

**The Development of a
Natural Health Products Bill**
Consultation Paper

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MANATŪ HAUORA

Foreword

In April 2009, the National Party and the Green Party announced that we would work together to develop a New Zealand-based regulatory system for natural health products that are sold in New Zealand.

Our key concern is to have a New Zealand based scheme that is cost-effective and gives New Zealanders confidence that the natural health products they use are safe and true to label.

We want the scheme to recognise that, in general, natural health products are low risk. The scheme also needs to be as simple, streamlined and low-cost as possible for industry and the government while providing assurance for the public.

Our draft proposals are set out in this consultation paper and the draft Regulatory Impact Statement in Appendix 1. We have taken into account work presented to us by representatives of New Zealand's natural health products industry as well as World Health Organization (WHO) guidance and regulatory schemes in other countries.

Please take the time to consider these proposals and provide feedback. Your comments will help us to finalise our proposals for New Zealand's Natural Health Products Bill.

There will be a further opportunity for input when the Bill is considered by Select Committee.

Hon Dr Jonathan Coleman
Associate Minister of Health

Sue Kedgley
Green Party Health Spokesperson

How to Make a Submission

The Ministry of Health is seeking submissions on the proposals made in this consultation paper in order to inform the development of a Natural Health Products Bill.

Please send your submission to:

Natural Health Products Consultation
Policy Unit
Health and Disability Systems Strategy Directorate
Ministry of Health
PO Box 5013
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OR

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The closing date for submissions is Monday 17 May 2010.

A submission form is included at the end of this consultation paper (see page 43).

A report on the analysis of submissions will be prepared and published on the Ministry of Health's website (<http://www.moh.govt.nz>) as soon as practicable.

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Part 1: Background

What does the term ‘natural health products’ cover?

In this paper, the term ‘natural health products’ encompasses products with a history of human use that are presented in therapeutic dose forms and contain ingredients such as vitamins and minerals or other substances derived from nature.

Such products are often also referred to under a variety of alternative umbrella terms such as ‘nutraceuticals’, or ‘alternative’, ‘traditional’ or ‘complementary’ medicines. Herbal essences and remedies and homoeopathic and anthroposophic medicines are examples of particular types of natural health products that have a long history of traditional use.

Natural health products are used mainly to relieve symptoms of minor, self-limiting conditions and to maintain good health and wellbeing. They are presented in a wide variety of dose forms, such as tablets, capsules, tinctures, solutions, creams, lotions, ointments and drops.

Why regulate natural health products?

While the safety risk from most natural health products is generally lower than for pharmaceutical medicines, safety concerns with natural health products can arise from:

- **poor quality in manufacture**, resulting in:
 - under or over potency or complete absence of the ingredients stated on the label
 - use of the wrong ingredient in the product due to mistaken identity or lack of testing of starting materials
 - adulteration with undeclared ingredients, including prescription medicines (for example, the prescription medicines sibutramine and sildenafil have been found in Chinese medicine products in New Zealand)
 - contamination with heavy metals, pesticides, microbes, radioactivity or other ingredients present in the starting material or used by the manufacturer
 - substitution of a toxic herbal ingredient for the ingredient stated on the label
- **distributors making unsubstantiated claims** about the health benefits of products, leading to some consumers ceasing to take prescribed medication or failing to seek appropriate medical treatment
- **inadequate information being available for consumers to make an informed choice**, for example, inaccurate or incomplete labelling, inadequate dosage instructions, inadequate warnings that a product may not be suitable for certain individuals or population groups (such as those at increased risk of adverse effects due to liver disease or pregnant or breastfeeding women)
- **the interaction** of natural health products with pharmaceutical medicines or with each other, for example, clinically significant drug interactions have been observed with St John’s wort, ginseng, valerian, kava and echinacea.

Risks can also arise when a person seeks medical attention and is not asked about, or does not feel comfortable with disclosing, their use of natural health products. The impact can be serious, especially if there are potential interactions with other natural health products or pharmaceutical drugs.

The risk profile of products within the broad natural health products group varies. Herbal products are considered to present the most risk because they often contain combinations of potent ingredients with complex actions and interactions. In addition, modern extraction and purification techniques can isolate and concentrate active substances to produce an extract that is more potent or more toxic than the herbal starting material or traditional extract.

Regulation of natural health products has been increasing internationally and is recommended by the World Health Organization (WHO).

How are natural health products currently regulated in New Zealand?

Currently many natural health products in oral dose forms are regulated as dietary supplements under the Dietary Supplements Regulations 1985 (which sit under the Food Act 1981). Other natural health products are regulated as related products,¹ medicines or herbal remedies² under the Medicines Act 1981.

The regulatory processes and controls that apply under this legislation are generally accepted as being out of date and inappropriate. In addition, a piecemeal approach to regulation has created a situation that is confusing for industry and difficult to enforce. The need for regulatory reform in this area has been discussed for some time.

International approaches to regulating natural health products

The WHO acknowledges that designing appropriate regulatory systems for natural health products is challenging. In part, this is because it is difficult to clearly define the boundary between natural health products, foods, medicines and dietary supplements.

It is also recognised that researching and evaluating the safety and efficacy of natural health products is often a more complex process than that required for conventional pharmaceuticals. It requires specific expertise in herbal and other natural health products and the development of appropriate and cost-effective evaluation techniques for this category of product.

¹ Under the Medicines Act 1981, a 'related product' is any cosmetic, dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose but does not include a medicine or a substance or article declared by regulations not to be a related product.

² Under the Medicines Act 1981, 'herbal remedy' means a medicine (not being or containing a prescription medicine or a restricted medicine or a pharmacy only medicine) consisting of:

- any substance produced by subjecting a plant to crushing, or any other similar process, or
- a mixture comprising two or more such substances only, or
- a mixture comprising one or more such substances with water or ethyl alcohol or any inert substance.

Internationally, the type of regulation for natural health products, the range of products covered and the level of scrutiny applied to them varies. There is, however a trend towards tighter regulation to provide assurance about product quality and safety for the increasing number of consumers who are choosing to use natural health products.

A comparison of the regulatory schemes in Australia, the United States, Canada, the United Kingdom/European Union, Singapore, Malaysia and China shows that the following types of controls are commonly found.

Pre-market controls:

- Ingredient safety is ensured by regulatory agencies establishing lists of permitted ingredients, lists of banned ingredients and requirements to test starting materials for integrity before use.
- Some form of regulatory approval for market entry is generally required, although this is not currently a requirement in the United States.
- Most countries set manufacturing standards and the regulator makes checks.
- Controls on the level of therapeutic claim that can be made (if any) generally relate to the robustness of the regulatory regime. The more robust the regulation, the stronger the claims that are permitted. In the United States, where the regulatory controls are relatively light, only low-level 'structure/function' claims³ are permitted. In Australia and Canada, where the regulatory controls are more stringent, higher-level claims are permitted (product producers are generally expected to hold the evidence to support the claims they make).
- Labelling requirements generally include requiring all ingredients to be listed in a standardised manner and usage and dose information to be included along with any relevant warnings. In the United States, labels also need to state that the product has not been evaluated by the Food and Drug Administration.

Post-market controls:

- Manufacturing processes are audited to provide assurance about product quality.
- Reporting of adverse reactions by suppliers is mandatory in some countries (particularly for serious reactions) and voluntary in others.
- Controls on advertising are generally aimed at providing truthful and balanced information for consumers.
- Interventions by the regulator range from working alongside producers to improve practice where issues arise to stronger enforcement actions such as mandating the recall of products from the market and imposing fines for breaches of the legislation.

Common features of regulatory schemes internationally include the use of product registers/databases, expert committees to review the safety of ingredients/products, appeals mechanisms and the capacity to undertake audits of manufacturing standards.

³ Claims that describe the effect a dietary supplement may have on the structure or function of the body.

Approach to regulating New Zealand natural health products

A considerable amount of work has been undertaken over the past few years to consider how best to regulate natural health products in New Zealand. This includes a Health Select Committee review, work by the previous and current governments to consider a joint scheme with Australia and more recent cross-industry work to agree fundamental points for the regulation of natural health products. Out of this work, industry agreement on some key principles has emerged. The proposals set out in this paper draw on a number of these principles, for example:

- natural health products should be regulated separately from food and medicines
- suppliers should be able to make health claims for products, supported by evidence
- internationally respected pharmacopoeia should be recognised
- ingredients approved in countries with a similar regulatory framework should be recognised
- there should be a list of permitted ingredients and a list of prohibited ingredients
- an advertising code should be developed by the regulator and the industry
- export-only products should meet the requirements of the importing country
- the regulator should issue appropriate export certificates.

Part 2: Proposals for the Regulation of Natural Health Products

Legislative vehicle

New legislation will be needed to implement a regulatory scheme for natural health products. It is proposed that a Natural Health Products Bill (the Bill) be developed to set out the framework for the new scheme.

