MANATŪ HAUORA
MINISTRY OF HEALTH

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23 December 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022017883

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 30 November 2022 for information regarding the Regulatory Impact Statement (RIS) for regulating natural health products. I respond to each part of your request below.

> *Can I please have copies of the original documents.*

Please find the documents requested listed in Appendix 1 and attached to this letter. Please note excerpts were provided in your previous response (ref: H2022016152) under section 16(1)(e) of the Act as the other content in the papers were deemed out of scope of your original request.

> *Can I please have a list of those that resulted in the statement inferring that consultation had taken place.*

On 6 December 2022 you were contacted by Manatū Hauora via email to clarify this part of request as the RIS stated*, "As noted in section 1.2, the preferred option has not been publicly consulted."*. You responded on the same day with the following:

> *Your previous response said (see attached)*
> *PARC had the following feedback for Brigid Borlase:*
> *• PARC thought the RIS was clear, concise, complete, consulted and mostly convincing...*
> *I'm presuming the PARC is the Ministry's Quality Assurance reviewing, agency/agencies*

The relevant excerpt from the RIS states: *"In the past decade there have been several formal consultation and engagement processes with the natural health products sector, consumers, and other interested stakeholders. These took place in 2010, 2012, 2015, and 2019."*

Please find details of the consultations below.

**2010**

On 19 March 2010, the Ministry of Health released the consultation paper *"The Development of a Natural Health Products Bill"* for public consultation. The aim of this was to consult on high level proposals for the regulation of natural health products, as well as to collect some market information to assist in better understanding the potential impact on industry.

The Ministry received around 1500 written submissions on the consultation paper. Eighty-five percent of submissions were from individual consumers, practitioners or others with an interest, such as academics. Fifteen percent were from organisations or groups. Several of the submissions had multiple signatures or had attached a typed list of names and email addresses of supporters.

More information about the consultation round, including a summary of submissions is available here: The Development of a Natural Health Products Bill | Ministry of Health NZ.

**2012**

On 7 September 2011 the Natural Health and Supplementary Products Bill was introduced to Parliament and referred to the Health Committee of Parliament for examination. The Committee made a request for submissions on the Bill, which closed 24 February 2012.

The Committee received and considered 739 written submissions from organisations and individuals, and 108 'form' submissions. It heard 67 of the submissions orally.

Information on Parliament's consideration of the Bill, including submissions made to the Committee can be found here: Natural Health and Supplementary Products Bill - New Zealand Parliament (www.parliament.nz).

**2015**

In 2015 the Ministry of Health sought public feedback on proposals on natural health products regulations and notices under the Natural Health and Supplementary Products Bill (the Bill).

The Ministry received 578 submissions. Of these, 336 submissions only commented on issues of the Natural Health Products Bill (presented as a form letter provided by the Health Trust) and did not provide comment on the specific issues or questions in the consultation document. In addition, a petition was also submitted, with 6975 signatures. This petition opposed the Bill but did not comment on the regulatory issues this consultation was centred on. This petition is counted as one submission in the figures, but the Ministry acknowledges that 6975 people held the opinions set out in the petition.

Information about this consultation round can be found here: The Regulation of Natural Health Products consultation | Ministry of Health NZ.

**2019**

The Ministry of Health consulted on an exposure draft of the Therapeutic Products Bill from December 2018 to April 2019.

While submitters were not asked for feedback on the regulation of natural health products, some chose to comment. Some commented that they considered NHPs should be regulated under the Therapeutic Products regulatory scheme, while others commented that they should not.

Information about that consultation and the submissions received are here: Therapeutic Products Regulatory Scheme consultation | Ministry of Health NZ.

> *Can I please have the names of two respondents referred to in the statement, "suggest rephrasing from "two respondents" to "a few" or "some" as they are representing views from a peak body*

The two submitters referred to are the Australasian College for Emergency Medicine (ACEM) and the Canterbury District Health Board (CDHB). The submissions have previously been

published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/general-information-releases/submissions-therapeutic-products-bill.

For ACEM please refer to page 43: submissions - part 9.pdf (health.govt.nz).

For CDHB please refer to page 270 at: submissions - lot 7.pdf (health.govt.nz).

