Submission

for the

Natural Health and Supplementary Products Bill

consultation document

2 March 2016

Details

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Confidentiality

Please keep my comments confidential: *(reasons including identity of specific comments if applicable)* ☐ Yes
This request can only be actioned if your reasons satisfy Official Information Act criteria

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Company organisation name and address: ☐ Yes

Contact phone number and email address: ☐ Yes

Additional information

I am, or I represent, an organisation that is based in:

✓ New Zealand ☐ Australia ☐ Other *(please specify)*:

I am, or I represent, a: *(tick all that apply)*

☐ Overseas manufacturer	✓ NZ based manufacturer	✓ Importer
✓ Exporter	☒ Retailer	☐ Government
✓ Wholesaler	☒ Institution (e.g. university, hospital)	☐ Member of the public
✓ Natural Health Practitioner	✓ Product notifier	

Please return this form to:

Email: mailto: naturalhealthproducts@moh.govt.nz

or post to: Natural Health Products, Ministry of Health, PO Box 5013, Wellington 6145

Consultation questions

The Natural Health Products Advisory Committee will be seeking comments on:

Ingredients

1 Are there other criteria that the Committee should consider when adding a substance to the permitted substances list?

✓ Yes

☐ No

If yes, please describe these.

- We support practitioner-only products being exempt from the permitted substances list.
- Provision should be made for export only ingredients to be listed as "export only".
- We believe it is vital to ensure there is alignment between the ingredients mentioned in the permitted ingredients list, and the ingredients listed in all herbal monographs and pharmacopoeias that can be quoted for claims under the Act. However, ingredients banned under CITES and other relevant treaties should be subject to controls.
- The guidelines should also be widened to include international pharmacopoeias and key herbal monographs used in herbal medicine. Examples that are currently missing include the new *European Community Monographs* and the *Pharmacopoeia Helvetica*.
- Consideration needs to be given to including guidance for ingredients used in topical products.

2 Of the criteria proposed, are there any that you think should not be considered by the Committee when adding a substance to the permitted substances list?

☐ Yes

✓ No

If yes, please outline your reasons.

-

3 Should the criteria to be considered by the Committee be weighted or ranked in some way?

✓ Yes

☐ No

Please outline your reasons below.

Toxicity: Safety assessment should consider level, risk and history of use when weighting or ranking ingredients for inclusion in the permitted ingredients list.

4 Do you agree that full formulation details of proprietary ingredients should be disclosed?

✓ Yes ***(BUT, SEE THE COMMENTS BELOW)***

☐ No

If not, what alternatives do you suggest?

We support there being a list of ingredients on the label and also provided to the regulator. However, consideration needs to be given to enabling manufacturers to protect their intellectual property by allowing proprietary blend ingredients to be listed without requiring manufacturers to also list the ingredient quantities or ratios on the labels. However, we support proprietary blend manufacturers advising the regulator of ingredient quantities.

5 Are there substances that could be added to or should be removed from the draft permitted substances list?

✓ Yes

☐ No

If yes, please detail below.

• Include food grade flavours and colours in the permitted substances list. • There needs to be a robust system to ascertain whether the new ingredients should be included or added on the list. • There must be a robust system for evaluating new ingredients to be added to the list. We request that applicants are provided with a timeline for this process. • There also needs to be quarterly updates on ingredients that are added to / removed from the list. • Any ingredients that are added by the Canadian or Australian authorities should automatically be added to the NZ list. • We support native NZ plants used in Te Rongo Maori being assessed for inclusion on the list. • Refer to the pharmacopoeia / herbal monograph comments in Qn 1 above.

Health benefit claims

6 Are the following factors the right ones to consider when deciding if claims may be made about named conditions:

	Yes	No
• non-serious	✓	☐
• self-limiting	✓	☐
• suitable for self-management	✓	☐
• suitable for self-diagnosis	✓	☐
• likely to cause serious consequences without health practitioner consultation?	✓	☐

7 Should other factors be considered?

✓ Yes

☐ No

If yes, please detail below.

We request the addition of allowable claims for products that may help in the prevention or management of certain non-self-limiting conditions such as high cholesterol, dementia, diabetes and spina bifida, etc.

8 Should the factors be weighted or ranked in some way?

☐ Yes

✓ No

Please outline your reasons below.

-

9 Are there conditions you think should be added to or removed from the draft list of conditions about which health claims may be made?

✓ Yes

☐ No

If yes, please detail below.

Please add weight management, sports performance, mild diuretic – fluid retention, dry eye (eye strain) to the list of conditions about which health claims may be made.

Ensure conditions cover self-manageable skin conditions fully (e.g. eczema).

Align health benefit claims with the list of conditions (refer to the bullet point at the top of page 7).

Evidence

Relevance and representativeness of evidence

10 Are there other criteria that should be included, or should any of the listed criteria be excluded?

✓ Yes

☐ No

If yes, please detail below.

