Regulatory Impact Statement

Regulatory Impact Statement

The Development of a Natural Health Products Bill

Agency Disclosure Statement

This Regulatory Impact Statement (RIS) has been prepared by the Ministry of Health (the Ministry).

In April 2009, the National Party and the Green Party announced plans to work together to develop a New Zealand-based regulatory system for natural health products that are sold in New Zealand. This RIS considers what functions, powers, and funding mechanisms the regulator might need to operate a regulatory scheme that is cost-effective and gives New Zealanders confidence that the natural health products they use are safe, true to claim and true to label.

The options and analysis in this RIS have been informed by a written public submission process, a meeting with representatives of the natural health products industry, and four hui with rongoā Māori providers, practitioners and consumers and representatives of WAI 262 (indigenous flora and fauna) claimants.

There is relatively little information about the number and turnover of natural health products in the market. Some information was provided by a small number of companies through the consultation process. This is insufficient to enable the Ministry to determine accurately the cost of regulation on industry, and particularly at the level of a per product-line charge. Accordingly, estimates presented in this paper on the cost of regulation are very much provisional. Published information suggests that there are around 6,600 products in the New Zealand market, however, a small industry group has submitted that the number could be as high as 20,000. At the lower end of estimates, the regulatory scheme may be unviable as industry would be unlikely to be able to sustain the costs. It is proposed that a regulatory scheme would have a transitional period that would enable the regulator to collect accurate information on the products in the market, on which subsequent fees and levies can be based.

Earlier work has aimed to establish a joint therapeutic products regulator with Australia, which would have included complementary medicines (natural health products). As the New Zealand Government has proposed to Australia that officials negotiate the establishment of a joint regulator (with an exclusion for natural health products in the New Zealand market), this option has not been considered in this analysis. The Government has, however, indicated to Australia an interest in progressing discussions on the establishment of the joint regulator. There are elements of the preferred option for New Zealand's regulatory scheme for natural health products that we know are inconsistent with Australia's preferences. This will need careful management if the Government wishes to realise a joint therapeutic products regulator (with an exemption for natural health products in the New Zealand market).

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Problem definition and Status Quo

Status Quo

Regulatory Environment

Natural health products are used mainly for the relief of symptoms of minor, self-limiting conditions and to maintain good health and wellbeing. They contain ingredients derived from nature, or their synthetic equivalents.

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. In addition, claims of therapeutic benefits may not be legally made.

All products used for a therapeutic purpose are regulated as medicines or related products under the Medicines Act 1981. Medsafe assesses the safety, quality and efficacy of new medicines to ensure that the benefits outweigh the risks if the product is used appropriately, prior to the Minister of Health giving consent for sale in New Zealand. However, obtaining an approval for a natural health product under the Medicines Act is not seen as a viable option as, unlike medicines, producers cannot generally patent natural products and recoup the costs associated with product approval through a period of exclusive marketing. At present, suppliers wishing to make therapeutic claims for natural health products mostly do so in breach of the Dietary Supplements Regulations 1985.

Officials are undertaking detailed work to define the interface between natural health products, medicines, food and cosmetics. An expert advisory group is to be convened to provide input to this work. The work aims to ensure that the interface between natural health products, medicines, food and cosmetics regulation is as clearly defined as possible. Despite best efforts to ensure a clear legislative boundary there will be instances where the categorisation of a product could arguably fall under two (or more) regulatory regimes[1]. To address such instances, the legislation will need to define who has the authority to declare a particular product to be a natural health product, a medicine, a food or a cosmetic. This work will be reported back to Cabinet when we seek approval to introduce the draft natural health products bill.

It is anticipated that, together, these four regulatory regimes will cover the full range of cosmetic, nutritional and therapeutic products on the market.

Market Information

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 which could provide robust information about suppliers and their products, officials

[1] In many instances, a range of products with the same key or active ingredient will fall under different regulatory regimes depending on the potency and form (ie, liquid, powder or tablet) of the active ingredient(s).

have used publicly available information from the internet[2] and the *New Zealand Bioactives Report 2008*[3] 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)[4] are young and small. More than 50 percent are less than 12 years old, 60 percent employ fewer than 10 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 5,300 of the 6,600 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.
- 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 ten employees.
- The turnover of most companies lies in the range $100,000 to $5 million, around 30 percent of companies have a turnover of $5-20 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 ten 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.