Scope of the Bill

It is proposed that the Bill regulate the manufacture, supply and promotion of natural health products.

Purpose

It is proposed that the purpose of the legislation be 'to provide assurance to consumers that natural health products are safe, true to claim and true to label'.

Principles

It is proposed that a small number of principles be set out in the legislation. Two possible principles are as follows.

- The level of regulatory control applied to natural health products should be commensurate with the risks associated with their use.
- Consumers should be supported to make informed choices about their use of natural health products.

Question 1

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

Definition of natural health product

The term 'natural health product' will need to be defined in the Bill.

It is proposed that the term cover products intended for oral use, or for application to the skin or hair, that contain generally low-risk ingredients that are derived from nature, or their synthetic equivalents.

Ingredients derived from plants, bacteria, algae, fungi and animals should not have been subjected to purification or extraction techniques that have altered their structure and properties to such a degree that they should be treated as medicines rather than natural products. For example, willow bark would be a suitable ingredient for a natural health product but acetyl salicylic acid (aspirin), which can be derived from willow bark,

would not. Natural health products will therefore typically contain ingredients such as vitamins and minerals, amino acids, herbs and substances such as honey and deer velvet that are derived from animals.

It is proposed that a natural health product:

- be intended for administration to human beings for the purpose of achieving a health benefit
- be in a form normally used for therapeutic products (tablets, capsules, powders, liquids, creams, lotions, ointments, etc)
- be labelled and promoted for one or more of a specified range of natural health product claims
- contain only ingredients from a published list of low-risk ingredients
- not be intended for administration to the eye or by injection
- not contain ingredients from a published list of prohibited ingredients.

The sorts of ingredients allowed to be included in natural health products would include substances such as herbs and herbal extracts, vitamins, minerals, amino acids and low-risk substances of animal, bacterial or fungal origin. Prescription medicines, pharmacist-only medicines, pharmacy medicines and controlled drugs would not be permitted to be included in natural health products.

Question 2

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

Structure of the legislation

A three-tiered legislative structure, comprising an Act, regulations and tertiary legislation is proposed.

The Natural Health Products Act (primary legislation) would set out matters such as:

- the definition of natural health product
- principles and objectives of the legislation
- functions and powers of the regulator
- obligations of the affected parties
- role of technical committees
- offences and penalties
- rights to an appeals process

- regulation-making powers
- the matters that could be specified in tertiary legislation.

Regulations under the Act (secondary legislation) would set out matters such as:

- labelling requirements
- advertising requirements
- fees
- administrative processes
- manufacturing requirements.

Other mechanisms such as Director-General notices, directions or orders (**tertiary legislation**) may be used for things such as technical lists (for example, lists of permitted and prohibited ingredients) so that they may be easily changed.

Administration

It is proposed that the regulatory authority be a small unit within the Ministry of Health. The Director-General of Health would have the responsibility and accountability for regulatory decisions.

It is also proposed that a technical expert advisory committee be established to provide advice and recommendations, when appropriate, to inform regulatory decisions. Its members would be appointed by the Minister of Health.

The following general principles could apply to the role and composition of a technical expert advisory committee:

- Committee members would be selected from appropriate experts in New Zealand. Relevant expertise could include manufacture of natural health products, consumer issues, clinical practice, herbal medicine, naturopathy, nutrition or nutritional medicine, pharmacognosy, pharmacology, toxicology and epidemiology.
- Membership of the committee would be determined on the basis of expertise, rather than appointing members to represent a particular interest group.

While terms of reference would need to be developed, the functions of the technical expert advisory committee would be likely to include giving advice and making recommendations on:

- quality, safety and efficacy of natural health products
- quality and safety of ingredients of natural health products
- standards for natural health products
- labelling and other information requirements for natural health products.

It is proposed that the usual Ministry processes to ensure accountability to Parliament and the public apply, for example, through annual statements of intent, Parliamentary select committee scrutiny, the annual report, etc.

It is also proposed that the regulator establish a consultative group comprising key stakeholders (including industry and consumer representatives) and conduct consultations with this group on a regular basis. The group would provide the regulator with feedback on its administration of the regulatory scheme and make recommendations on ways in which the scheme or its administration could be improved.

Question 4

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

Question 5

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

Product approval

It is proposed that pre-market product approval be required for natural health products supplied in New Zealand.

Who would need to obtain a product approval?

A person wishing to import or manufacture a natural health product for distribution in New Zealand would need to obtain a product approval. This person (who could be an individual or body corporate) would be called the 'sponsor' of the product. A separate product approval would be required for each natural health product.

The product approval holder would be responsible for the safety and quality of the product and for activities such as maintaining records and reporting adverse reactions.

For each product, only one product approval would be required to be held by a single product approval holder. Others in the supply chain, such as retailers, would not need to hold product approvals provided the products they sell already have approvals obtained by the manufacturer (or person commissioning the manufacture) or the importer.

How would a product approval be obtained?

A product approval would be obtained by making an online application, using a purpose-built electronic application system.

The applicant would need to provide details about the product and its manufacturer. They would do this by entering the name of the product, details of its ingredients (by selecting them from a drop-down list) and details of the manufacturer in an electronic application form. The applicant would also certify that the product met specified requirements for natural health products. For example, an applicant would need to certify that only allowable natural health product claims would be made about particular products and that the applicant held the evidence to support those claims.

Once an application was completed and the applicant had made the required declarations, a product approval would be issued on the basis of the information supplied to the approvals database. The information would then be used to facilitate post-market monitoring.

Would it be possible to recognise decisions of other trusted regulators?

In effect, there would be unilateral recognition of decisions made by trusted overseas regulators in relation to approved manufacturers and the ingredients that would be permitted in natural health products from the time that the scheme commenced as this information would be pre-loaded into the approvals database.

Trusted overseas regulators would be those regulators that have a similar or more rigorous regulatory scheme than the New Zealand scheme. A list of trusted regulators would be issued and kept up to date.

Mutual recognition of decisions would not be achievable in the short to medium term, but it would be a longer-term aspiration that could be realised once the scheme had been operating long enough for other regulators to have confidence in it and its administration. Even in a mutual recognition environment, it would still be necessary to capture product details and the applicant's overseas certifications in the approvals database in order to use this information for post-market monitoring.

How long would a product approval be valid for?

A product approval would remain in force indefinitely, provided the approval holder continued to meet their obligations (such as paying any applicable regulatory fees and reporting adverse reactions) and the product approval had not been cancelled by the approval holder or suspended or revoked by the regulator. A modification process would be used where product ingredients had changed.

Are there some natural health products for which a product approval would not be required?

There would be some situations where a product approval would not be required. It is proposed that these would include the following.

- A product made by a rongoā Māori (or other, for example, traditional Chinese medicines) practitioner for a particular patient. This would mirror the existing exemption in the Medicines Act 1981 and would apply irrespective of whether the practitioner charged for the product or their services.

If, however, a rongoā Māori (or other, for example, traditional Chinese medicines) practitioner wished to import or manufacture and distribute a product outside the consultation setting that focused on the preparation of small quantities of a product for the care of an individual patient, that product would require an approval. This is because an unregulated larger-scale manufacturing process may produce an unsafe or poor-quality product that is used by a large number of people without reference to a learned practitioner who can monitor its safety in use.

The regulatory scheme is not intended to affect intellectual or cultural property ownership issues and would not prejudice the determination of these issues (which form part of the WAI 262 indigenous flora and fauna claim, which is currently before the Waitangi Tribunal).

- Products that are exported from New Zealand but not supplied here.
- Products (or categories of product) that are declared by the Director-General of Health to be exempt from product approval requirements (examples might include certain homoeopathic preparations or aromatherapy products).

Question 6

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

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.

Question 8

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

Safety of ingredients

Developing and maintaining a list of permitted natural health product ingredients

It is proposed that only ingredients on a list of permitted ingredients be included in natural health products. Permitted ingredients would be those active ingredients and excipients⁴ considered to present a low risk to health and safety when included in natural health products that are self-selected by consumers.

It is proposed that the regulator maintain a database of ingredients permitted to be used in natural health products. As a starting point, that list could include:

- a large number of substances allowed to be used in 'natural health products' in other jurisdictions where a similar level of regulatory control is applied (for example, Canada, Australia, Europe)
- a small number of substances that are important in the New Zealand market and that have been assessed for safety and determined to be of low risk.

⁴ Ingredients other than an active ingredient, for example, binding agents.

Such a starting list would contain several thousand ingredients and could be expected to cover most of the ingredients used in products that would fall within the definition of a natural health product.

In some instances, an ingredient might be permitted only in restricted circumstances. For example, a particular vitamin (such as vitamin A) would be permitted to be included in a natural health product but only when used at or below a certain recommended daily dose.

