133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

8 March 2023

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2023020136

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 14 February 2023. Please find a response to each part of your request below:

> *1. May I please request the annual budgets of MoH, medsafe, and medicines control, from 2000-2023, and*
>
> *2. any published estimates by these departments for future costs and health needs based upon trends for each of these years*
>
> *3. I also request information/clarification as to what proportion - if any – of these departments budgets are funded by levies on industry or products.*

Information concerning the budgets of Manatū Hauora can be found at:

- www.treasury.govt.nz/publications/search?search_api_views_fulltext=Health&field_issue_date=1%20Jan%202001&field_issue_date_1=31%20Dec%202023&sort_by=field_issue_date&sort_order=DESC&f%5B0%5D=field_tsy_publication_category%3A2697.

Further information about key initiatives and programmes, as well as a financial summary, for each financial year can be found in our annual reports at:

- www.health.govt.nz/about-ministry/corporate-publications/annual-reports?page=1.

The annual reports also include information about department budgets and their funding from levies on industry or products.

> *4. May I also have the estimates as to the likely budgets for MoH, medsafe, and medicines control; given the proposed expansion of medsafe in the therapeutic product's bill.*

As the Therapeutic Products Bill (the Bill) has not yet been passed, it would be premature for budgets to be developed. Consequently, this part of your request cannot be fulfilled as the document requested does not exist and is refused under section 18(e) of the Act.

Some general information pertaining to funding for the proposed new Regulator is available in a publicly released Cabinet paper on the Manatū Hauora website: www.health.govt.nz/system/files/documents/pages/therapeutic_products_and_natural_health_products_regulatory_scheme_1_redacted.pdf.

Paragraphs 10-11; 61-70; 142-144; and recommendations 11-12 may be relevant to your query. As the new Regulator would be responsible for a wider range of products and activities, its budget is anticipated to be larger than the current regulator, Medsafe.

5. How these costs are likely to be recovered.

The Bill does not state annual administration costs, rather the Bill provides for regulations that would impose fees, charges and levies to fund many of the costs associated with administering the future regime (clause 335-342). The Bill also requires the Regulator, Chief Executive of Manatū Hauora, and the Minister of Health to take reasonable steps to ensure those costs are recovered in a way that is equitable, efficient, justifiable, and transparent. If the Bill passes, secondary legislation will be developed (in consultation with the public) in relation to any proposed fees and levies.

You may also find the following publicly available documents relevant to your query:

- The 2016 Regulatory Impact Statement: Therapeutic products regulation, available at: www.health.govt.nz/system/files/documents/pages/regulatory-impact-statementtherapeutic-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.
- A 2022 Regulatory Impact Statement that considers how the Regulator will be funded, in the context of optimising outcomes for the new therapeutic product: www.health.govt.nz/about-ministry/informationreleases/regulatory-impact-statements/therapeutic-and-natural-health-productsregulation-supplementary-analysis-2022-no-2. 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.
- A related 2021 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.

6. May I please have copies of the evidence demonstrating the dangers to public health of the dietary supplements regulations.

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/informationrelease/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.

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/ourwork/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.

> *7. In previous emails regarding the curious way medsafe ignored its own advice that CBD was not a controlled drug, you released a series of emails from* s 9(2)(a) *in 2009. Could you please advise me as to the OIA number, or resend that information?*

On 23 February 2023 we contacted you in regards to this part of your request in order to verify the particular response under the Act you wanted re-sent to you. You responded with the following:

> *"The emails from* s 9(2)(a) *to I forget who in medsafe, were written in 2009. He was replying to an internal medsafe request as to whether CBD (Cannabidiol) was a controlled substance or not; as they expected it to be, despite being safe and non intoxicating.*
> s 9(2)(a) *confirmed in specific detail how CBD was not controlled.*
> *My apologies for not having more details. The OIA request was probably pre 2020. Thank you."*

Manatū Hauora conducted a search of the centralized Official Information Act Services team database and did not find any response previously sent to you matching the limited description you provided.

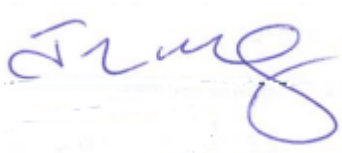
Prior to around the middle of 2018, Official Information Act requests were handled in a de-centralised fashion. This means that responses prior to that point are held by the team responsible for providing the response. Medsafe was also unable to identify a response matching the description you provided.

Therefore, this part of your request is refused under section 18(e) of the Act as the information requested does not exist or, despite reasonable efforts, cannot be found.

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



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