This information may be an underestimate of the number of products on the market. In recent consultation (*The Development of a Natural Health Products Bill*, Ministry of Health, March 2010), one submitter representing eight companies advised that they have over 2,000 products between them, suggesting the estimates above are a significant underestimate. However, the absence of a database of products makes it difficult to estimate the true amount of market activity.

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[2] Companies use the internet to showcase their businesses and advertise their products. The information provided is not always accurate, complete or up to date. Alternative sources (such as information in on-line government records) have been used to cross-check information where possible.

[3] The *New Zealand Bioactives Report 2008* was commissioned by New Zealand Trade and Enterprise and produced by L.E.K. Consulting Pty Limited.

[4] This term covers companies who produce cosmetics, nutraceuticals and supplements, and bioactive functional foods and starting materials.

Problem Definition

Legislation out of step with development of natural health products market

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 that were on the market at the time (mainly vitamins, minerals and herbal substances in controlled dose forms used to supplement the dietary intake of those substances). The multi-million dollar industry that exists today was not envisaged and it now encompasses a vast range of products from simple vitamin preparations through to potent herbal medicines and substances derived from animals.

As the range of ingredients used in dietary supplements has expanded, so too 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 some cases, evidence has emerged to indicate that a substance is effective in managing the symptoms of a disease or disorder (eg, St John's Wort for mild depression).

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. Whilst 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 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.

The lists of allowable technological additives (eg, colours, tabletting aids, sweeteners, enzymes) in the Dietary Supplements Regulations 1985 have not been updated in line with developments in the food or natural health products fields in the last 20 years. The lists therefore contain some substances that are no longer in use, and do not include new substances that are now commonly used in food and in natural health products overseas. Various attempts have been made, unsuccessfully, over the past two decades to modernise therapeutic products legislation, including work to establish a joint agency with Australia. As a result, separate work has not been undertaken to update the Dietary Supplements Regulations 1985, other than in March 2010 to remove food-type products from the scope of the Regulations.

There is little information on the adverse events resulting from the use of natural health products in New Zealand. This is because there is no systematic testing of products or reporting of adverse events. However, based on overseas information, officials consider that some natural health products will be causing health problems amongst New Zealanders. For example, a 2005 report showed Australia as having just under 400 reported adverse events per year and 62 deaths over the previous ten years associated with natural health products. These figures were considered to be an under-estimate. In recent months, Medsafe has identified and recalled a number of imported products adulterated with prescription medicines.

Inadequate controls on safety and quality of products

Given that dietary supplements sit somewhere between foods and medicines (because they often contain the sorts of substances found in food 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 in a number of respects 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 dietary supplements. In addition, food manufacturers must meet the requirements of the Australia New Zealand Joint Food Code relating to composition and labelling but the composition and labelling requirements for dietary supplements in the Dietary Supplements Regulations do not provide the same level of safety assurance. 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.

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 entirely covered by the sorts of manufacturing standards that apply to manufactured foods, such as HACCP (Hazard Analysis & Critical Control Points) systems.

The absence of manufacturing controls may expose 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.

New Zealand is out of step with many other OECD countries 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

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 information is available about the risks of using products and that information about benefits is truthful and not misleading. Significant risks arise where adequate information is not provided about risks, or where the information that is available is misleading or exaggerates the benefits of using the product. This is particularly the case 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.

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.

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 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.

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.

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

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.

Enforcement actions usually arise following investigation of a complaint or concerns about product arriving at the New Zealand border. Enforcement is complicated because the interface between the Medicines Act and Dietary Supplements Regulations 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 product or 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.

Enforcement of the Dietary Supplements Regulations 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 are important to their health and well-being).

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.