It is also proposed that a list of prohibited ingredients be maintained.

Adding new ingredients to the list

It is proposed that a manufacturer or importer wishing to supply a product containing a new ingredient (or an ingredient on the prohibited list for which a manufacturer holds new evidence of its safety) be able to apply to have a safety assessment undertaken by the regulator.

Once such an ingredient had been assessed and made a permitted ingredient, it could be used in natural health products supplied by any other manufacturer or importer.

It is proposed that the regulator be required to notify the applicant of the outcome of an initial safety assessment within 30 working days. At this point, the regulator would be able to inform the applicant that:

- the substance would become a permitted ingredient
- the substance would not become a permitted ingredient because there was insufficient evidence of safe use or because there was evidence to indicate the substance would not be safe for use in natural health products, or
- additional time would be required to complete the safety assessment process (including reviewing the available evidence and seeking advice from an expert advisory committee).

For many substances, it would be possible to complete the safety assessment and reach a decision within the 30-day period. However, a longer period would be required where the assessment was more complex. Allowing a longer timeframe in such circumstances would reduce the risk of a substance being rejected simply because the safety assessment was complex and could not be completed in the time allowed or an unsafe substance being added to the list because the time allowed for the safety assessment had run out.

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.

Question 10

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

Claims

It is proposed that the regulator maintain a list of permitted claims about natural health products. It is proposed that only low-level claims (such as aiding digestion, helping to maintain joint mobility, preventing or relieving the symptoms of minor illnesses) be included on the list of permissible natural health product claims. Claims about preventing or treating a serious disease would not be permitted.

When applying for a product approval, the applicant would be able to select the claims they wished to use from the list of permitted natural health product claims. The claims selected would depend on the product's ingredients and the expected health benefits of that product.

Having selected the appropriate claims, the applicant would be required to confirm that they were holding appropriate evidence to support each of the selected claims.

It is proposed that product sponsors and industry groups be able to make a request to the regulator for additional natural health product claims to be added to the list.

The intended purpose of a natural health product would be required to be included on the product label and to be consistent with the natural health product claims specified in the product approval. If a manufacturer or importer made therapeutic claims not included in the list of permitted natural health product claims, the product would be considered to be a medicine and would be regulated under the Medicines Act 1981.

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.

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?

Labelling

It is proposed that mandatory labelling requirements be set out in regulations and that the label of products other than those manufactured and supplied by a practitioner to a client include requirements such as:

- the trade name (if any) of the product
- the name and quantity of each active ingredient in the product

- a statement of the net weight or volume or number of the contents of the product's package or container
- a description of the product, including dose form or presentation, sufficient to indicate the true nature of the product
- the intended purpose of the product, consistent with the natural health product claims for which it has been approved
- the recommended daily dose (stated as quantity and frequency) for adults and children (if applicable) for products for internal use, or the directions for use and frequency of use for products for external use
- details of the trading name and the New Zealand business address of the importer or sponsor of the product
- a batch or lot number on each container
- any relevant warning statements (including allergen warnings) or other specific labelling requirements for ingredients specified on the permitted ingredient list
- an expiry date (being no later than five years after the date of manufacture) appropriate to the product
- the storage conditions (where appropriate).

It is proposed that there also be generic requirements relating to the legibility and durability of the labelling of products.

It is proposed that products manufactured by a natural health practitioner for supply to a client following a consultation be exempt from the labelling requirements applying to commercial stock in trade. Practitioners would be expected to label a product in a manner that provides the key elements of information about the product and how it is to be used safely.

It is proposed that there be general provisions covering the requirements for primary containers to provide adequate protection against moisture and contamination of the contents during storage, as well as protection against degradation from exposure to light.

Question 13

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

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?

Question 15

Are there other situations where a labelling exemption should apply?

Advertising

It is proposed that the regulations set out basic requirements for all advertisements for natural health products, such as a requirement for advertisements to:

- be truthful, balanced and not misleading
- provide a balanced representation of the risks and benefits of the product.

It is proposed that 'advertisement' be defined in the legislation to cover promotional material that is published in print media as well as information conveyed through electronic media such as radio, television and the Internet. Labels and price lists would not be defined as advertisements.

It is proposed that a minimum set of mandatory information be included in any written advertisement or advertisement on the Internet. This could include information such as:

- the brand name, or common name of the product
- the uses for the product
- a statement such as 'Always read the label before use'
- the name of the advertiser.

It is proposed that an appropriate and smaller set of requirements for advertisements broadcast on radio or television be developed in recognition of the transitory nature of such advertisements.

Question 16

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

Question 17

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

Question 18

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

Export

It is proposed that sponsors be responsible for ensuring that exported products meet the standards of the importing country. A New Zealand product approval would not be mandatory for an export-only product.

The regulator would, at the sponsor's request, be able to issue an export certificate for a product for which there was a New Zealand product approval. In accordance with cost-recovery guidelines, it is proposed that there be a fee to cover the cost of the regulator providing this service.

The certification would be based on information from the product register and would reflect the level of regulatory control applied to natural health products in New Zealand. Export certification would not be available for products for which there was no New Zealand product approval because the regulator would not hold any information on which to base the certification.

Exporters would still need to obtain from the New Zealand Food Safety Authority (NZFSA) any certification required by the importing country in relation to ingredients or products derived from animals.

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?

Question 20

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

Manufacturers

In order to address the potential risks associated with poor manufacturing practices, it is proposed that manufacturers be required to demonstrate that their manufacturing operation meets minimum standards set out in a risk-appropriate code of practice that is specific to the manufacture of New Zealand natural health products. The code would be developed in consultation with the manufacturing sector and would cover risk management requirements such as the need for:

- clean premises and equipment
- trained staff
- adequate controls on starting materials and finished products
- manufacturing records.

It is intended that the Code of Practice for Manufacturing Natural Health Products apply less rigorous requirements than the Code of Good Manufacturing Practice that currently applies to the manufacture of medicines.

Manufacturers based in New Zealand would need to apply for a licence to manufacture natural health products. The regulator would issue licences to manufacturers when satisfied, on the basis of an audit of the manufacturing operation, that the manufacturer complied with the code. A licence would remain in force unless revoked because a manufacturer failed to maintain its operation in compliance with the code. It is proposed that initially manufacturers be audited annually to check for ongoing compliance.

To ensure that imported products are also produced in facilities operating to an equivalent standard, it is proposed that New Zealand-based companies wishing to source products from an overseas manufacturer supply evidence of acceptable manufacturing standards when applying for a product approval. The evidence could take the form of certification from a trusted regulator. The New Zealand regulator would recognise manufacturer approvals issued by trusted overseas regulators such as Australia's Therapeutic Goods Administration (TGA).

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?

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?

Cost and cost recovery

It is proposed that there be full cost recovery by the industry, in line with The Treasury and Auditor-General principles and guidelines for charging for government services.

It is proposed that the Bill provide principles and mechanisms for cost recovery and that regulations set out who will pay, what mechanisms of cost recovery will be employed and the level of the fees, charges or levies.

It is proposed that the costs of issuing the pre-market approval be recovered by fees charged to the applicant company and that the level of fee match actual costs. Where the regulator recognises product approvals of overseas regulators, a product approval fee will still apply because this fee recovers the cost of maintaining the approvals database, including scrutiny of the overseas data.

It is proposed that the costs of post-market activities be recovered through an annual product approval maintenance charge. This could be a set amount for each product or a levy based on turnover. The cost-recovery mechanism could provide for an exemption from, or reduction in, annual charges or levies for small businesses and/or those supplying low-turnover products.

The cost of completing safety assessments on new ingredients could be recovered from the applicant on a 'fee for service' basis. Alternatively, given that the whole industry benefits from being able to use a new permitted ingredient, the cost could be spread across all product approval holders and recovered through an annual product approval maintenance charge.

It is proposed that a combination of these cost-recovery mechanisms be used for new ingredient safety assessments. The applicant would be required to pay an application fee as a disincentive to lodging applications for substances that would be unlikely to be approved or for substances that have no history of safe use. However, most of the costs would be recovered through an annual maintenance charge paid by all product approval holders.

It may be desirable to put a cap on the number of new ingredient safety assessments undertaken by the regulator each year in order to enable the assessment work to be adequately resourced and the regulator to complete the more complex assessments within a reasonable timeframe and to avoid the need to increase annual product approval maintenance charges if an unexpectedly large number of new ingredient applications were to be lodged within a particular time period.

Further consultation on cost recovery, including the level of proposed fees and levies, would occur during the development of regulations.

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.

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?

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)).

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?

