

Submission Form

Please provide your contact details below.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	New Zealand Self-Medication Industry Association
Please provide a brief description of the organisation if applicable:	See introductory letter
Address or email:	tim.roper@nzsmi.org.nz
Interest in this topic (for example, consumer of natural health products, health professional, manufacturer of natural health products, etc):	Industry trade organisation representing the manufacturers, distributors and suppliers of OTC medicines and complementary health products

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) 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?

We agree with the proposed scope, purpose and principles of the Bill. We would encourage sufficient flexibility to consider the work of other international regulators in comparable jurisdictions. There should be an emphasis on finding a scope that minimises costs and factors in other economic considerations and has an appropriate risk-benefit approach.

Question 2

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

The definition of Natural Health Product in the Bill needs to be broad but clear.

The definition should include a reference to purification and /or extraction techniques which alter structure and properties, however this definition needs expansion or a qualifying statement to allow the purification and/or extraction of components of animal/mineral/vegetable origin if they have been assessed and approved as an allowable ingredient or component in their own right e.g. CoQ10 derived from bacteria/yeast, SAmE, Choline bitartrate, Inositol ,MSM and Curcumin, Lycopene, Lutein ,Reservatrol, probiotics, concentrated fish/crustacean oils.

The proposed definition does not cover all areas of the mucous membranes. The safety concerns which arise from consumers using natural products for ocular, aural, vaginal, anal, nasal or application to any other mucous membranes are serious and should exclude these routes of administration. Safety for these routes of administration has not been established for the majority of natural health products.

We would also comment that in our view cosmetics and sunscreen products that make SPF claims should be excluded from the Natural Products Bill

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?

There are also some ingredients that have no natural equivalents, therefore consideration needs to be given to resolve this issue. We believe the list of permitted ingredients should not include excipients. Some products that are currently classed as low risk medicines should be considered now as natural health products.eg. psyllium husk, urinary alkalinisers There are also some dietary supplements in Australia that

should be considered as natural products in New Zealand. Examples include vitamin, mineral, and herbal preparations containing between 15mg and 25mg of zinc and /or greater than 50mcg of Vitamin B 12.

We are concerned that the Natural Products Bill itself in its definition does not become too prescriptive. Experience shows that the Medicines Act 1981 is now so outdated it makes functioning under this Act almost impossible. We suggest therefore that the Regulations and the Guidelines are used more effectively to avoid in future a need to make changes to the Act. Issues like labelling, advertising, fees, administrative processes, manufacturing need to be in the tertiary rules, not in the Act itself.

Question 4

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

We believe that a further function is the establishing and reviewing of claims. There should be an expert on the team who understands natural products and derivatives and also the international regulatory environment. The expert should understand the environments of all major reference countries and be in a position to assess and recommend best practice by comparing all other recognised regulators. In terms of criteria for such a person we believe that they should have a minimum of 5 years experience in the natural products arena and also be able to show commercial expertise. We would also recommend that an industry representative be appointed to be involved in such decisions.

Question 5

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

Yes – A consultative body should include appropriate organisations, e.g. Natural Products New Zealand, New Zealand Self Medication Industry .It should also include practitioners and consumer representatives. The consultative body should have two functions:

- 1. Technical; and*
- 2. Commercial.*

The committee should represent “best international practice”.

Question 6

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

Yes – This should be via online certification for product approval.

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.

No – We believe a complete list should be compiled of all products being distributed in New Zealand for the purposes of legislative compliance, pharmacovigilance and recall oversight if necessary.

Question 8

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

No – Except where the product is compounded for an individual or solely for export use from New Zealand. We believe that there should be different levels of approval. For example, if the product is compliant in other recognised jurisdictions it would have that fact recognised, when approval is sought in New Zealand.

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.

Yes – The Chinese herbal medications list should be included. Any other AYURVEDIC medicines that are covered by either:

- 1. Chinese pharmacopeia or other reputable pharmacopeias; and*
- 2. All ingredients that were included in the trans-Tasman permitted ingredient list.*
- 3. Substances that may be used in “Listed medicines in Australia” in the Therapeutic Good Order.*

Question 10

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

Yes – But the list would need to be agreed by the technical committee after consultation with industry and stakeholders.

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.