Why specific legislation, over and above existing consumer protection legislation, is needed

Consumers cannot detect safety or quality deficiencies in a product and the consequences of any deficiencies will not be apparent at the time of use. In addition, consumers do not always have the knowledge and skills to distinguish between valid claims made by reputable distributors and the sorts of extravagant claims made for some products. In these circumstances of market failure, consumer protection legislation is of little use, although it provides for some recourse after a problem has been detected. The proposal provides for some assurances as to safety and quality prior to a product being marketed, as well as a register of products, which will facilitate post-market activities such as recalls and responding to safety alerts.

Objectives

The primary objective of the proposed regulatory scheme is "to provide assurance that natural health products are safe, true to claim and true to label" ie, they do not cause harm, they do what they say they will do, and contain the ingredients they claim to contain. The principles of the proposed regulatory scheme are that:

- 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.

Some other key objectives for the proposed regulatory scheme are to:

- make use of decisions by other trusted regulators (which is consistent with the Government's commitment to do the same with respect to regulation of medicines)
- be relatively low cost for the natural health products industry, such that it does not result in a significant number of products being taken off the market due to cost
- create a clear and coherent regulatory framework across natural health products, medicines, foods and cosmetics.

Regulatory impact analysis

This regulatory impact analysis considers the issue of regulating natural health products by asking:

- how robust or stringent a regulatory process should there be for natural health products? (Part A)
- what are the options for different elements of the preferred regulatory vehicle (eg, claims and evidence, labelling and advertising, product notification process, safety of ingredients, manufacturing standards)? (Part B)
- what is the appropriate regulatory vehicle for natural health products? (Part C)

Part A: How robust should regulation of natural health products be?

Regulation of natural health products could potentially range from having no specific regulation through to a very rigorous regulatory process, involving substantial testing and monitoring through every step of the process (somewhat like the process for medicines).

Some possible approaches are:

- No specific regulation ie, natural health products are not regulated as a class of product, but might be covered through general consumer protection legislation.
- Minimal regulation ie, some manufacturing standards and labelling requirements, but no product register or product approvals, evidence required for safety of new ingredients only, responsibility for product claims sits with manufacturer, voluntary reporting of adverse events. This is the model in the United States.

- Moderate regulation ie, product register but no product approval, no manufacturing standards but some labelling requirements, lists of prohibited and permitted/acceptable ingredients, no claims allowed for preventing, treating or curing disease. This is the model in the United Kingdom and European Union for food supplements.

- Significant regulation ie, product approval required, manufacturing standards and labelling requirements, lists of prohibited and permitted ingredients, no claims permitted for treatment of serious diseases. Variations of this model are found in Canada, Australia and the United Kingdom/European Union (for traditional herbal medicines).

It is assumed that having no regulation of natural health products is not a feasible approach given the objectives listed above, and that this would actually amount to **reducing** regulation relative to the little we currently have. Comparing these four approaches with the objectives above:

- Having no specific regulation does not provide consumers with adequate information about the products they may wish to consume. It would also fail to provide a regulatory scheme commensurate with risk, as it provides little regulation of higher risk natural health products. It would fail to improve the coherence of the regulatory framework across foods and therapeutic products. However, it would be low cost.

- The minimal regulation approach provides little benefit relative to the status quo, and therefore, it is doubtful whether it is worth establishing a new regulator and regulatory scheme to achieve it.

- The moderate regulation approach provides better safeguards to consumers, while remaining relatively low cost to manufacturers (eg, no product approval or manufacturing audits). By being less robust than medicines regulation, it would reflect the relatively low risk nature of these products.

- The significant regulatory approach would provide consumers with good information and ensure products are safe, would create a coherent framework, and could make use of decisions of other trusted regulators. It could potentially be designed to be somewhat commensurate with the risk of products. However, it is likely to be relatively high cost, and would potentially result in some products becoming uneconomic to market.

The Ministry of Health considers that the moderate regulation option best achieves the objectives for the regulatory scheme. It will provide mechanisms for managing the safety of products, and would potentially be a relatively low cost scheme. The Ministry considers that the addition of appropriate manufacturing standards would strengthen this option.