Question 27

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

Sanctions and penalties

The purpose of compliance monitoring and enforcement activities is usually to achieve:

- detection and prevention of non-compliant behaviour that places consumers at risk (through monitoring and testing activities)
- containment of identified non-compliant activities or products (through the use of processes such as recall, seizure, publicising events, etc)
- correction of non-compliant behaviour (through warnings, prohibitions, closures, withdrawal of approvals).

In order to deal with serious or repeat non-compliant behaviour, it is proposed that a compliance and sanctions 'tool box' be developed for use in conjunction with education and training. The tool box could include tools such as infringement notices, prohibition notices, recall or seizure of products, publicising incidents and prosecution.

The tool used in relation to a particular incident would depend on the level of risk inherent in the incident. The available tools would be flexible and extensive enough to enable the regulator to respond appropriately to the level of risk.

It is proposed that there be offences for selling products that do not have approval or that do not meet required standards (for example, for labelling, manufacturing or advertising), for breach of duty and for obstruction of an officer. Other possible offences include endangerment of human health and deception.

It is proposed that the penalties be in line with other recent legislation, such as the Animal Products Act 1999 and the Wine Act 2003; that is, they are likely to range from fines of \$50,000 up to \$500,000 and imprisonment from two years to not more than five years.

Question 28

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

Question 29

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

Appeals and dispute resolution

It is proposed that an appeals and dispute resolution process be developed using best practice principles. There could be an appeal to the decision-maker (most likely the Director-General of Health) in the first instance followed by an appeal to the High Court if there is unsatisfactory resolution. Alternative Dispute Resolution (ADR) could also be considered. In particular, determinative processes such as adjudication, arbitration and expert determination could be appropriate, with the possibility of setting up a review committee to hear disputes. Such a committee could consist of a lawyer skilled in alternative dispute resolution and others appointed by the regulator and the industry.

Question 30

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

Transitional arrangements

It is proposed that transitional measures be put in place to ensure that natural health products already on the market in New Zealand could continue to be sold for a specified period (12 months is proposed) while suppliers take the necessary steps to achieve compliance with the legislation. Similarly, manufacturers of natural health products would be able to continue manufacturing for a specified period (two years is proposed), within which time they would need to achieve compliance with manufacturing standards.

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?

Question 32

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

Interfaces

It is proposed that there be clear boundaries between products regulated under the Medicines Act 1981 (medicines and related products), natural health products and foods.

The Government has amended the Dietary Supplements Regulations 1985 and issued the Supplemented Food Standard for products presented as foods that were formerly regulated under the Dietary Supplements Regulations. Only products that are presented in therapeutic dose forms (therapeutic-type dietary supplements) remain under the amended Dietary Supplements Regulations.

Following passage of the proposed Natural Health Products Bill, the Dietary Supplements Regulations 1985 would be revoked. Therapeutic-type dietary supplements would then become either natural health products (if they met the natural health product definition) or medicines or related products (if they did not meet the definition).

- 'Natural health products' would be products presented in therapeutic dose forms and intended for administration to human beings for the purpose of achieving a health benefit. Products intended to be administered to animals would not be natural health products.

- The definition of ‘medicine’ and ‘related product’ in the Medicines Act 1981 would be amended to exclude natural health products. This means that if a product met all the criteria for categorisation as a natural health product, that product would not be a medicine or a related product and would not be regulated under the Medicines Act 1981. Conversely, therapeutic products that were not natural health products would be regulated under the Medicines Act.
- Products that were presented as foods would be regulated under food legislation. Products such as muesli bars containing herbal ingredients or bottles of orange juice fortified with vitamins and minerals are foods. Any decision about whether it is permissible to make a health claim in relation to such products would be made by the food regulator.
- If a natural health product contained a new organism, as defined in the Hazardous Substances and New Organisms Act 1996, approval from the Environmental Risk Management Authority (ERMA) would be required in addition to any approval under natural health products legislation.
- A product to be used for the purpose of moisturising, softening or soothing the skin to which it is applied is a cosmetic, provided no therapeutic or natural health product claims are made for the product. Cosmetics are regulated by ERMA under the Hazardous Substances and New Organisms Act 1996.

International trade obligations

The proposed regulatory scheme for natural health products on the New Zealand market, and the implementing legislation, would be designed in accordance with New Zealand’s relevant international trade obligations.

Appendix 1: Draft Regulatory Impact Statement

Natural Health Products Bill 2010

Executive summary

Problems

1. Natural health products,⁵ which are used mainly for the relief of symptoms of minor, self-limiting conditions and to maintain good health and wellbeing, are currently inadequately regulated. This poses potential risks to public health, constrains industry growth and limits informed choice for consumers.
2. Natural health products in oral dose form are covered by the Dietary Supplements Regulations 1985 made under the Food Act 1981. The regulations, which state the maximum daily dose for some nutrients, limit the content of some vitamins and minerals, and restrict some other ingredients, are inadequate to manage the safety risks posed by the wide range of ingredients currently found in supplements. The regulations are silent on manufacturing standards for supplements (a key requirement to provide assurance about the safety and performance of the product) and the minimal labelling requirements are inadequate to ensure consumers receive accurate advice about the content, risks and uses of a product. Therapeutic claims are not permitted for supplements.
3. Products intended for application to the skin or hair (for example, creams, lotions, gels) are regulated as cosmetics under the Hazardous Substances and New Organisms Act 1996, provided therapeutic claims are not made about them.
4. All products used for a therapeutic purpose are regulated as medicines or related products under the Medicines Act 1981. However, obtaining an approval for a natural health product under the Medicines Act 1981 is not seen as a viable option as the costs and information requirements are too high for lower-risk products. At present, suppliers wishing to make therapeutic claims for natural health products mostly do so in breach of the Dietary Supplements Regulations 1985.

Preferred option

5. The National Party and the Green Party have agreed to work together to develop a regulatory scheme for natural health products that is specific to New Zealand.
6. There is broad agreement that a modern, risk-commensurate regulatory scheme is needed to provide assurance to the public that natural health products are safe, true to claim and true to label.

⁵ These are products that are presented in therapeutic dose forms (such as tablets, capsules, tinctures, solutions, creams, ointments and drops) and contain ingredients such as vitamins and minerals, or other substances derived from nature. They are often referred to using a variety of 'umbrella' terms such as nutraceuticals, alternative medicine and traditional or complementary medicines.

7. It is proposed that a relatively light regulatory scheme for natural health products be developed and administered by the Ministry of Health. The scheme would apply to products containing only ingredients that have been assessed as being safe for use in products that are not subjected to the sort of stringent pre-market controls that apply to medicines. Natural health products would not be promoted for the treatment or prevention of serious diseases and would not be for use by injection or in the eye.
8. The purpose of the scheme would be to provide assurance to consumers that natural health products are safe, true to claim and true to label.
9. The scheme would regulate the manufacture, supply and promotion of natural health products. The scheme will not, however, apply to products 'tailor-made' by a practitioner (for example, a rongoā Māori practitioner or a traditional Chinese medicine practitioner) to meet the needs of a specific patient who has sought advice from that practitioner (whether or not the practitioner receives a fee from the patient). If however, a practitioner decided to manufacture products in commercial quantities for retail sale or distribution to other practitioners, then such products would come under the proposed scheme.
10. Key elements of the proposed scheme are:
 - product approval, based on notification of products on a database
 - unilateral recognition of the decisions of trusted overseas regulators and, over time, mutual recognition with trusted overseas regulators
 - a list of prohibited ingredients
 - a list of permitted ingredients, and a process for adding new ingredients
 - a list of permitted health claims
 - labelling requirements
 - advertising rules
 - export certification
 - a tailor-made manufacturing code of practice
 - a principle of full cost recovery
 - sanctions commensurate with other modern legislation
 - an appeals mechanism.

Main impacts

Costs

11. Full cost recovery of the proposed natural health products scheme is preferred in line with Government guidelines.

12. The scheme will be fully costed once the parameters have been determined following public consultation. Initial estimates, however, are that the set-up cost (funding of which would be provided by the Crown but could be recovered subsequently through fees or charges) is \$1.4 million and ongoing costs are approximately \$4.25 million per year. Of this ongoing cost, up to an estimated \$0.5 million per year relates to post-market monitoring and enforcement activities that could be Crown funded, depending on decisions yet to be taken.

Benefits

13. The benefits of regulation for consumers will be:
- increased assurance of the safety of products
 - assurance that products contain the correct ingredients in the stated amounts and do not contain undeclared ingredients that may be harmful
 - the provision of reliable information about the risks and benefits of products
 - assurance about the truthfulness of claims.
14. In addition, providing assurance about the safety, efficacy and quality of the products will facilitate the uptake of natural health products within the primary health care setting.
15. The benefits for industry will be the ability to:
- expand sales by lawfully making natural health product claims about their products
 - position the industry to expand into export markets that value quality and natural ingredients
 - obtain export certification that attests to the regulated environment in New Zealand
 - achieve greater recognition and uptake of natural health products within the New Zealand health sector.

