Please answer this question directly, in plain English, with no links to other material.*

Between 2013 and 30 September 2018 the Centre for Adverse Reactions Monitoring (CARM) received 193 cases of suspected adverse reactions associated with dietary supplements and herbal medicines. You can find this information in a previous OIA response, which is publicly available here: www.medsafe.govt.nz/publications/OIA/20Dec2018ADRsCompMed.pdf.

Manatū Hauora maintains its decision to withhold specific information regarding hospitalisations and deaths under Section 9(2)(a) and Section 9(2)(ba)(i) in response to your request for information. We understand that you are not requesting names however, specific outcomes such as hospitalisation or death related to specific products could prejudice the privacy of individuals even if their names are withheld. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under your requests. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

The only products that have been recalled are those that were medicines under the Medicines Act 1981 and may have been incorrectly marketed as dietary supplements or as NHPs. I note your request to not be provided with links, however, publicly available information on some recalls and warnings notified by Medsafe can be searched on the Medsafe website:

- Safety Communications can be found at: www.medsafe.govt.nz/safety/SafetyCommunications.asp
- Media releases can be found at: www.medsafe.govt.nz/hot/MediaContents.asp.
- The recalls database can be found at: www.medsafe.govt.nz/hot/Recalls/RecallSearch.asp

> *How many New Zealanders have been harmed in the last 10 years due to contamination of NHPs, or because they did not contain the ingredients listed or because the propotions were not in safe concentrations? How many New Zealanders were hospitalised and how many died in these circumstances?*

As stated in response to your previous request for information (H2023019499 refers) Manatū Hauora does not hold specific information on harm related to NHPs as there is no legislative provision for a product to be marketed as a NHP in New Zealand. Medsafe is aware of harm resulting from medicines that have been incorrectly marketed as dietary supplements when they were actually unapproved medicines, but not information related to contamination of such products. In regard to products determined to be medicines, Medsafe has received reports of hospitalisation from heavy metal poisoning from some Ayurvedic medicines, and harm from some products marketed as Traditional Chinese Medicines because they have been adulterated with prescription medicines.

Any reported issues relating to the manufacture of dietary supplements would be referred to the Ministry of Primary Industries (MPI), as the Dietary Supplements Regulations do not include quality requirements in manufacture.

The difficulty with reporting on such products is the lack of regulation, including a post market monitoring system. There is no obligation for companies supplying them to inform Medsafe when an adverse reaction occurs. And an adverse reaction may not always be attributed to something thought to be ‘natural’. The Therapeutic Products Bill seeks to amend this.

> *How many complaints to MedSafe that health benefit claims relating to NHPs are not backed by traditional or scientific evidence have been upheld in the last 10 years and which products do these relate to?*

There is currently no legislative provision for a product to be marketed as a NHP in New Zealand with health benefit claims that are supported by traditional or scientific medicine. Medsafe does not, therefore, keep a record or investigate complaints of this type. Medsafe would only investigate if a complaint indicated that the product was actually a medicine.

The Dietary Supplements Regulations do not regulate health benefit claims. Regulation 11 of the Dietary Supplements Regulations specifies that therapeutic claims are not permitted.

Medsafe does not therefore have information about any health benefit claims relating to NHPs and whether they are backed by traditional or scientific evidence, and this part of your request

of your request is refused under section 18(g)(i) of the Act, as the information requested is not held.

I hope this additional information fulfils your request. 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

Tim Vines
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Strategy, Policy and Legislation | Te Pou Rautaki