Part B: Elements of the regulatory scheme

The main elements of a moderate regulatory framework for natural health products, strengthened by the addition of appropriate manufacturing standards, (which are also elements of regulatory schemes in other countries) would be:

- requiring products to be notified to an online register, which would automatically assess whether those products meet pre-established criteria (eg, in relation to ingredients, manufacturing standards) before they are placed on the market
- requiring manufacturers of products to meet a Code of Practice for Manufacturing of Natural Health Products (based on Good Manufacturing Practice principles)
- setting standards for labelling and advertising

- requiring suppliers to hold evidence to substantiate natural health product claims.

In keeping with the objective to design a risk commensurate scheme, the natural health products covered by the regulatory framework would be lower-risk products that do not require the sort of stringent pre-market controls that apply to medicines. They would not be promoted for the treatment or prevention of serious diseases, such as cancer, and would not be for use in forms that must be sterile, eg, injections or eye drops.

The small proportion of higher-risk natural health products that would not be covered by the new regulatory framework 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. The Ministry of Health estimates that 90 percent of products would fall under the natural health products regulatory framework and 10 percent under the Medicines Act. Products falling under the Medicines Act would be products that are used for a therapeutic purpose and that the general public would consider to be natural, however, the risk associated with them would require a more robust level of regulation, such as pre-market assessment, use under the supervision of a qualified health professional or higher manufacturing standards than is anticipated under the natural health products bill. Such products would include sterile preparations and products with such high levels of vitamins or minerals that they are currently provided on prescription or only available from a pharmacy. These products are currently regulated under the Medicines Act.

When the new legislation came into effect, the Dietary Supplements Regulations 1985 would be revoked.

A. Verification that products meet the criteria to market as a natural health product

Status quo and problem

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 natural health products, unless they have been approved by a credible overseas regulator.

There is no requirement for a manufacturer or importer of a natural health product to obtain any sort of authorisation to market a product. This means that there is no mechanism for providing some assurance that products contain only the ingredients they claim to contain and in the correct quantities; are manufactured under adequate conditions; and, when used correctly, are likely to achieve the health benefits claimed.

In addition, the lack of a register means it is difficult to take action, eg, to recall a product, when safety concerns are identified.

Specific objectives

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

To facilitate post-market activities when a product is associated with harm.

Preferred option

Suppliers notify their products to a database held by the regulator, self-certifying compliance with aspects of the scheme, eg, that ingredients are suitable for inclusion in natural health products and that evidence is held to support therapeutic claims.

Details would include contact details of the supplier and manufacturer and basic product details such as common and brand name, dosage, dose form, active and non-active ingredients. The database would automatically assess whether the product met the parameters of the scheme. If the product did meet the parameters of the scheme, then the supplier would be able to market the product as a natural health product.

The regulator would undertake random audits to verify the accuracy of self-certified statements. Over time, such audits could focus on those parts of the industry shown to have low levels of compliance.

Alternative

Suppliers would notify their products on a database held by the regulator, but there would be no assessment of the information provided.

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.

Consultation outcomes

There was general support for an electronic notification process whereby suppliers would self-certify compliance with aspects of the scheme (eg, that evidence was held to support any therapeutic claims) and the database would validate that the product met the parameters of the scheme (eg, that the product did not contain prohibited ingredients).

Net benefits

There would be additional compliance costs compared to the status quo as suppliers would be required to enter information into a database. 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 products would facilitate enforcement because there would be a specific sponsor for each product on the market.

B. Safety of ingredients

Status Quo and Problem

There is no independent assessment of the safety of an ingredient used in a dietary supplement prior to the product being placed on the market, unless it has been approved by a credible overseas regulator. Unsafe ingredients can only be identified and removed from the market after a problem has been identified and consumers have been harmed.

Specific objective

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

Preferred option

The regulator would develop and maintain both a list of prohibited ingredients and an open-ended list of ingredients able to be used in natural health products (initially based on ingredients approved by overseas regulators, as well as those accepted in traditional medicine).

