

# Submission on the Development of a Natural Health Products Bill (Consultation Paper)

## Submission Form

Please provide your contact details below.

Name:	Philip Berghan-Whyman
If this submission is made on behalf of an organisation, please name that organisation here:	The New Zealand Association of Rationalists and Humanists (NZARH)
Please provide a brief description of the organisation if applicable:	<p>The NZARH is a not-for-profit organisation that serves the interests of the non-religious (i.e. those who do not have a belief in gods).</p> <p>The NZARH advocates: the secular society; rational enquiry; and the removal of privilege for religion.</p> <p>The NZARH tries to balance religious influence in government, law, state, education, and media.</p>
Address or email:	pjwhyman@yahoo.co.uk
Interest in this topic (for example, consumer of natural health products, health professional, manufacturer of natural health products, etc):	The Association is concerned that law and public practice in New Zealand ought to be rationally based on evidence. We feel that this is particularly important in fields such as medicine, where there is potential for people to delay effective treatments and therapies while mistakenly undertaking courses of treatment that are ineffective or much less effective than is stated or implied.
<b>Conflict of interest declaration</b>	One of the people involved in the preparation of this submission is Philip Berghan-Whyman, who is a team leader in the Ministry of Health's Government Relations team. He has asked to declare his involvement with this submission, to note that it reflects his personal view, to note that he does not work in the nutrition or medsafe teams or in any other related area, and finally to note that no Ministry resources (including time) were used in preparation of this submission.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982 (the Act). If there is any part of your correspondence that you consider should be properly withheld under the Act, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health (the Ministry) will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box.

I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be placed on the Ministry of Health's website ([www.moh.govt.nz](http://www.moh.govt.nz)) as soon as practicable. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

## Questions on Proposals for a Natural Health Products Bill

### Question 1

Do you support the proposed scope, purpose and principles for natural health product legislation? If not, what other suggestions do you have?

- If a Bill is to be put forward, then the scope appears fine. The Association does ask why such assurance could not be provided by amending the Medicines Act 1982. Medsafe has existing processes for regulating medicines and medical devices. This expertise seems highly relevant to the task of regulating natural products. Moreover, this also seems to be in-line with the Government's priorities on avoiding duplication in the Public Sector.
- The purpose should be amended to "to provide assurance to consumers that [approved] natural health products are safe, true to claim, and true to label"
- The two example principles look good. We suggest a third principle:
  - The level of risk associated with a natural health product ought to be considered in terms of evidence-based medicine.

### Question 2

Do you think the scope proposed for the definition of natural health product is appropriate?

- The scope seems appropriate.

### Question 3

Are there products that would fall outside the definition that you think should be included? Conversely, are there products that fall within the definition that should be excluded?

- Where such products are not already covered by the Medicines Act 1981, the definition of a natural health product should include: nasal sprays, ear drops, ear candles, pessaries, suppositories, and natural health product that are inhalable (for example by smoking, by burning candles, or by aerosol).
- The Association notes that the definition of natural health products needs to be carefully constructed. Many homeopathic products, in particular, do not contain active ingredients in any meaningful amount, and therefore would not be captured by the criterion listing safe ingredients (but would of course be captured by several of the other criteria). Clearly the intention of the Act is to capture these products, it would be unfortunate if a loophole allowed them to not be covered.

### Question 4

Are there any other functions that you consider the advisory committee should have?

- The functions seem fine.

### **Question 5**

Do you agree with the concept of a consultative body and its possible role?

- The Association agrees with the concept of a consultative body.
- It should be mandatory for expertise in the field of toxicology to be represented in any consultative body.
- A danger of such a body is its capture by interest groups.
- The Association is concerned that those with expertise in natural health products should be balanced by people with formal scientific and medical expertise.

### **Question 6**

Do you agree with the proposed self-certification scheme for product approval? If not, what would you like to see instead?

- It is important that New Zealand maintains the ability to override the decisions of overseas regulators, especially in cases where the claims or safety of the product is thought to be questionable by experts in New Zealand.