*We believe that anything that is claimed in Australia and other acceptable jurisdictions practising “international best practice” should be acceptable in New Zealand, e.g. **temporary relief of pain of arthritis**. This encourages alignment with comparable markets such as Australia, Canada, USA and EU countries. The claim needs to be linked to the dose and the sponsor needs to hold evidence to support the link between claim and dose. The type of claim that should be allowed on a natural health product*

must be at least the same if not higher than that currently allowed on a food product but not to the same level as a product registered as a medicine.

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?

No – Where the claim made is one that is on the general list. However sponsors should hold evidence to support the specific claims made for their product, so that a paper based audit could be carried out in certain circumstances e.g. if a complaint was made. Note that some allowance for “free text claims” needs to be made to allow for innovation and development. Free-text claims would include low level modifications to claims allowed on the general list.

Question 13

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

We do not believe the New Zealand business address is required (not required by the Medicines Act). The current Dietary Supplements Regulations 1985 allow for the trading name and business address of the manufacturer or seller or packer of the dietary supplement or of the owner of the rights of manufacture or of the principal or the agent or any of them. We believe this is a better definition for natural products.

Secondly, the Expiry Date should be an option with the alternative of “Best Before” date as a statement on the label. It is also important not to have a prescriptive label layout imposed on industry.

Thirdly, all requirements should be specified in the Guidelines to allow for all possible label applications eg. Special requirements for small bottles and blister foil. The Bill should reference the current industry guidelines and /or orders. Defining certain types of packaging which are not considered labelling will avoid potential misunderstandings eg. shrink wrap on pallets is not considered primary packaging or labelling.

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?

Yes – There should be an exemption but we would expect that sufficient information be on the label to ensure the safe use of the product by the end user. The requirements should be covered by the Natural Health Practitioners code or equivalent.

Question 15

Are there other situations where a labelling exemption should apply?

There are other situations indicated below:

- 1. Products not sold in New Zealand, specifically for export.*
- 2. Multi-packs where individual product is kept contained within a multi-pack, e.g. blisters or sachets, not for sale singularly or individually.*

Question 16

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

No – Of the minimum mandatory information detailed in the proposal, we would exclude:

- A statement such as “Always read the label before use”; and*
- The name of the advertiser.*

We believe the only two statements that need to be included are:

- 1. The brand name or common name of the product; and*
- 2. The uses for the product.*

We would also propose that the brand name is only required on promotional items such as pens, t-shirts, etc, and also for items specifically for the trade and not for resale to the consumer. We would suggest that with the two bulletpoints recommended above, that these are sufficient to cover both radio and TV and no further specific statements are required.

Question 17

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

See above re question 16

Question 18

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

Different requirements should be set for advertising in pamphlets, displaying the product or product name, advertisements containing only the price of the product and location of purchase. We would want clarification around whether or not TAPS approval is to be given to meet compliance and whether Healthcare Professional advertising requirements be different from advertising to general consumers-and if so how are they to be outlined.

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?

We have some concerns here as to the impact of the proposal on New Zealand Manufacturers who are involved in export.

Products “not for sale” in New Zealand should not be included on the registry and should only be required to comply with the relevant importing countries’ regulations. Export Certification (also known as Free Sale Advice Notice-issued by NZFSA) is a mandatory requirement for product registrations in overseas markets. If a product is specifically formulated for export, it is possible that some of the ingredients will NOT be on the Permitted List for Natural Health Products sold in New Zealand.

Consequently that product would not be able to go on to the New Zealand register. Sponsors are unable to influence regulators’ decisions in other markets; therefore this proposed change, as it stands, will significantly disadvantage New Zealand sponsor’s ability to grow export markets.

It is imperative that alternative Export Certifications be issued for products that are Export-Only, but not on the register. The current “Regulatory Statement to Foreign Government” Certificate would be a suitable alternative. A copy of the current Certificate is attached for reference.

We propose the current Export Certification system remains for Export- Only Natural Health Products.

Question 20

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

The country importer- not the New Zealand manufacturer- needs to be the sponsor and take responsibility for meeting the standards in that particular country. We believe that this is the only way that the situation would work from a practical perspective.

If separate NZ product approvals could be granted for each country/market. This could aid the registration process and therefore improve the ability to export. But a lower cost/fee would be expected for the second and subsequent product approvals for the same product.

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?

We do not believe a new code of practice is required or needs to be developed. We believe as a minimum standard a list of acceptable codes from other jurisdictions including Australia, Canada, USA or EU countries, Or a list of other trusted codes that industry supports and agrees to adhere to.