Manufacturers and suppliers would advise the regulator of all ingredients in a product being registered at least three months prior to marketing. Products containing prohibited ingredients could not be marketed. Manufacturers and suppliers would be required to identify any “new” ingredients (ie, those not on the open-ended list of ingredients able to be used). The ingredients listed would be compared to all known and approved ingredients, to ensure that nothing novel was included. The regulator could require further information about an ingredient that they (and other regulators) were not familiar with. Products containing new

ingredients would be able to be marketed unless the regulator expressed concern within the three month period, seeking an assessment of the ingredient.

Alternatives

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.

Only maintain a list of ingredients permitted to be used in natural health products and 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 be permitted.

Consultation Outcomes

Approximately one quarter of submitters opposed having a permitted list and a new ingredients assessment process. Many of these were 'form submissions'.

At a meeting with industry representatives[5], the group advised that it had reached a 'compromise position'; instead of a permitted list and a new ingredients assessment process, it preferred a 'non-exclusive white list' (ie, a permitted list, however, any new ingredients could be used without assessment provided they were not on the prohibited list; the onus would be on the regulator to identify and raise any concerns about new ingredients).

Written submissions from the industry differed in that most businesses expressed their personal views, rather than reiterating the compromise reached at the industry meeting. Most suggested existing lists which New Zealand could draw on in compiling its permitted list. A few suggested a non-exclusive white list.

Net benefits

Comparing listed ingredients against ingredients approved by other regulators and requiring notification of new ingredients prevents new potentially harmful ingredients from being included in products and going on to the market before they have been assessed. Costs to businesses will be minimised through recognition of products approved by trusted overseas regulators or recognised in traditional medicine.

Maintaining a list of prohibited ingredients provides transparency for industry about ingredients that have been identified as unsuitable. This avoids wasting time and money preparing applications for unsuitable ingredients.

Assessing new ingredients, about which the regulator has concerns, before they are marketed provides assurance to consumers that they are safe to use. This aspect would add to businesses costs in that applications would need to be prepared and the process may slow time to market.

C. Controls on manufacturing

Status Quo and problem

There is currently no requirement for manufacturers of natural health products to meet specified manufacturing standards, unless it is an animal product produced under a Risk Management Programme under the Animal Products Act 1981. Therefore there is no government assurance of the quality of the final product other than those produced under a Risk Management Programme.

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[5] Generally comprising the key industry umbrella groups.

Without such guarantees, 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.

Safety here has two aspects:

- the safety of the formulation of the product. This includes the safety of the active ingredient and excipients (additives etc) used in the product

- the safety of the manufacturing process. This goes to the sanitary and hazard control process in the production of the product, and may include systems to ensure that the formulation is as intended by the specification for the product (which in turn would be reflected on the label).

Currently, there are minimal provisions concerning product formulation. A wide range of active ingredients may be used in natural health products with no mechanism in place to provide for pre-market assessment of those substances, or for monitoring or product formulation by regulators.

In addition, there is currently no government mandated requirement for manufacturers to meet specified manufacturing standards, unless their product is an animal product manufactured under a Risk Management Programme (as required by the Animal Products Act 1981). Consequently, for products not made under a Risk Management Programme, there is no government assurance for consumers that the products they purchase will be true to label, ie, will contain the claimed amount of the stated ingredients, will not contain other undeclared ingredients, and will not be contaminated.

Specific objective

To ensure quality manufacture of natural health products.

Preferred option

A Code of Practice for Manufacturing of Natural Health Products (or alternatively guidance to the application of Good Manufacturing Practice or GMP) is considered the most appropriate option. The Code would be less onerous than pharmaceutical GMP and would be specifically tailored for natural health products. The bill would allow for the specification of manufacturing standards (ie, the Code) in regulations. The Code would be developed in consultation with the industry. Companies manufacturing natural health products would be required to meet the requirements of the Code. If a manufacturer was based offshore it would also need to show evidence that it could meet the Code. The bill would also allow for the regulator to specify in tertiary legislation which other regulators' manufacturing licenses it would recognise. However, New Zealand-based manufacturers without recognised audits and licences would be audited and licensed by the New Zealand regulator (subject to further work by officials on streamlining audits across agencies).