### **Question 7**

Should an exemption from product approval apply to any particular types of natural health products (for example, certain homoeopathic preparations or aromatherapy products)? If so, please specify which types of products and indicate why you consider an exemption should apply.

- If the purpose of the proposed Act is to assure the veracity of claims about and the safety of products of this type intended for sale or consumption in New Zealand, then particular types of products should not be exempted from meeting the agreed standard.
- Aromatherapy and homeopathy should definitely be covered by the proposed Act.
- As noted in Question 3, other natural products that are not covered by the Medicines Act should be included, regardless of their method of delivery (including those that are smoked, inhaled, inserted into the ear or ears, or inserted into any other body orifices).
- Exemptions typically create opportunities for people to exploit unintended loopholes.
- A person's belief about the safety and efficacy of a treatment – whatever the source of that belief – should not override the need to demonstrate the actual safety and efficacy of a product.

### **Question 8**

Are there other situations in which it should be permissible to supply natural health products without a product approval?

- The Association does not wish to express a view on this aspect of the Bill.

### **Question 9**

Are there specific lists of substances used in other jurisdictions that you think should become part of New Zealand's list of permitted ingredients? If so, please specify.

- The Association does not wish to express a view on this aspect of the Bill.

### **Question 10**

Do you think there should be a list of prohibited ingredients, as well as a list of permitted ingredients?

- Yes. It seems prudent that certain ingredients ought to be prohibited.

### **Question 11**

Are there specific claims used in other jurisdictions that you think should become part of New Zealand's list of allowable claims for natural health products? If so, please specify.

- The Association does not wish to express a view on this aspect of the Bill.

### **Question 12**

Do you believe that the regulator should conduct audits to assess compliance with the requirement that sponsors hold evidence to support natural health product claims?

- Absolutely yes. Not doing so would greatly limit the usefulness of the proposed legislation. The regulator should also assess complaints about the claims and safety of natural health products.
- To ensure transparency in the regulatory scheme and that consumers are able to make an informed choice about the effectiveness of a product, the information supporting any claim should be available to the public.
- A minimum standard of appropriate evidence should be required to support claims. Anecdotal evidence and trials that are too small to determine statistically significant results should not be accepted. If this is not done then the regulatory scheme will fail to meet its purpose of ensuring that products are true to claim.

### **Question 13**

Do you agree with the proposed list of labelling requirements? If not, are there requirements that should/should not be included?

- Quantities should be presented in natural numbers, so as to make the claims more intelligible to consumers who lack a scientific background (for example, using descriptions such as one part per million rather than scientific notations on dilution).
- Descriptions should be in plain English, again, to make them intelligible to consumers who lack a scientific background.
- It should be mandatory that ingredients listed on the label are actually present in an effective dose. For example, claiming the presence of an ingredient – where dilution has effectively removed that ingredient – should be prohibited.

### **Question 14**

Do you agree that an exemption from the general labelling requirements should apply to products that are 'tailor-made' by a natural health practitioner for supply to an individual? If so, what do you think the labelling requirements for such products should be?

- Anyone selling natural health products should have to make their claims about their product in writing. If tailor-made products are to be exempted from labelling requirements, then this should be balanced with a requirement to provide claims and assurances about their product in writing to the consumer.

### **Question 15**

Are there other situations where a labelling exemption should apply?

- As noted, exemptions can lead to unintended loop-holes. Any exemptions should have very strong justification.

### **Question 16**

Do you agree with the proposed minimum requirements for advertisements? Is there any other information that should be included?

- Yes.

### **Question 17**

What information should be required to be provided in radio and television advertisements?

- Information about the following should be required in any radio or television advertising:

- any known serious allergic reactions
- a statement to see your GP first if you are on any other medication (to avoid adverse drug interactions)
- any appropriate warnings for pregnant women, HIV+ people, children, elderly, people with cancer patients, and those who are immune-compromised
- a statement to see you GP if the condition persists.

### **Question 18**

Are there any other types of advertising for which different requirements should be set?

