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17 February 2023

s 9(2)(a)

By email: s 9(2)(a)  
Ref: H2023019499

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 15 January 2023 for information regarding natural health products. Each part of your request is responded to below.

1. *The estimated or budgeted annual costs of administering the proposed new regulations for Natural Health Products (NHPs).*

The Therapeutic Products Bill (the Bill) does not state annual administration costs. It provides a broad cost recovery power, with regulations able to impose fees and levies to fund the costs of administering the Bill (clause 335-342). In particular, the Regulator, Chief Executive of Manatū Hauora, and the Minister of Health are required to take reasonable steps to ensure those costs are recovered in a way that is equitable, efficient, justifiable, and transparent. If the Bill passes, proposed fees and levies will be publicly consulted on as part of the development of regulations.

In preparing the Bill, multi-criteria analysis was used when considering cost implications. This can be found in the following publicly available documents:

- The 2021 *Regulatory Impact statement: Regulating natural health products*, is available at: [www.health.govt.nz/system/files/documents/pages/regulatory\\_impact\\_statement\\_-\\_regulating\\_natural\\_health\\_products.pdf](http://www.health.govt.nz/system/files/documents/pages/regulatory_impact_statement_-_regulating_natural_health_products.pdf). The related Cabinet paper discuss this further: [www.health.govt.nz/system/files/documents/pages/regulating\\_natural\\_health\\_products\\_cab\\_paper\\_redacted\\_redacted.pdf](http://www.health.govt.nz/system/files/documents/pages/regulating_natural_health_products_cab_paper_redacted_redacted.pdf).
- The 2016 *Regulatory Impact Statement: Therapeutic products regulation*, is available at: [www.health.govt.nz/system/files/documents/pages/regulatory-impact-statement-therapeutic-products-regulation.doc.docx](http://www.health.govt.nz/system/files/documents/pages/regulatory-impact-statement-therapeutic-products-regulation.doc.docx). This includes an analysis of the appropriateness of maintaining a cost recovery basis for many of the regulator's functions. This analysis remains current.
- The 2022 Regulatory Impact Statement that considers how the Regulator will be funded, in the context of optimising outcomes for the new therapeutic product

regulatory regime available at: [www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/therapeutic-and-natural-health-products-regulation-supplementary-analysis-2022-no-2](http://www.health.govt.nz/about-ministry/information-releases/regulatory-impact-statements/therapeutic-and-natural-health-products-regulation-supplementary-analysis-2022-no-2). In particular, paragraph 8 on page 5 notes that the Medsafe operating budget is currently \$12.2 million, of which \$10 million is from third party revenue. Paragraph 1 on page 4 notes that Medsafe reports that fees and charges cover approximately 90% of Medsafe's costs. The new regulator will be larger than this to include the regulation of a broader range of products, and therefore will have a larger budget. The related Cabinet paper discusses the cost recovery broadly and is publicly available at: [www.health.govt.nz/system/files/documents/pages/therapeutic\\_products\\_and\\_natural\\_health\\_products\\_regulatory\\_scheme\\_1\\_redacted.pdf](http://www.health.govt.nz/system/files/documents/pages/therapeutic_products_and_natural_health_products_regulatory_scheme_1_redacted.pdf).

2. *The estimated impact the new regulations will have on the price to consumers of NHPs overall.*
3. *Please release all feedback, advice the Ministry has received on point two from manufacturers, importers or retailers of NHPs.*

The Bill does not set a price to consumers for NHPs. As such, this part of your request is refused under section 18(e) of the Act, as the information requested does not exist. The Regulator will be able to recover costs from businesses, but it will be up to the businesses to determine whether they pass on or absorb the costs. Whether, and to what extent, businesses pass on costs to consumers is not quantifiable, given the large number of actors in the sector and uncertainties over other contributors to prices – such as inflation, changes in supply or demand and the freedom businesses (manufacturers, wholesalers and retailers) have in determining the price of their products.

Specific feedback from manufacturers, importers and retailers will not be received until subsequent regulations are drafted and consulted on once the Bill has passed. Currently the Health Committee is calling for submissions on the Bill, with the closing date being 5 March 2022. Some businesses may comment on costs. These submissions will be publicly available here: [www.parliament.nz/en/pb/bills-and-laws/bills-proposed-laws/document/BILL\\_130084/tab/submissionsandadvice](http://www.parliament.nz/en/pb/bills-and-laws/bills-proposed-laws/document/BILL_130084/tab/submissionsandadvice), following closure of the submission period.

4. *Please disclose all evidence the Ministry holds which supports the idea that existing legislation as it applies to Natural Health Products (NHPs) is substantively failing to protect the public.*

Current regulations, which apply to some kinds of products that are commonly called NHPs, are outdated and fragmented, resulting in issues that are outlined in the section 'The need to regulate natural health products.' This is publicly available at: [www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime](http://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime). This is also discussed in the 2021 'Regulatory Impact statement: Regulating natural health products', which is publicly available at: [www.health.govt.nz/system/files/documents/pages/regulatory\\_impact\\_statement\\_-\\_regulating\\_natural\\_health\\_products.pdf](http://www.health.govt.nz/system/files/documents/pages/regulatory_impact_statement_-_regulating_natural_health_products.pdf).

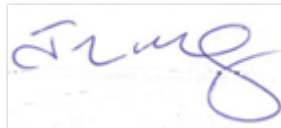
5. *Please include all data showing the number of people who are harmed by year by NHPs and how the Ministry has quantified the gravity of that harm. In particular, please disclose how many deaths, hospitalisations and long term injuries/illnesses are attributed to NHPs each year over the number of years for which the Ministry holds this data.*

There is no specific data for NHPs. However, information relating to adverse reactions relating to dietary supplements and herbal products from 2013 to 2021 is publicly available here: [www.health.govt.nz/system/files/documents/information-release/h2022018873\\_response.pdf](http://www.health.govt.nz/system/files/documents/information-release/h2022018873_response.pdf). The Centre for Adverse Reaction Monitoring (CARM), which collects, evaluates, and analyses spontaneous reports of adverse reactions to medicines and vaccines, herbal products and dietary supplements used in New Zealand, has data that predates 2013.

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](mailto: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](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests).

Nāku noa, nā

A handwritten signature in blue ink, appearing to read 'J. McGrath', enclosed in a thin black rectangular border.

John McGrath  
**Director Priority Projects**  
**Strategy, Policy and Legislation | Te Pou Rautaki**