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

Steve Waldegrave
**Associate Deputy Director-General**
**Strategy, Policy and Legislation | Te Pou Rautaki**

**Appendix 1: List of documents for release**

| # | Date | Document details | Decision on release |
|---|---|---|---|
| 1. | 21 May 2021 | Email Correspondence: PARC review of therapeutic products RIS x 2 on 21 May 2021 | Some information deemed out of scope of your request. |
| 2. | | PARC Minutes from 21 May 2021 | |
| 3. | June 2021 | QA assessment Regulation Natural Health Products June 2021 | Released in full. |

Document 1

**From:** Sarah Paterson on behalf of PARC
**Sent:** Friday, 21 May 2021 5:09 pm
**To:** Andrew Matheson; Brigid Borlase
**Subject:** PARC review of therapeutic products RIS x 2 on 21 May 2021

Kia ora

Thank you for sending the two therapeutic products RIS to PARC for review and for attending our PARC meeting today.

As discussed, feedback from PARC was as follows:

Out of scope

[redacted]



**Regulating natural health products**

- PARC thought the RIS was clear, concise, complete, consulted and mostly convincing
- PARC had a few minor refinements to make the RIS more convincing
- Suggest making status quo as option one
- Section 2.4, page 11 Rongoā Māori, suggest rephrasing from “two respondents” to “a few” or “some” as they are representing views from a peak body
- Suggest not using the word “illegal” in relation to natural health products (post dietary supplements regulation expiring)
- RIS needs a proofread

When you bring the cabinet paper to PARC, please send the updated RIS to PARC also and PARC can provide the Quality Assurance statement. If you have any questions please do not hesitate to contact me or one of the other PARC members.