Included	Excluded	Reasons
	Formulations	Some of a formulation's ingredients may have no relevance to its effectiveness. For example, excipients in tablets and capsules.
	Exclude point 2 on page 9 (i.e. Be relevant to the target population).	We do not think this is necessary because it is not relevant.
	Reword first bullet point on page 9 to read: "Relate to the same method of administration, specific active ingredients, species part and dose form as the product."	The current wording uses the words "dose" and "formulation" in the wrong context and in a manner that is not the industry norm or standard.

Traditional evidence

11 Are these appropriate sources of traditional evidence?

☐ Yes

✓ No

If not, why not?

In a New Zealand context, we do not believe that any one individual can have the "authority to speak on such matters".

12 Are there other sources of traditional evidence that should be accepted?

✓ Yes

☐ No

If yes, please detail below.

Traditional use by medical herbalists or naturopaths of NZ indigenous species over a sufficiently long period of time should be accepted as a source of traditional evidence. Bluemnthal M et al (eds) (2000) Herbal Medicine – Expanded Commission E monographs, American Botanical Council, Austin, Texas Health Canada, Monographs http://www.hc-sc.gc.ca

13 Do you think 75 years is an appropriate minimum period of use for something to be considered to be traditionally used?

☐ Yes

✓ No

If not, what would be an appropriate minimum period and why?

Appropriate minimum period	Reasons
In accordance with EU legislation we propose a period of 30 years for traditional evidence.	Article 16c (1) states: 1. The application shall be accompanied by: (c) bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community.

Scientific evidence

14 Are there other factors we should consider when determining if a type of study is acceptable?

✓ Yes

☐ No

If yes, please detail below.

• Human, animal and in vitro studies should be deemed as valid sources of scientific evidence. • Accept as scientific evidence case studies that are published in peer reviewed journals. • Consider the relative weighting of each type of evidence using traditional use and evidence-based medicine principles.

15 Are the types of studies that are acceptable clear?

✓ Yes

☐ No

16 Should other types of studies be considered acceptable?

✓ Yes

☐ No

If yes, which ones and why?

Other acceptable types of studies	Reasons
See our response to Qn 14.	

Summary of evidence

17 Are the evidence guidelines clear?

✓ Yes

☐ No

18 Are there other evidence-related topics that should be included in these guidelines?

✓ Yes

☐ No

If yes, which ones and why?

Evidence-related topics	Reasons
IP protection	We believe there must be a mechanism that enables companies to protect their IP when presenting evidence to the regulator.
Evidence	• We suggest that the word "summary" is replaced with "file". • We request that the evidence should be available to consumers on request (e.g. via a web link to relevant studie/s), and that natural product manufacturers and marketers do not have to summarise this information on an open domain themselves. • We are concerned that the definition of what should be included on an Internet site in relation to "summary of evidence" is too broad and detailed. Instead the evidence summary should be very brief. Please refer to the Bill in its narrowest definition.

Manufacturing

The Code of Manufacturing Practice

19 Do you agree with the proposed Code of Manufacturing Practice?

☐ Yes

✓ No

If not, why not?

This question is too general and there are insufficient supplementary questions asked to cover the possibilities.

Manufacturing exemptions

20 How frequently should audits be required? Refer to comment below.

Should this differ for different levels of risk?

- ✓ Yes
- ☐ No

Please outline your reasons below.

The frequency should be based on performance as well as size and there should be just one minimum performance standard across the industry. With reference to 4.4.1 and 4.4.2 there is an inconsistent definition of small, medium and large. Please clarify.

21 Do you think there should be exemptions from manufacturing licensing?

- ✓ Yes
- ☐ No

If yes, on what grounds and within what thresholds?

Grounds	**Thresholds**
Practitioner related	As currently stipulated.
Small manufacturers	There could be exemptions on small manufacturers. Please refer to our comments in Qn 20 above.

Fees

22 Are these the right things for the Authority to charge for?

- ✓ Yes
- ☐ No

Are there other things for which the Authority should charge?

- ☐ Yes
- ✓ No

If yes, please outline below.

-

23 Are the charges structured appropriately?

- ☐ Yes
- ✓ No ***(SEE OUR COMMENTS BELOW)***

If yes, please outline below.

- We believe that notification fees are too expensive, and should be under $100 including GST.
- There should be no charges for amendments.
- The export certificate cost should be comparable to MPI (i.e. $30). We also believe that the wording should be changed from "per product" to "per application" and could include multiple products.

24 Do you have any comment on the proposal that notification be for a July–June financial year, and/or the proposals to handle the transition period?

✓ Yes

☐ No

If yes, please outline below.

We suggest that all of the transition periods should be three years so as to ensure alignment between product status and notification.

25 Do you have any comment on the level of the charges?

✓ Yes

☐ No

If yes, please outline below.

- We agree that the first year should be free.
- The fee structure could be reduced by removing the requirement for the evidence summary to be made available in the public domain.
- Also refer to our comments in Qn 23 above.