Status quo

16. There is a wide range of products on the market in New Zealand that:
- are presented in controlled dose forms intended for oral administration (for example, tablets, capsules, oral liquids and powders) or as creams, lotions, etc, intended for application to the skin
 - contain ingredients such as vitamins, minerals and other substances derived from nature, including herbal and animal-derived substances.

A collective term for such products is 'natural health products'.

17. There is no single regulatory framework covering natural health products. Many are sold as dietary supplements, which are regulated by the Dietary Supplements Regulations 1985 made under the Food Act 1981 and administered by the New Zealand Food Safety Authority (NZFSA). A few are sold as 'medicines' or 'related products', which are regulated under the Medicines Act 1981 administered by the Ministry of Health. Yet others are sold as cosmetics, which are subject to standards administered by the Environmental Risk Management Authority (ERMA). While most natural health products are used to obtain a health benefit of some kind, a supplier is not permitted to make a therapeutic claim for a product unless that product has been approved as a medicine or related product. However, the requirements for obtaining such an approval are considered too onerous and too costly for most natural health products.
18. Consultation on the reform of the natural health product regulation to address its piecemeal nature and introduce risk-appropriate controls has been ongoing for many years. The *Consultation Paper on the Development of a Natural Health Products Bill* reflects the government's current view on regulatory reform; this view may change following consultation on the proposals set out in the consultation paper.

Current regulation of natural health products

19. When dietary supplements first started gaining popularity among consumers in the early 1980s, the government recognised the need to ensure these products were safe and suitable. This led to the establishment of the Dietary Supplements Regulations 1985, under the provisions of the Food Act 1981. The regulations set labelling and compositional requirements for these products, based on what was available on the market at the time.
20. Most natural health products intended for oral administration are currently sold as dietary supplements under the Dietary Supplements Regulations 1985. The regulations cover supplements (vitamins, minerals, amino acids, herbs, etc) that are in orally administered dose forms (tablets, capsules, powders, liquids).
21. The regulations state the maximum daily doses for some nutrients, limit the content of some vitamins and minerals, and restrict other ingredients (such as preservatives and colouring substances) that can be included in a dietary supplement to those listed in the regulations.
22. Rudimentary labelling requirements are set out in the regulations, and the principal display panel of the label on a dietary supplement must include the words 'Dietary Supplement'.
23. Therapeutic claims for dietary supplements are not permitted. The explanatory note for the regulations states:

These regulations, in a sense, fill a gap between the Food Regulations 1984 and the Medicines Regulations 1984, in that dietary supplements are not **food** or **medicine** in the ordinary sense of those words. However, they are **food** within the meaning of the Food Act 1981, and will be **related**

products within the meaning of the Medicines Act 1981 if therapeutic claims are made for them.

24. Products intended for application to the skin or hair (such as creams, lotions, gels, shampoos) are regulated by the Environmental Risk Management Authority as cosmetics, provided they are only for purposes such as cleansing, beautifying or protecting the skin.
25. All products used for a therapeutic purpose (that is, preventing, treating or curing a disease or disorder) are regulated as medicines or related products under the Medicines Act 1981.

Profile of the New Zealand natural health products sector

26. There is no comprehensive set of reliable information about the natural health products on the market in New Zealand or the businesses supplying them. In the absence of a regulatory database that could provide robust information about suppliers and their products, officials have used publicly available information from the Internet⁶ and the *New Zealand Bioactives Report 2008*⁷ to obtain the following picture of businesses that are active in this sector.
 - There are around 450 companies supplying natural health products on the New Zealand market.
 - Around 168 companies supply products that are made in New Zealand from bioactive ingredients that are made or harvested in New Zealand. The majority of companies are specialised and have a strong focus on a limited set of bioactive ingredients. The five most common classes of ingredients are plant oils and seeds, other plant extracts, herbals and botanicals, marine animal extracts, and manuka honey.
 - The majority of bioactive companies (the 168 referred to above)⁸ are young and small. More than 50 percent are less than 12 years old, 60 percent employ fewer than 10 full-time equivalent staff (FTEs) and over 75 percent of companies generate less than \$5 million in annual revenue.
 - The number of bioactive products that are commercially available is large. The majority of these have been commercialised by large nutraceuticals and supplements companies. Seventeen percent of companies have a broad product range (averaging nearly 300 products per company) accounting for around 5300 of the 6600 products on the market. The remaining 83 percent of companies have a narrower product range, with an average of 26 products per company. Many companies have fewer than 10 products.

⁶ Companies use the Internet to showcase their businesses and advertise their products. The information provided is not always accurate, complete or up to date. Alternate sources (such as information in online government records) have been used to cross-check information where possible.

⁷ The *New Zealand Bioactives Report 2008* was commissioned by New Zealand Trade and Enterprise and produced by LEK Consulting Pty Limited.

⁸ This term covers companies that produce cosmetics, nutraceuticals and supplements, and bioactive functional foods and starting materials.

- Around 20 percent of companies say they comply with Australian manufacturing requirements, and around 50 percent claim to comply, to some extent, with a Good Manufacturing Practice standard.
- Around 165 companies import finished products.
- Around 113 companies supply products that are made in New Zealand from mostly imported ingredients, or ingredients of unknown source. The majority of these companies have fewer than 10 employees.
- The turnover of most companies lies in the range \$100,000 to \$5 million, around 30 percent of companies have a turnover of \$5 to \$20 million and around 14 percent of companies have a turnover above \$20 million.
- Around 95 companies claim to export products, and just over half of those have fewer than 10 employees. Forty-five exporters say they are exporting to Australia. The industry considers its key overseas markets to include Australia, United Kingdom, United States, China, Japan, Korea and Singapore.

Problems

Legislation out of step with development of natural health products market

27. Since the Dietary Supplements Regulations were promulgated in 1985, technological advances and industry innovation have significantly increased the range of products available. The regulations were designed to cover the relatively small range of products (mainly vitamins, minerals and herbal substances in controlled dose forms used to supplement the dietary intake of those substances) that were on the market at the time. The multimillion-dollar industry that exists today was simply not envisaged, and it now encompasses a vast range of products, ranging from simple vitamin preparations through to potent herbal medicines and substances derived from animals.
28. An estimated 80 percent of products currently being sold as dietary supplements can be described as natural health products because they are presented in a pharmaceutical dose form and are used for the purpose of obtaining a therapeutic or health benefit.
29. As the range of ingredients used in dietary supplements has expanded, so has the size of the international market for such products, the number of manufacturers supplying that market and the competition for market share. With this has come increasing pressure for manufacturers to obtain a marketing edge by promoting their products as treatments for diseases rather than simply as supplements. In a few cases, evidence has emerged to indicate that a substance is effective in managing the symptoms of a disease or disorder (for example, St John's wort for mild depression).

30. Suppliers who wish to make therapeutic claims for their products continue to sell the products as dietary supplements, even though this puts them in breach of the regulations. The alternative (obtaining an approval for the product under the Medicines Act 1981) is not seen as a viable option. While these products are technically related products or medicines (because of the therapeutic claims being made), the requirements that must be met in order to obtain approval under the Medicines Act 1981 are designed to manage the risks associated with pharmaceutical medicines and present a barrier to market entry that is too high and too costly for most natural health products.
31. The lists of allowable ingredients in the Dietary Supplements Regulations 1985 have not been updated in line with developments in the natural health products field in the last 20 years. The lists therefore contain some substances that are no longer in use and do not include new substances now commonly used in therapeutic products.
32. Thus neither the natural health products industry nor the public is well served by the existing regulatory framework.

Inadequate controls on safety and quality of products

33. Given that dietary supplements sit somewhere between foods and medicines (because they contain the sorts of substances found in foods but have characteristics and uses more akin to medicines), it could be expected that the controls on the safety and quality of dietary supplements would also sit somewhere between those applying to foods and those applying to medicines. However, this is not the case. The level of regulation of dietary supplements is lower than that for foods. For example, while a novel ingredient must be assessed for safety before it can be included in a food, there is no such assessment of safety for ingredients used in a dietary supplement. In addition, food manufacturers must meet the requirements of the Australia New Zealand Food Standards Code relating to composition and labelling, but there are no minimal manufacturing standards set for dietary supplements. Manufacturers must currently only comply with the Food Hygiene Regulations 1974 and the general requirements for safety and suitability of food under the Food Act 1981.
34. The absence of manufacturing controls exposes consumers to significant risks including:
 - under or over potency, or complete absence of ingredients stated on the label
 - poor formulation leading to non-availability of active ingredients
 - adulteration with undeclared ingredients (including prescription medicines such as steroids) or substitution of a toxic herbal ingredient for the ingredient stated on the label (the international literature provides many examples of such adulteration. Because these products are traded internationally, New Zealand consumers are at risk. Actual examples of adulterated product imported for commercial and personal use have been identified at the New Zealand border and in products that have been the subject of a complaint)

- contamination with heavy metals, microbes, pesticides, radioactivity or cross-contamination with other substances used by the manufacturer.
35. Appropriate formulation, quality in the manufacturing process and accuracy of labelling and dosage are essential to the safety, effectiveness and appropriate use of a product that is presented in a pharmaceutical dose form and used for a claimed health benefit. These requirements are not well covered by the sorts of manufacturing standards that apply to foods, such as hazard analysis and critical control point (HACCP) systems.
 36. New Zealand is out of step internationally in not regulating natural health products under an evidence-based system that can support informed choice and provide assurance about safety and quality.