Alternatives

Manufacturing standards vary from minimal requirements regarding basic hygiene, to HACCP (Hazard Analysis & Critical Control Points)-type food controls, through to pharmaceutical Good Manufacturing Practice (GMP).

HACCP would be a necessary component of a regulatory system for natural health products. It was developed specifically as a food control programme and is intended to address safety and contamination issues in processing. However, it does not normally extend to ensuring that specific amounts of active ingredients are included in natural health products (as in GMP). Existing Risk Management Programmes for animal products may include steps to ensure appropriate formulation (as in GMP) as well as hygienic processing, in which case it may be appropriate to recognise them.

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.

Consultation Outcomes

Most submitters considered that pharmaceutical-style GMP was not necessary. There was general support for the development of a code specific to New Zealand's natural health products industry, provided it is not too costly to implement. Some submitters expressed a preference for guidance to the application of GMP, rather than a separate code.

Some submitters considered that any risk management system should be recognised, including HACCP, and that third party auditors should be used or that manufacturers should be able to self-certify compliance with international food codes.

There was general support for the recognition of manufacturing licenses issued by trusted overseas regulators (ie, with schemes similar to or more rigorous than New Zealand's).

Net benefits

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. It will increase actual and compliance costs for manufacturers who are not currently certified as GMP compliant (eg, by Medsafe or Australia's regulator). The actual cost will depend on the requirements to be set out in the Code, however, costs would be incurred for manufacturers that had to upgrade equipment or buildings, introduce a new quality assurance system or begin starting or testing materials and finished products. Some manufacturers may need to use a contract manufacturer or reposition their products as foods or cosmetics. Recognition of manufacturing licenses issued by trusted overseas regulators (such as Australia's Therapeutic Goods Authority) will keep costs down for businesses exporting into some overseas markets.

D. Claims and evidence

Status quo and problem

Under the Dietary Supplements Regulations 1985, suppliers of products may not make therapeutic claims even where evidence exists. Currently, claims tend to be made in breach of the regulations or are distributed through a variety of channels, eg, websites, flyers. There are no standards against which to determine whether claims are supported by evidence or traditional use; nor is there any enforcement, except where they are deemed to be a breach of the Medicines Act 1981 (eg, claims to cure a serious disease, such as cancer).

Preferred option

A standard for setting the levels for specific types of claims should be set in conjunction with a list of acceptable claims. The regulator would, in consultation, develop a standard setting out levels of evidence required to make specific types of claims. Generally, higher-level claims would require a higher level of evidence. Suppliers would assess the evidence they held against this standard in order to determine an acceptable claim for their product. Given that the regulatory scheme is intended to be light, covering products suitable for self selection, there would be a limit to the level of claim that could be made. Claims of preventing and treating serious diseases, eg, related to the heart or lungs, or to cancer would not be permitted; approval would be required under the Medicines Act 1981 which has independent, rather than self certified, pre-market assessment.

Alternative

The regulator would develop a list of permitted claims about natural health products. These would be only low-level claims (such as aiding digestion, helping to maintain joint mobility, preventing or relieving the symptoms of minor illnesses). Claims about preventing or treating a serious disease would not be permitted. When notifying a product, the supplier would

choose from a drop down list of permitted claims, depending on the products ingredients and uses.

Consultation outcomes

There were strong views in submissions that the scheme should not limit the claims that could be made, but that if claims were evidence-based or truthful that they should be allowed.

Net benefits

Compared with the ability to make any claim that is evidence-based or considered truthful, consumers will have confidence that the level of health claim made is commensurate with the controls on safety and quality within the regulatory scheme.

E. Advertising

Status quo and problem

At present, there are no advertising standards established under the Dietary Supplements Regulations. The advertising industry self regulates. The Advertising Standards Authority (ASA) has developed Codes of Practice, including the Therapeutic Products Advertising Code and the Therapeutic Services Advertising Code. Complaints about advertisements are heard by the Advertising Standards Complaints Board, with a right of appeal to an appeals board. If a complaint is upheld, the advertiser, advertising agency and media are requested to withdraw the advertisement. Compliance is high, although with non-members the ASA relies on persuasion and cannot enforce a decision. The ASA currently refers serious complaints to Medsafe where it considers enforcement is needed. Medsafe would enforce breaches under the Medicines Act.

