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12 May 2023

s 9(2)(a)

Ref: H2023023504

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your follow up request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 13 April 2023 for information regarding natural health products (NHPs). Each part of your request is responded to below.

> *Have you done any cost modelling on the costs of administering the proposed new regulations for Natural health Products (NHPs) Yes/No If yes please provide the annual budget in numbers not in a link to a 20-page document, where will this money come from in plain words no links to documents,*

Initial work has commenced to estimate the costs of administering new regulations for therapeutic products (including NHPs), if or when the Therapeutic Products Bill is enacted. However, any documentation within scope of your request will contain information about costings, estimates and discussions, which may, if released, prejudice or disadvantage future commercial activities of Manatū Hauora. As such, this documentation is withheld in full under the following sections of the Act:

- Section 9(2)(f)(iv), to maintain the constitutional conventions that protect the confidentiality of advice tendered by Ministers and officials, and
- Section 9(2)(i) to enable a Minister of the Crown or any public service agency or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities
- Section 9(2)(j), to enable a Minister or any public service agency to carry on negotiations without prejudice or disadvantage (including commercial and industrial negotiations).

I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time. If the Bill passes, then the cost of administering the new NHP regulations will be subject to usual budget processes and will be analysed carefully in terms of their net benefits.

> *Up to 50% of New Zealanders take NHPs. MedSafe is proposing regulations which will cause vendors to incur significant additional costs. MedSafe has no idea what the impact of the regulations will be on the cost of these products to ordinary New Zealanders during a period of high inflation. On this basis alone Medsafe does not have sufficient information justify that the proposed regulations are proportionate. ie that they will do more harm than good. Is this statement correct?*

A response to your question is included in a publicly available list of common questions on the Therapeutic Products Bill here: www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime/common-questions-therapeutic-products-bill Please refer to the section titled *'Will consumers see an increase in the cost of NHPs?'*

> *Why would you pass legislation and then seek feedback? Would it not make sense to consult on the potential cost impact on consumers first in order to better understand whether the solution proposed is proportionate to the alleged problem?*

Manatū Hauora engaged with a range of stakeholders in 2022 on different aspects of the Bill, including targeted consultation with the natural health products sector on 1 and 3 November 2022. Most recently, Parliament's Health Select Committee received more than 16,500 written submissions on the Bill. The Select Committee process is an important part of seeking the public views on legislation and will inform the Committee's recommendations to Parliament on the Bill, including possible amendments. If the Bill passes, subsequent regulations will be drafted and consulted on, which will provide another opportunity for engagement with the natural health products sector.

Finally, Manatū Hauora notes that cost impacts are only one consideration that may be relevant to a decision to regulate a sector or activity. Other considerations that supported the Government's decision to regulate NHPs (including ensuring products are manufactured appropriately and their health benefit claims are substantiated) are set out in the publicly available documents referred to in our previous correspondence.co

> *The data covering 2013-2018 shows 2 recalls and 193 adverse events and I presume no hospitalisations or deaths? Please advise which products were recalled and why? Is this the only evidence that is available showing harm caused by NHPs?"*

In response to your previous OIA request reference: H2023019499, we included a document containing information relating to adverse reactions relating to dietary supplements and herbal products from 2013 to 2021. Please note, some information has been withheld under the following sections of the Act:

- Section 9(2)(a), to protect the privacy of natural persons, and
- Section 9(2)(ba)(i), to protect information which is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information from the same source.

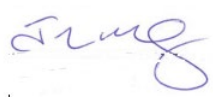
I have considered the countervailing public interest in releasing the withheld information referred to above and consider that it does not outweigh the need to withhold at this time. Therefore, it is not possible to comment on hospitalisations and deaths relating to the adverse events contained in this document. Likewise, information on product recalls is also withheld.

There is no other specific data demonstrating physical harm caused by NHPs in Aotearoa New Zealand. It is unclear if this is due to NHPs being safe or due to underreporting and limited investigations, as the reporting of adverse events from the use of NHPs is voluntary. As outlined above, physical harms are not the only risks that have been taken into account by the Government. The Bill is intended to protect, promote and improve the health of New Zealanders by ensuring NHPs are not contaminated, actually contain the ingredients listed (and in safe concentrations) and make health benefit claims that are substantiated by traditional or scientific evidence.

I trust this information fulfils your request. 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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