Inadequate or misleading information for consumers

37. Natural health products are frequently self-selected by the consumer and are used for a perceived health benefit. In order to support informed choice and safe use, it is imperative that adequate, truthful information is available about both the benefits and the risks of using the product. Significant risks arise where adequate information is not provided, where the information that is available is misleading or exaggerates the benefits of using the product, where there is inaccurate or incomplete labelling, such as non-disclosure of ingredients, or inadequate dosing instructions and warning statements to enable the product to be used safely.
38. Significant health and safety risks also arise where consumers attempt to treat serious conditions or stop taking prescribed medications in the belief that the claimed benefits of a natural health product are true when there is, in fact, no basis to the claims.
39. In spite of the prohibition on therapeutic claims in the Dietary Supplements Regulations 1985, many of the products now sold as dietary supplements are labelled or promoted with therapeutic claims. A systematic review of websites undertaken in March 2007 identified that 78 percent of the 263 company websites reviewed were non-compliant with the Medicines Act 1981 in relation to some or all of the products advertised because of the therapeutic claims being made. Examples of low-level claims included claims for providing relief from the symptoms of arthritis or psoriasis, relieving the symptoms of seasonal allergies such as hay-fever, relief of pre-menstrual tension or temporary relief of the pain of gout, headaches or migraine. Higher-level claims included claims for preventing, treating or curing serious diseases, such as cancer.
40. In a subsequent compliance awareness programme, the websites reviewed contained advertisements for over 12,000 products with just over half of these advertisements including therapeutic claims. Out of 355 websites reviewed as part of this programme, 107 were found to be making high-level claims.

41. Evidence-based therapeutic claims are permitted for similar products supplied in other markets where there is more stringent regulation (such as pre-market approval and/or a requirement for the supplier to hold evidence to support the claims they wish to make).

Compliance and enforcement difficulties

42. It has long been recognised that the regulation of natural health products is inadequate, and work on achieving new legislation has been underway for close to 20 years. Because new legislation has been anticipated, only limited amendments have been made to update existing legislation, and enforcement activities have largely been limited to dealing with the most serious breaches, such as promoting a product as a cure for cancer when that product is not an approved medicine or supplying a product that purports to be a dietary supplement but contains undeclared ingredients that are prescription medicines.
43. Enforcement actions usually arise following investigation of a complaint or concerns about a product arriving at the New Zealand border. Enforcement is complicated because the interface between the Medicines Act 1981 and Dietary Supplements Regulations 1985 is not clearly stated. As a consequence, it is usually unclear whether non-compliance should be dealt with under food or medicines legislation. The outcome is generally destruction of the product or its removal from the market rather than prosecution. The penalty for non-compliance is extremely low (\$500) in comparison with other similar legislation and does not act as an effective deterrent.
44. Enforcement of the Dietary Supplements Regulations 1985 has also long been problematic due to the large number of breaches relating to the prohibition on therapeutic claims. Past attempts to increase awareness and enforcement of the legislation relating to natural health products met with resistance from both suppliers (who fear they will lose sales) and consumers (who fear they will lose access to products they consider to be important to their health and wellbeing).
45. There is no provision in the regulations for a register of dietary supplement products or suppliers. Hence, it is difficult to trace suppliers and take appropriate action to protect the public from harm when safety issues arise.

Overarching policy objective

46. The objective is to have a New Zealand-based regulatory scheme that is cost-effective, supports informed choice and gives consumers confidence that natural health products are safe and true to label.

High-level policy options

47. The high-level policy options relate to the question of whether natural health products should be regulated and, if so, whether they should be regulated under food legislation (as at present), under therapeutic products legislation (the existing Medicines Act 1981 or any replacement), or under separate natural health products legislation.

Option 1: No specific regulation of natural health products

48. Under this option, the Dietary Supplements Regulations 1985 would be repealed and no new legislation would be developed. Those products that met the definition of 'medicine' or 'related product' set out in the Medicines Act 1981 would be subject to the requirements set out in that Act. The remaining natural health products would not be subject to any specific regulatory controls.
49. In such an unregulated environment, there would be a lack of incentive for suppliers of natural health products to provide balanced information about the risks and benefits of their products. Consumers would find it extremely difficult or impossible to identify quality products from substandard and potentially harmful products or to take a case under consumer protection legislation because of the high burden of proof required.
50. If therapeutic claims were made for natural health products, those products would become medicines or related products regulated under the Medicines Act 1981. Suppliers would continue to have difficulty meeting the requirements for obtaining approvals under medicines legislation.
51. Public education programmes (designed to enable consumers to evaluate the risks and benefits of products, make informed choices and use products safely), would not be effective since most consumers cannot be expected to have the knowledge or skills required to assess the accuracy or completeness of the available information or to interpret that information appropriately. Additionally, safety and quality are not self-evident through visual scrutiny of products.

Option 2: Regulate natural health products under food legislation

Sub-option 2A: Maintain the status quo

52. Under this option, the Dietary Supplements Regulations 1985 would be retained without significant change. Hence, the problems associated with the current regulation of natural health products would remain.

Sub-option 2B: Amend and increase enforcement of the Dietary Supplements Regulations 1985

53. The Dietary Supplements Regulations 1985 could be amended to provide updated and more robust regulation of dietary supplements and the amended regulations could then be rigorously enforced. However only natural health products that are taken by mouth come under these regulations, and even for those that are covered, the scope of the regulations is limited by the fact that dietary supplements are considered foods under the Food Act 1981. This would impact on the limitations on ingredients and the sorts of claims that could be permitted. In addition, food-type standards are not sufficient to manage the risks associated with the manufacture of products (as set out above).

Option 3: Regulate natural health products under therapeutic product legislation

54. Under this option, natural health products would be regulated as a sub-category of medicines under new or amended medicines legislation.

Sub-option 3A: Amend the existing Medicines Act 1981 to include natural health products as a sub-category of medicines

55. This option would involve substantive amendment to legislation that is already outdated in numerous respects and drafted in a way that makes it difficult to understand. Introducing further complexity into a statute that is already presented in a piecemeal fashion would make it more difficult for the industry and the regulator.
56. It is clear from past consultation that much of the industry and many consumers consider natural health products to be different from medicines. Some parts of the sector, such as suppliers of homoeopathic preparations, would support use of the term 'medicine' because this is the term traditionally used for such products.
57. The benefits of this option are that it would meet the objective and would provide recognition that natural health products are part of the wider continuum of therapeutic products. However, the resulting legislation would be clumsy and difficult to use.

Sub-option 3B: Develop new domestic therapeutic product legislation incorporating natural health products as a category of therapeutic products

58. This option would involve developing a completely new domestic regulatory framework for all therapeutic products, including natural health products.
59. In December 2003, the New Zealand and Australian governments signed an international agreement for the establishment of a joint risk-based regulatory framework for therapeutic products to be administered by the Australia New Zealand Therapeutic Products Authority (ANZTPA). The New Zealand implementing legislation, the Therapeutics Products and Medicines Bill (TPM Bill), was introduced to Parliament and referred to the Government Administration Committee in December 2006. A postponement of ANZTPA was announced in July 2007 following controversy about the proposal to include complementary medicines within the scope of the joint scheme.
60. The benefits of this option are that it would meet the objective, recognise natural health products as part of the wider continuum of therapeutic products and be more sustainable in the long term. It avoids taking a piecemeal approach to the reform of therapeutic product legislation, an approach that could result in inconsistencies and inefficiencies.
61. However, it would not be feasible to progress this option until it is clear whether the joint regulatory scheme with Australia will proceed, and it is difficult to know when this issue will be resolved. Hence, it does not enable the most pressing problems to be addressed in the short term and leaves the public without

assurance of product safety in the interim and the industry in a hiatus for an indeterminate period of time.

Option 4: Regulate natural health products as a separate category of product under new legislation

62. Under this option, new natural health products legislation would be developed separate from food or medicines legislation.