- Internet advertising should be included in the advertising definition and should include the following information:
  - any known serious allergic reactions
  - a statement to see your GP first if you are on any other medication (to avoid adverse drug interactions)
  - any appropriate warnings for pregnant women, HIV+ people, children, elderly, people with cancer patients, and those who are immune-compromised
  - a statement to see you GP if the condition persists.

### **Question 19**

What impact do you envisage the proposed regulatory scheme will have on the ability or willingness of businesses to export natural health products?

- The Association does not wish to express a view on this aspect of the Bill.

### **Question 20**

How would having to obtain product approvals for different markets affect your willingness or ability to export?

- The Association does not wish to express a view on this aspect of the Bill.

### **Question 21**

Do you agree that a code of practice for the manufacture of natural health products should be developed? If not, what standards do you think should apply?

- Yes. The Code of Practice for Manufacturing Natural Health Products should be subject to the same requirements as the Code of Good Manufacturing Practice.

### **Question 22**

What key risk management principles do you think should be included in a code of practice for the manufacture of natural health products?

- Risk management should include:
  - *A procedure for adverse reaction monitoring.* The manufacturer should not be relied on to report adverse reactions to their product, there should be an independent route for such reporting. Patients should be informed on how to report an adverse natural health product reaction via their health practitioner.
  - *A procedure for rapid and effective product recalls*
  - *Evidence of independent testing of imported materials in New Zealand for harmful ingredients or adulterants (such as pharmaceuticals).*

### **Question 23**

Would you prefer the costs of post-market activities to be recovered through an annual product approval maintenance charge or an annual levy based on company or product turnover? Please give reasons for your preference.

- The Association does not wish to express a view on this aspect of the Bill.

### **Question 24**

Should there be an exemption from, or reduction in, the annual charge or levy for small businesses or those supplying low-turnover products? If so, who should qualify and how should 'low turnover' be defined?

- It seems reasonable that the charges should not prohibit small businesses from operating, but small businesses should still have to comply with the terms of the Act.

### **Question 25**

What would be the impact on your business if there were to be an annual product approval maintenance charge of \$500 or \$1,000 or \$2,000? What do you consider would be a reasonable charge?

(For each business that would need to have products entered onto the New Zealand register under these proposals, please include details of number of products supplied in New Zealand, number of products also supplied in Australia, number of products exported to other countries, annual turnover and number of low-turnover products (based on your definition of low turnover in Question 24)).

- It would not be relevant for the Association to express a view on this aspect of the Bill.

### **Question 26**

Do you agree that the costs of completing new ingredient safety assessments should be largely recovered through levies paid by all product approval holders? If not, what cost-recovery mechanism would you prefer?

- Yes.

### **Question 27**

Should there be a cap on the number of new ingredient assessments undertaken each year?

- There should be a mechanism to prevent large manufacturers from flooding the process with an excessive number of applications.

### **Question 28**

Do you agree with the range of tools suggested for inclusion in the compliance and sanctions tool box?

- Yes.

### **Question 29**

Do you think the legislation should include other types of offences? Please specify.

- The Association feels that it is absolutely critical that endangerment of human health be included as a punishable offence. Deception should also be included as an offence.

### **Question 30**

Do you have any specific suggestions about how to manage appeals and dispute resolution?

- The most important thing is to make sure that dispute resolution is timely, accessible and affordable.
- Having clear regulations for natural health products that enable quick decisions would be of great benefit. While mediation is sometimes a good starting point, endless mediation without resolution may be stressful and taxing on those involved.
- Some disputes might appropriately be dealt with by the small claims tribunal.
- The parties involved in a dispute ought to have appropriate opportunity to present their case before final decisions are made about the dispute.

### **Question 31**

Do you think the proposed transition periods for product approvals and manufacturing standards would be adequate to give suppliers and manufacturers time to achieve compliance with the legislation?

- Yes.

**Question 32**

Are there any other aspects of the proposed regulatory scheme for which transitional measures would be needed? Please specify.

- The Association does not wish to express a view on this aspect of the Bill.