

**Submission on NZ Ministry of Health Consultation Paper:
The Development of a Natural Health Products Bill.
(Published March 2010) - 12 PAGES**



Herb Federation of New Zealand Inc.(HFNZ)

Key Objectives of HFNZ:

- 1. To promote education in the cultivation and use of herbs amongst the general public through the production of written educational materials, coordination of national programmes, presentation of public workshops and any other relevant activities.**
- 2. To promote co-operation and encourage unity among herb groups throughout the country and to assemble and disseminate information of interest to members from sources within and beyond New Zealand using appropriate means of communication,**
- 3. To speak to Government through a national body and to promote or oppose bills, legislative or other measures or programmes relating to herbs and allied fields.**

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Herb Federation of New Zealand Inc. interest this topic :

Members of HFNZ use plants in their daily living to assist health and wellbeing. Many are consumers of natural health products and want these products to be widely available, affordable, and of good quality. Some of our members are health professionals with a particular interest in natural therapies. Some manufacture natural health products for personal use and sale.

HFNZ is aware that any members of the public may have access to our submission under the Official Information Act 1982.

Introductory comments:

HFNZ believes that the submission form format is too directive and limits the true spirit of consultation. We have commented using the format because we are of the view that it is better to attempt some influence than not participate because the questions indicate a closed rather than open approach to information collection.

Herbs have been used for centuries by millions of people as food and medicine with very little cause for concern.

We observe that natural health products do not carry the same risks as pharmaceuticals on the market in New Zealand, however it seems that politicians nationally are intent on natural product regulation.

We recall that the previous Labour Government attempted to present legislation to Parliament proposing a combined Australia/New Zealand regulatory system for all therapeutic products, including natural

products. HFNZ and many other consumer groups protested this move and the plan for a combined authority was shelved.

This latest move to regulate natural products is a combined National Party and Green Party initiative and this time plans a New Zealand-based regulatory system. This is a step in the right direction if regulation is inevitable,

however, it is also important that New Zealand does not just adopt the previously proposed ANZTPA system minus the combined authority.

From what we can see of the proposed system in the consultation paper

it would appear that many of these features have been "cut and pasted".

Regulation will cover natural product ingredients, manufacture, health claims, labelling, and advertising. We are unaware of any vast evidence suggesting that natural health products are a safety risk in any of these areas. The consultation document certainly does not alert us to this.

It needs to be remembered that there are many foods and ordinary food products that are more dangerous to some consumers eg. peanuts, monosodium glutamate, food colourings, than many of the natural health products on the market. No one has suggested removing these from the market or restricting their use.

We believe New Zealanders should continue to have access to a wide range of herbs eg. New Zealand native plants, traditional European/Western herbs, Chinese, Ayurvedic herbs, and would view with great concern any attempt to reduce the range of herbs presently available to consumers or to limit consumer access to herbs found in future to have health benefits.

Of real concern to us is that rather than achieving the envisaged low cost, simple, streamlined system intended to regulate these low risk products as set out in the foreword to the consultation document, the system developed will mirror too closely the systems developed to regulate high risk pharmaceutical medicines. This after all is where Medsafe's (the medicines regulatory unit of the Ministry of Health) regulatory experience lies to date.

For some low risk natural products it may be that all that is required is a simple list of ingredients so that a potential consumer can make informed purchase and use decisions.

There is also concern that the cost of compliance will be excessive and that small New Zealand producers may be forced out of business.

We cannot stress too strongly that the personnel designing and operating the natural products regulatory scheme must have appropriate training and expertise in herbal medicine and natural therapies.

Our replies to the submission format questions follow.

Ministry of Health 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?

We agree with the proposed scope, purpose and principles. It is important that the level of risk assigned a natural health products is appropriate and proven. There has been a lot of hype and scaremongering in the media and from some health professionals about risk of some herbs and herbal products. Often claims made are based on single cases with confounding variables or wild generalizations. Examples are given of clinically significant interactions of drugs with some specific herbs. Regulation of these natural products themselves will not prevent herb/drug interactions. Prevention of interactions between drugs and natural products depends on appropriate health practitioner prescribing and teamwork between all health professionals caring for the consumer.

We agree with utilizing features of regulatory schemes internationally but New Zealander consumers have demonstrated to the previous Government that they will not tolerate adoption of the Australian system.

We agree that internationally respected pharmacopoeia should be recognized, including herbal pharmacopoeia. Some of these important works are not available in English and require expert translation/interpretation.

Question 2

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

We agree with the proposed definition of natural health product on page 5/6 of the consultation document. While we agree that products needing to be administered by injection be excluded. With good manufacturing processes that produce a sterile product it would seem that products applied in drop form to eyes need not be excluded.

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?