Sub-option 4A: Separate natural health products legislation administered by the New Zealand Food Safety Authority

63. Under this option, new legislation would be developed to regulate natural health products as a separate category of product (that is, neither food nor medicine), with the regulatory scheme administered by the NZFSA.
64. The NZFSA has stated that it does not have the expertise to administer the regulation of products that are presented in pharmaceutical dose forms and used for a therapeutic purpose. This is, in large part, why Cabinet has already agreed to transfer responsibility for administering the Dietary Supplements Regulations 1985 (after amendment to exclude food-type dietary supplements from coverage) to the Ministry of Health.

Sub-option 4B: Separate natural health products legislation administered by a stand-alone regulator

65. Under this option, new legislation would be developed to regulate natural health products as a separate category of product (that is, neither food nor medicine), with the regulatory scheme administered by a new stand-alone regulator.
66. This is the model advocated by many who support domestic regulation of natural health products, provided they are regulated as a separate category of product and the regulatory scheme is not administered by the existing medicines regulator. Proponents of this model consider that those with expertise in the area of pharmaceuticals will be biased against natural health products and therefore will not administer the regulatory scheme appropriately.
67. The advantage of the model is that it would be more acceptable to those in the natural health products industry who do not consider regulation administered by an existing regulator to be appropriate.
68. However, there would be considerably higher costs associated with establishing a dedicated regulator. These costs would be borne by both the industry (through higher fees and ultimately passed on to the consumer in increased prices) and the government (through higher set-up costs and ongoing Crown funding of those activities not cost recovered from the industry). When compared with the option of using a unit within the Ministry of Health, establishing a separate regulator would result in higher costs and duplication of resources in areas such as corporate services. It would also be more difficult to manage interface issues for products at the boundary between natural health products and other therapeutic products. For these reasons, this option has been disregarded.

Sub-option 4C: Separate natural health products legislation administered by the Ministry of Health (the preferred option)

69. Under this option, new legislation would be developed to regulate natural health products as a separate category of product (that is, neither food nor medicine), with the regulatory scheme administered by a unit within the Ministry of Health.
70. This option is preferred because it offers the benefits described in sub-option 4B but without the cost disadvantages associated with a stand-alone regulator.

Specific problems, objectives and policy options

71. Developing new separate legislation will enable implementation of a risk-based regulatory framework specific to natural health products. The main elements of this framework are:
 1. requiring products to meet safety standards and to be approved before they are placed on the market
 2. maintaining a register of products
 3. requiring manufacturers of products to meet a Code of Practice for Manufacturing Natural Health Products (based on Good Manufacturing Practice principles)
 4. setting standards for labelling and advertising
 5. requiring suppliers to hold evidence to substantiate natural health product claims.
72. The controls would be designed to give suppliers of lower-risk natural health products (estimated to be around 90 percent of products currently on the market) a viable route to obtaining approval to supply a natural health product in New Zealand.
73. The natural health products covered by the regulatory framework would be lower-risk products containing only ingredients that were on a list of more than 4000 substances that have been assessed by other regulators as being safe for use in products that are not subjected to the sort of stringent pre-market controls that apply to medicines. They would not be promoted for the treatment or prevention of serious diseases and would not be for use by injection or in the eye.
74. Approval would require completion of a quick and simple web-based application process involving self-assessment and a declaration of compliance by the applicant.
75. The small proportion of higher-risk products that would not be covered by the new regulatory framework (either because they contain higher-risk ingredients or are used to treat serious diseases) would be regulated as medicines, and suppliers would need to obtain consent for distribution of the product under the Medicines Act 1981 as they do at present.
76. When the new legislation came into effect, the Dietary Supplements Regulations 1985 would be revoked.

A. Quality and safety of products

Status quo and problems

77. It is not uncommon for consumers to assume, when buying a product of some kind, that some sort of regulator is protecting their interests and making sure that only safe, good quality products are allowed to be sold in New Zealand. This is not the case for most natural health products.
78. There is no independent assessment of the safety of a natural health product before the product is placed on the New Zealand market. A consumer selecting a product does not have access to the information on which to base an assessment of its safety and must therefore rely on the knowledge and integrity of the manufacturer or importer of the product.
79. There is no requirement for manufacturers to meet specified manufacturing standards. Consequently there is no assurance for consumers that the products they purchase will be true to label – that is, will contain the claimed amount of the stated ingredients, will not contain other undeclared ingredients and will not be contaminated.
80. There is no requirement for a manufacturer or importer of a dietary supplement to obtain an approval to market a product.

Specific objective

81. To provide consumers with assurance that the products they use are safe and true to label.

Alternative

Notification of products on a database

82. Under this option, suppliers would notify their products on a database. Details would include contact details of the supplier and manufacturer and basic product details, such as common and brand name, dosage, dose form and active and non-active ingredients. However, simple notification of products on a database, without any assessment of the information provided or a product approval being issued, would do little to provide assurance of product safety or quality. It would provide a list of products, manufacturers and suppliers and would therefore facilitate follow-up action when a safety issue was identified. However, it would not provide a mechanism for safety or quality issues to be identified before the product was placed on the market.

Preferred option

Pre-market product approval

83. This option would see suppliers notify a set of details into an electronic application handling system. The supplier would be required to self-assess some aspects, while other aspects would be 'assessed' against specified validation criteria built

into the database. If all requirements were met, the database would issue an approval notice. The amount of data entry required to make an application would be the same as that for the simple notification described above.

Net benefits

84. Compared with a notification-only process, there would be no additional compliance costs for the supplier. Regulatory fees may be higher, depending on the marginal costs of developing and maintaining a more complex database system. Suppliers would gain reassurance that their products met the requirements and that they were in compliance with the legislation. The resulting register of approved products would facilitate enforcement because there would be a specific approval-holder for each product on the market.

B. Safety of ingredients

Status quo and problem

85. There is no independent assessment of the safety of an ingredient used in a dietary supplement before the product is placed on the market. Unsafe ingredients can only be identified and removed from the market after a problem has been identified and consumers have been harmed.

Specific objective

86. To ensure the safety of ingredients used in natural health products.

Alternatives

87. Maintain only a list of ingredients that are prohibited from being in natural health products. This identifies obvious problems without unduly delaying market entry and is a lighter form of assessment with reliance on post-market monitoring to detect problems. However, it means that problems do not become evident until products are on the market and an association is made between reported adverse events and an ingredient.
88. Only maintain a list of ingredients permitted to be used in natural health products and fully assess ingredient safety before adding any new ingredients to the list. However, not having a prohibited ingredients list means that suppliers may waste time and money applying for new ingredients to be added to the list that the regulator would never consider appropriate to permit.

Preferred option

89. Maintain a list of permitted ingredients and assess applications from manufacturers and suppliers regarding new ingredients before adding them to the list. Also maintain a list of prohibited ingredients.

Net benefits

90. Maintaining a list of permitted ingredients prevents new potentially harmful ingredients from being included in products and going onto the market before they have been assessed.
91. Maintaining a list of prohibited ingredients provides transparency for industry about ingredients that have been identified as unsuitable for addition to the permitted ingredients list. This avoids wasting time and money preparing applications for unsuitable ingredients.

C. Controls on manufacturing

Status quo and problem

92. There is currently no requirement for manufacturers of natural health products to meet specified manufacturing standards and therefore there is no assurance of the quality of the final product.

Specific objective

93. To ensure quality manufacture of natural health products.

Alternatives

94. Manufacturing standards vary, from minimal requirements regarding basic hygiene through to HACCP-type food controls through to pharmaceutical Good Manufacturing Practice (GMP).
95. HACCP is not considered appropriate for natural health products as it was developed specifically as a food control programme and would therefore not address all the risks that could arise during the production of natural health products. Pharmaceutical GMP requirements at the other end of the continuum are considered to be too detailed and onerous for a regulatory scheme of the sort that is envisaged.

Preferred option

96. A Code of Practice for Manufacturing Natural Health Products is considered the most appropriate option. The code of practice would be less onerous than Pharmaceutical GMP and would be specifically tailored for natural health products. The code would be developed in consultation with the industry. Companies manufacturing natural health products would need to meet the requirements of the code. If a manufacturer were based offshore, it would also need to show evidence that it could meet the code.

Net benefits

97. A code of practice as outlined above fits well with the controlled dose nature of natural health products and the types of risks needing to be managed. A specially tailored code can be kept commensurate with relevant risks.

Impacts

Cost recovery

98. The Treasury's *Guidelines for Setting Charges in the Public Sector* identifies three types of 'goods' that determine the appropriate source of funding: public goods, private goods and industry or club goods. These goods can be summarised as follows.