Whatever code is agreed to for New Zealand it needs to be along GMP principles but not necessarily to the same standard as would be applied to Prescription medicine

manufacture. This would ensure the capture of poorly manufactured products. It must be developed and agreed to with strong industry representation. Other country codes could be used as a list of approved regulators for imported products. The minimum standard needs to meet the bulletpoints below:

- *Clean premises*
- *Trained staff*
- *Adequate controls on starting materials and finished products*
- *Manufacturing records*

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?

Key risk management principles that include:

- *Safety;*
- *Identity;*
- *Purity;*
- *Quality; and*
- *Strength of the product.*

The personnel being employed within the company in quality and production/manufacture are suitably qualified persons. All processes need adequate documentation e.g. SOP's, training records, raw material documentation, batch manufacturing and packing documentation, in-process and release documentation, equipment records, validation records, and any changes to equipment, processes or formulations, contract manufacturers, quality processes to ensure that the correct substance is being used in the final product and adverse reaction reporting.

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.

Neither – Because it is a government cost in terms of post market activities. If this is not acceptable an alternative could be based on a cost per product but certainly not based on the turnover of the company. The Crown needs to ensure that there are sufficient funds with regard to assessing post marketing activities to restrict the efforts of substandard manufacturers who are not members of the Industry Association. Post market surveillance needs to have a published benchmarking reference against which all products are assessed the reason being that this will allow all products in the market to meet the same standard. Any performance above this standard will be purely voluntary and reference point will apply equally to all participants.

A focus should be on those companies that don't invest to meet these standards rather than on established companies who are industry leaders.

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?

No – There should not. The costs should be sufficiently low to allow all who wish to enter into this industry to be involved commercially. Exemptions or reductions might provide perverse incentives for companies participating in the regulatory scheme and create an unfair advantage for some participants.

As previously stated a levy or fee for low turnover products is only acceptable if the scale is qualified on which this levy or fee is based. This qualifier needs to be established by the natural health products agency. It should require sufficient documentary evidence to justify a low turnover product status.

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)).

We believe that an annual product approval maintenance charge of the order of \$100 per product is more in line with the size and opportunity of the market in New Zealand. This would align with charges in other jurisdictions.

Setting fees too high could discourage companies to launch new products-especially for niche products with low sales volumes/revenue.

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?

We believe that whichever company applies for a new ingredient should be the one that pays the levy. But there should be a period of exclusivity for that company for the new ingredient applied for. We would recommend 3 years minimum. This exclusivity benefit must be able to be monitored and enforced if it is granted.

Question 27

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

No – We do not believe there should be a cap on the number of new ingredient assessments undertaken each year. But this should be included in the tertiary guidelines –not the Bill.

Question 28

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

Yes – We agree but there needs to be appropriate resource and it needs to be on a risk/benefit basis.

Question 29

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

Yes – where a company is a repeat offender the legislation should provide for this.

Question 30

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

No further comment.

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?

We believe the period of 24 months should be used for products that can be continued to be sold and also 24 months for manufacturers of natural health products being allowed to continue manufacturing. This is in contradiction to the 12 months and 2 years proposed.

Question 32

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

We suggest there should be incentives for companies that register products early and meet all the requirements. There should not be any financial disincentives e.g through the payment of fees from date of registration which could deter companies registering products until the end of the transition period. There needs to be a process in place that ensures an orderly registration process continues during the transition.

We would request a 2 year period before any post market surveillance audits on approved products are conducted by the regulator. This will allow companies time to transfer all products through the approval process and become familiar with the new regulations before requests for further information.

It must also be established how products currently classified as medicines, due to claims made, transition into a natural health product.

EXTRA COMMENTS

Within the body of the consultation document, it suggests that the regulator will be a division of the Ministry of Health. We are concerned at the level of cost to set up such a unique division to look after industry after the implementation of the Natural Products Bill- and the cost that is likely to be passed on to industry. We would suggest that Medsafe be reconsidered as the regulator under the Natural Products Bill as we believe the economies of scale that could be gained due to the current resources that are already in place could be significant. We believe that sufficient independence could be established to ensure that the product registration process is done at a low level and not with evaluators who may well also be working on prescription evaluations.

We would be happy to be involved in further discussions around this issue.