Animal products or products derived from animals.
eg. Bear gall bladder, snake venom, tiger parts etc.

Question 4

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

We agree that the regulatory authority should be a small unit within the Ministry of Health and that the work of this unit be informed by a technical expert advisory committee.

We believe it is essential that consumers and herbal medicine be represented on this committee.

Question 5

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

We agree with the concept of a consultative body.

The Herb Federation of New Zealand (HFNZ) would like consideration when consumer representation is being actioned.

We agree with the role proposed for this body.

Question 6

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

We agree with the proposed self-certification scheme for product approval.

The applicant's evidence to support product claims should be readily available through the approvals database.

Question 7

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

No, there should not be any exemptions from product approval.

Homeopathic preparations and aromatherapy products both require adherence to good manufacturing process to be safe.

Aromatherapy products are made from plant essential oils and are safe if manufactured and administered appropriately. Labelling is a particularly important issue for use of essential oils.

Question 8

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

Only those manufactured on an individual basis in the context of a clinical consultation by a qualified health practitioner as per the existing conditions in the Medicines Act 1981.

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.

New Zealand should develop its own permitted ingredients list utilizing all appropriate international knowledge.

Question 10

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

New Zealand should develop its own prohibited ingredients list utilizing all appropriate international knowledge.

Reasons for exclusion must be evidence based.

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.

No comment

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?

Yes, but as previously mentioned -the applicant's evidence to support product claims should be readily available through the approvals database. This will reduce audit costs if audit can predominantly be done on-line.

Question 13

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

We agree with the proposed labeling requirements set out on page 12/13 of the consultation document, including the requirements for products manufactured by a natural health practitioner for a client in the context of a consultation.

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?

Client name

Date of prescribing

Description of product

Total amount in mls/mg

Dosage instructions – amount, how often, before/after food.

Practitioner name and contact

Question 15

Are there other situations where a labelling exemption should apply?

No

Question 16

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

Agree

Question 17

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

Product key ingredients

Product use

Contraindications/warnings

How to obtain the product

Question 18

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

No comment

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 New Zealand regulatory scheme should be promoted internationally so that it has credibility in countries our manufacturers are likely to be exporting to. It has the potential to reduce red tape in the country of receipt for exporters.

Question 20

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

See Question 19 above

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, fully support this.

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?

Preferred suppliers of raw materials
Requirements re use of agrochemicals during plant production
Harvesting
Storage of harvested plants
Raw materials inspection/testing
Production specifications
In-process testing
End process testing
Traceability/batch
Packaging
Labelling
Storage
Distribution/traceability
Quality records
Market surveillance

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.

A flat rate maintenance charge

Basing the fee/charge on turnover turns regulation into a money making business for the regulatory authority and takes attention away from the key purpose as set out on page 5 of the consultation document.

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?

Should be an incentive for those supplying low –turnover specialist products where they are the only supplier.

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)).

Regulation of natural health products is to provide assurance to consumers that products are safe, true to claim and true to label.
Regulation should not be viewed or used as a money making exercise for the Government.

If the system is expected to run at a breakeven level then fees should cover the necessary system expenses (management, advisory, consultatory, products database, surveillance and audit activities etc).

The budget also needs to take into account any likely income from sanctions and penalties. Therefore it is impossible to answer Question 25 above re the maintenance charge until full details of the budget are made available.

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?

Agree with a "fee for service" charge. It is unfair to apply a generalized levy on all product approval holders.

Question 27

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

No. Not if payment is on a fee for service basis.

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.

No comment

Question 30

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

It is inappropriate for The Director General of Health to be both the regulatory "decision maker" and the appeals arbitrator.

The Appeals authority could be a sub-committee of the Technical Expert Advisory Committee with membership relevant to the particular appeal/dispute and appropriate legal advice. They could also have the power to co-opt expert members. The sub-committee would report to the Director General of Health in the first instance. The Director General of Health should not be able to veto technical advice.

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?

Time to collect data and set up systems is not the only issue here. There is a huge set up cost for manufacturers who already produce a range of products. Cost of set up (and allowing time to accommodate this) may be more important than time if manufacturers are to remain in business.

Question 32

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

(1) We agree with the three tier legislative structure proposed i.e. the Act – covering definitions, principles, regulator powers etc regulations to cover manufacturing requirements, labelling, advertising etc, and technical lists eg. permitted and prohibited ingredients.

(2) We agree that the regulatory authority should be a small unit within the Ministry of Health and that the work of this unit be informed by a technical expert advisory committee. We believe it is essential that consumers and herbal medicine be represented on this committee.

(3) The question of copying and copyrighting is not addressed in the consultation document. There is some concern regarding possible patenting of some of our native plants and remedies, thus reducing their availability.

END