- **Public good:** Excluding people from the benefits of a public good is either difficult or costly, and its use by one person does not prevent its use by another person. Public goods should be government (taxpayer) funded.
- **Private good:** People can be excluded from the benefits of a private good if they do not pay for it, and its use by one person conflicts with its use by another (so there is an additional cost incurred in providing the service to another person). Private goods should be funded by the users or beneficiaries (or by those whose actions create the risk, if applicable).
- **Club good or industry good:** A club good has some characteristics of a public good in that its use by one person does not detract from its use by another, but either group can be excluded from the benefits of the good at low cost, or the beneficiaries are a narrow identifiable group. Industry/club goods should be funded by the identified groups of the users or beneficiaries (or risk makers).

The following table summarises the Ministry's assessment of the outputs for the new scheme, which category they fall into, who should pay and how.

Table 1: Assessment of scheme against The Treasury guidelines

Service	Type of good	Who pays	Cost recovery mechanism
Policy advice	Public	Crown	Crown funding
Standard setting	Industry	Industry	Fixed annual charge/levy
Export certificates	Private	Industry (exporters)	Fixed charge
Auditing	Private	Industry (manufacturers)	Fixed charge or hourly rate
Pre-market			
Product approval	Private	Industry (product approval holders)	Fixed charge
Ingredient approval	Industry/ (private)	Industry (product sponsors)	Small fixed charge with balance recovered through annual charge/levy
Post-market			
Compliance, surveillance and monitoring	Private/ industry	Industry (products sponsors)	Fixed annual charge/levy
Enforcement (investigations, sanctions and prosecutions)	Public/ industry	Industry	Fixed annual charge/levy

99. Under this model, the Crown would fund the costs of policy advice, and all other costs would be recovered from industry. Determining who should pay for some components of post-market activities is finely balanced, and an argument can be made that the Crown should fund the costs of enforcement (also see paragraph 101 below).
100. Preliminary costings of the proposed regulatory scheme have been undertaken. They take into account staffing costs, regulatory infrastructure development and operational budget. The estimated ongoing costs of the scheme (which in the longer term are proposed to be fully recovered from industry) are estimated at \$4.25 million per year. The set-up costs (which would be provided by the Crown but could be recovered subsequently through fees or charges) are estimated to be \$1.4 million. Of the ongoing costs, up to an estimated \$0.5 million relates to post-market monitoring and enforcement activities, which would initially be funded by the Crown, leaving \$3.75 million to be recovered from industry, should it be decided that the Crown fund some components of post-market activities.

Table 2: Preliminary estimate of costs to regulate natural health products

Type of cost	\$ million
Set-up costs: product register, ingredients lists, amendments to existing adverse reactions systems, manufacturing code of practice	1.40
Ongoing personnel costs, including related costs such as ACC charges, training, etc	2.50
Ongoing operating budget (random product testing programme, compliance monitoring, running expert advisory committee, engagement and communication with industry, regulatory advice to Government, contracting expert opinion when needed)	1.75
Indicative total	4.25
Ongoing annual partial post-market costs to be funded by the Crown (if it is agreed that the Crown should fund enforcement)	0.50
Ongoing annual pre-market and partial post-market cost (to be recovered from industry)	3.75

101. Full cost recovery through fees paid by the industry is proposed and would be consistent with The Treasury and Auditor-General principles and guidelines for charging for government services.
102. It is proposed that the costs of pre-market approval be recovered by charging the applicant company a fee and that the level of fee match actual costs.
103. The cost of completing safety assessments on new ingredients could be recovered from the applicant on a 'fee for service' basis. Alternatively, given that the whole industry benefits from being able to use a new permitted ingredient, the cost could be spread across all product approval holders and recovered through an annual maintenance charge.

104. It is proposed that a combination of these cost-recovery mechanisms be used for new ingredient safety assessments. Most of the costs would be recovered through an annual product approval maintenance charge paid by all product approval holders. However, the applicant would be required to pay an application fee as a disincentive to lodging applications for substances that would be unlikely to be approved, or for which there is no history of safe use.
105. It may be desirable to put a cap on the number of new ingredient safety assessments undertaken by the regulator each year in order to enable the assessment work to be adequately resourced and more complex assessments to be completed within a reasonable timeframe and to avoid the need to increase annual maintenance charges if an unexpectedly large number of new ingredient applications were to be lodged within a particular period.
106. The cost to companies supplying only the New Zealand market is expected to be lower than it would have been under the joint scheme with Australia proposed by the previous government, as the New Zealand-only scheme is intended to have lower regulatory barriers to reflect the relatively low-risk nature of natural health products. By comparison, companies that market products in Australia may face higher costs under the proposed New Zealand-only scheme than they would have under the proposed joint scheme with Australia as they would have to become familiar with, and contribute to the cost of administering, a separate regulatory scheme in each country. However, the extent of the additional cost is dependent on the actual fees in Australia and New Zealand compared with what they might have been under a joint regulator.

Costs

107. The introduction of New Zealand-only risk-based regulation of natural health products, with cost recovery through fees and annual maintenance charges paid by industry, would result in new regulatory fees and compliance costs for New Zealand manufacturers and distributors of natural health products.
108. For suppliers, compliance costs would arise from the time taken to understand the new requirements and complete the web-based approval process. Regulatory costs would arise from approval fees and annual maintenance charges. The greatest impact would fall on small- to medium-sized businesses, particularly those importing and distributing large ranges of products. These costs would be minimised through the use of web-based applications with tools to minimise data entry.
109. Costs would be incurred by manufacturers if they needed to upgrade equipment or buildings, introduce a quality assurance system or begin testing starting materials and finished products in order to meet the new manufacturing standards.
110. Based on the information currently held, there are approximately 150 New Zealand-owned stand-alone companies supplying natural health products that are made in New Zealand. Some of these are very small operations (often farm based) that also make other products, such as cosmetics, and may need to cease manufacturing natural health products because they would be unable to

meet the new manufacturing standards or use a contract manufacturer to produce their products. Another option for many of these manufacturers would be to reposition their products as foods or cosmetics.

111. Implementation of a regulatory scheme for natural health products is likely to lead to some rationalisation of product ranges and consequently some reduction in the number of brands containing a particular ingredient or combination of ingredients. While there may be some reduction in brand choice for consumers if non-viable products were removed from the market, the impact on the range of ingredients available in the market place would be negligible.

Benefits

112. Consumers would benefit from increased assurance of the safety of products, the provision of adequate and reliable information about the use and benefits of products, assurance about the truthfulness of claims and assurance that products contain the correct ingredients in the stated amounts and do not contain undeclared ingredients that may be harmful. In addition, providing assurance about the safety, efficacy and quality of the products would facilitate uptake of natural health products within the primary health care setting.

113. The benefits for industry would be the ability to:

- expand sales by lawfully promoting their products with natural health product claims
- position the industry to expand into export markets that value quality and natural ingredients
- obtain export certification that attests to the regulated environment in New Zealand
- achieve greater recognition and uptake of natural health products within the New Zealand health sector.

Implementation and review

114. Drafting of a Natural Health Products Bill (the Bill) is expected to begin during 2010. It is anticipated that the Bill would be enacted in 2011. There would be a transition period of 12 months for product approvals and two years for meeting manufacturing standards. The legislation would be reviewed after three years. Once the Bill was enacted, the Dietary Supplements Regulations 1985 would be revoked.

115. The Medicines Act 1981 would also need substantial amendment to exclude natural health products from the scope of the Act.

116. There would be a public education campaign before the Bill was enacted and more focused assistance for industry to help them to understand and comply with the new requirements. Following commencement, the Ministry would continue to run a 'help desk' for industry enquiries and liaise regularly with the sector to obtain feedback on any issues of concern. A product-testing programme would be

initiated to check on the quality of product in the market, and an audit programme for manufacturers would be instigated to provide early advice on any upgrades that would be needed by the end of the proposed two-year transition period.

Consultation

117. There has been extensive consultation with the industry over the last 10 years. In relation to development of the Natural Health Products Bill, the industry developed its own draft Bill, which the Government considered in developing its consultation paper. There have been two meetings between Government Ministers, the Green Party Health spokesperson and representatives from the industry.
118. Officials are contacting the national rongoā collective (Te Paepae Mātua mō Rongoā) and WAI 262 claimants to determine a process for consultation on the development of a natural health products bill.

Submission Form

Please provide your contact details below.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address or email:	
Interest in this topic (for example, consumer of natural health products, health professional, manufacturer of natural health products, etc):	

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?

Question 2

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

Question 4

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

Question 5

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

Question 6

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

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.

Question 8

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

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.

Question 10

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

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.

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?

Question 13

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

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?

Question 15

Are there other situations where a labelling exemption should apply?

Question 16

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

Question 17

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

Question 18

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

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?

Question 20

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

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?

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?

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.

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?

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)).

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?

Question 27

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

Question 28

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

Question 29

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

Question 30

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

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?

Question 32

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