26 Do you have any comment on the assumptions around volumes each year?

✓ Yes

☐ No

If yes, please outline below.

We think some of the numbers are incorrect. Refer to our answer in Qn 27 below.

Would you expect higher volumes in the first year?

✓ Yes

☐ No

If yes, please outline your reasons below.

- The assumption for new permitted substances and changes to existing conditions should be amended to read: 40-50.
- The export certificate assumption is too low; it could be as many as 5000 or more.
- Applications for licence to manufacture could be around 80.

27 How many products do you anticipate notifying initially, and in the next two to three years?

Initially	**Next two to three years**
N/a	N/a

28 Do you agree that manufacturers are best placed to commission any quality control activities, such as audit, that might be required by the Code of Manufacturing Practice?

✓ Yes

☐ No

If no, please give your reasons below.

29 Are there additional issues relating to fees and charges that you would like us to consider?

✓ Yes

☐ No

If yes, please outline below.

The transitional years should have a significant governmental subsidy so as to keep the costs down during the period that businesses are needing to align their processes with the new law.

Very low-volume products

30 Do you see a case for reducing fees for very low-volume products?

☐ Yes

✓ No

31 How would you define very low-volume products?

-

32 Do you have any suggestions for the design of any provisions, including:

- limits on the number of products that any notifier can have fee exemptions for
- administrative efficiency
- any other issues that might be associated with low-volume products?

☐ Yes
✓ No

If yes, please outline below.

-

Labelling

33 Do you agree that labels should meet the proposed presentation requirements?

✓ Yes – ***(BUT, SEE THE COMMENTS BELOW)***
☐ No

If not, why not?

• Proprietary products should not be required to list the quantity or proportion of ingredients on the label. Refer to our comments in Qn 4. • Please remove the requirement to include the manufacturer's name and contact details if these are different to the product notifier's name and contact details (refer to page 20, bullet point 8 in paragraph 2).

34 Are the proposed minimum labelling requirements the right ones?

☐ Yes
✓ No

If not, what should be included or excluded and why?

Refer to our comments in Qn 33 above.

35 Should product labels include unique identifiers?

✓ Yes
☐ No

If not, why not?

-

36 Is there any other information that should be included, or should any of the listed information be excluded?

☐ Yes

✓ No – **REFER TO OUR COMMENTS IN QNS 33 AND 34.**

If yes, please detail below.

Included	Excluded	Reasons

Notification

37 Is there information that you think should be included in, or excluded from the notification process?

☐ Yes

✓ No

If yes, please give reasons below.

Included	Excluded	Reasons

38 What information that we are proposing be notified do you think should **not** be made publicly available and why?

- Proprietary ingredient blend quantities and ratios.
- Finished product testers in retailers
- Manufacturing licence status
- Retailers
- License status compliance
- Manufacturers
- Contact person
- Compliance with code of Manufacturing Practice

REASON: This information is private to the notifier and is their IP

39 Should products that sell in less than a certain quantity per year be exempt from notification?

☐ Yes

✓ No

If yes, what should this quantity be?

40 Should products for which the annual sales amount is less than a certain figure per year be exempt from notification?

☐ Yes

✓ No

If yes, what should this figure be?

41 Should exemptions on other grounds be considered?

☐ Yes

✓ No

If yes, what would these grounds be?

42 To be fair to all product notifiers, how should requests for exemptions be verified to ensure they actually qualify?

N/a

Recognised authorities

43 Are there any additional purposes for which you think the Authority should also consider recognising other authorities?

☒ Yes

☐ No

If yes, please outline below.

Not necessarily additional, but ref Q 45. EU/Health Canada/TGA ingredients should be automatically recognised. Possibly FDA as well. Where there are products with export only ingredients could those ingredients be recognised by the importing country's authority only allowing a specifically worded export certificate to be issued for that shipment?

44 Are there any purposes for which you think the Authority should **not** consider recognising other authorities?

☐ Yes

☒ No

If yes, please outline below.

45 What other authorities do you think the Authority should recognise and for what purpose?

Health Canada
FDA
TGA – Australia
EU
Substances on the approved Food List
If another appropriate agency has deemed the ingredient as safe after assessment, it should be given that status in New Zealand.

Determining if your product is a permitted natural health product flowchart

46 Does the flow chart to determine if your product is a permitted natural health product make sense to you?

✓ Yes – ***(BUT, SEE THE COMMENTS BELOW)***

☐ No

If no, please outline your reasons below.

Clarification is required so as to cover the scenario where someone sells something in the form of a capsule that is actually a food (e.g. garlic). There needs to be a clear definition of what a natural health or therapeutic product is. This definition should not be determined by the ingredient's delivery method.

47 Are there other considerations that we should take into account?

✓ Yes

☐ No

If yes, please outline below.

- A list of the "local trusted regulators" must be published.
- Homeopathic products should NOT be exempt.
- Add a way to assign the notifications to a new owner (where ownership of a product changes).
- Also add change of company processes.