Ngā mihi

Sarah Paterson

**[PARC secretariat]** she/her
Analyst | National Investigation and Tracing Centre (NITC) |

**Substantive role**
Advisor | Rights and Protection | Mental Health and Addiction | Manatū Hauora | DDI: 04 816 2489 |

Document 2

**PARC Minutes**

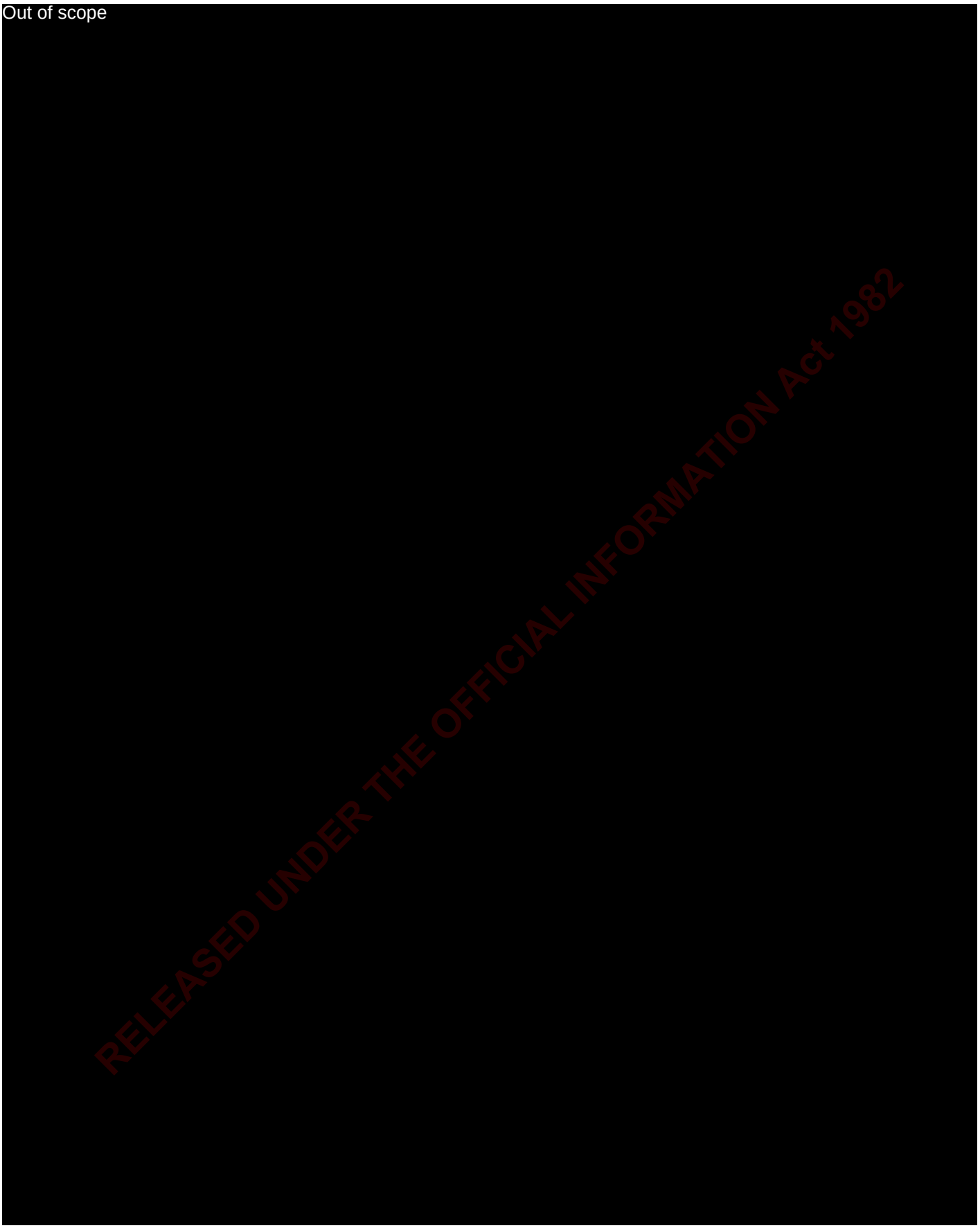
21May 2021, 9.30 – 11 am

Venue: 3S1/ Teams

| | |
|---|---|
| **Attendees:** | Sarah Paterson, Alison Cossar Eve Kloppenburg, Phil Knipe, |
| **Apologies:** | Kiri Dargaville, Richard Taylor, Jo Burgi, Haley Ataera, Emily Kay, |

| ITEM | DISCUSSION/SUGGESTIONS | ACTION |
|---|---|---|
| | | |

Document 2



| | | |
|---|---|---|
| Review of Regulating natural health products RIS | PARC had the following feedback for Brigid Borlase:<br>• PARC thought the RIS was clear, concise, complete, consulted and mostly convincing<br>• PARC had a few minor refinements to make the RIS more convincing<br>• Suggest making status quo as option one<br>• Section 2.4, page 11 Rongoā Māori, suggest rephrasing from “two respondents” to “a few” or “some” as they are representing views from a peak body<br>• Suggest not using the word “illegal” in relation to natural health products (post dietary supplements regulation expiring)<br>• RIS needs a proofread | PARC needs to see the RIS again when it is going up with the cabinet paper and PARC will provide a QA statement |

Out of scope

[redacted]

**Quality Assurance Statement:** Statement for insertion into Cabinet paper

## Comments on: Regulation of natural health products under the Therapeutic Products Bill

| | |
|---|---|
| Date: | 21 May 2021 |
| Comment prepared by: | Phil Knipe (Ministry of Health)<br>MoH Papers and Regulatory Committee (PARC) |
| Name of originating agency: | Ministry of Health |



### Quality Assurance Review

The Ministry of Health's PARC Committee has reviewed the Impact Statement for the above legislative/regulatory proposal in accordance with the quality assurance criteria set out in the CabGuide.

### Text for the *Regulatory Impact Analysis* Section of the Cabinet Paper

As required by the CabGuide, you need to include a *Regulatory Impact Analysis* section within your Cabinet paper. This section must read as follows:

> "The Ministry QA panel has reviewed the Impact Statement titled "*Regulating Natural Health Products*", produced by the Ministry of Health and dated 20 May 2021.
>
> The panel considers that the Impact Statement **meets** the quality assurance criteria.
>
> The Impact Statement is clear, concise, consulted, complete and convincing. The analysis addresses the decisions sought from Cabinet, is balanced in its presentation of the information and the major impacts are identified and assessed."

### Informing PARC of any Further Changes

You must ensure that any substantive changes made to the Regulatory Impact Assessment following receipt of this Quality Assurance Statement are notified to us.

We will either provide confirmation that the Quality Assurance Statement can remain intact or notify you of any further changes we require in order to ensure the quality assurance criteria are met. Providing the changes in "track changes" or highlighting will assist us in responding quickly.

### Publication Requirements

Regulatory Impact Assessments (and Supplementary Analysis Reports, if any) must be published on the websites of the Ministry **and** the Treasury.

The URLs to the published Regulatory Impact Assessment (and Supplementary Analysis Report, if any) must be included in the Explanatory Note to any Bill, Supplementary Order Paper, or regulations for which it was prepared.

Full details of these requirements are available in Section 14 of the Guide to Cabinet's Impact Analysis Requirements.

In order to have the Regulatory Impact Assessment published on the Treasury website, please send to ria@treasury.govt.nz:

- a Word version of the document, and
- a completed Publication Form (available at http://www.treasury.govt.nz/regulation/impact-analysis/publication-form.doc).