Specific objective

To ensure that consumers receive truthful and balanced information about a product.

Preferred option

Inclusion of minimum requirements in the natural health products regulations, on which the ASA can build revised Codes of Practice. ASA would be the preferred route of complaints against natural health products advertising, but the regulator would have back-up powers of enforcement.

Alternatives

The industry self regulates as at present, with no inclusion of advertising requirements in the natural health products regulatory scheme.

Align with the food regime whereby the Food Standards Code provides that advertisements must not make any statements about a food that would not be permitted on the label of the food, combined with ASA standards that contain a broader best-practice set of guidelines.

Consultation outcome

A large number of submitters considered that a Code overseen by ASA would be sufficient and that no requirements were needed in legislation. ASA considered that the self-regulatory system works well most of the time, but that it is important to have back-up enforcement.

Net benefits

Inclusion of advertising requirements in the natural health products regulations would enable the regulator to take action where ASA is unable to enforce its decisions or where advertisers or media offend repeatedly. Alternatively, ASA would rely on Medsafe, which could only take action where breaches were made under the Medicines Act 1981. The preferred option makes the preferred route for complaints clearer, avoiding a situation where both ASA and the regulator might duplicate effort investigating the same complaint.

Part C: What is the appropriate regulatory vehicle for natural health products?

There are several different ways that natural health products could be regulated. As noted previously, natural health products fall somewhere between foods and medicines, so two options would be to regulate them entirely under either the Food Act or the Medicines Act, depending on which set of products they were considered to be most like. Within these two broad options, there are also some sub-options. The third major option is to create a new regulatory framework for natural health products, which would sit alongside the Food Act and Medicines Act.

Option 1: Regulate natural health products under food legislation

Amend and increase enforcement of Dietary Supplements Regulations

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. This would impact on the limitations on ingredients and the sorts of claims that could be permitted.

In addition, New Zealand shares its food standards setting system with Australia and there is an expectation underpinned by bilateral agreements that New Zealand's and Australia's food laws will be harmonised to the greatest extent possible. As natural health products are regulated as therapeutic products under Australian legislation, keeping natural health products under food legislation would not be consistent with New Zealand's bilateral undertakings.

Further, food-type standards are not sufficient to manage the risks associated with the manufacture of natural health products (as set out above).

In recent consultation there was minority support for retaining the status quo but, amongst these submitters, no support for strengthening enforcement.

Option 2: Regulate natural health products under therapeutic product legislation

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

Sub-option 2A: Amend the existing Medicines Act 1981 to include natural health products as a sub-category of medicines

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.

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, though they would not support the level of regulatory controls applied to medicines.

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.

In recent consultation, very few submitters proposed amending the Medicines Act 1981 to include natural health products as a sub-category of medicines.

Sub-option 2B: Develop new domestic therapeutic product legislation incorporating natural health products as a category of therapeutic product

This option would involve developing a completely new domestic regulatory framework for all therapeutic products, including natural health products.

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 ANTZPA was announced in July 2007 following controversy about the proposal to include complementary medicines within the scope of the joint scheme.

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 which could result in inconsistencies and inefficiencies.

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.

In recent consultation, no submitter expressed support for the development of a new Medicines Act incorporating natural health products; however a small number of submitters expressed a preference for a joint therapeutic products scheme with Australia which included natural health products.

Option 3: Regulate natural health products as a separate category of product under new legislation

Under this option, new natural health products legislation would be developed, separate from food or medicines legislation. It would be important that the interface between natural health products, medicines, food and cosmetics regulation is as clearly defined as possible. Despite best efforts to ensure a clear legislative boundary there will be instances where the categorisation of a product could arguably fall under two (or more) regulatory regimes[6]. In some instances, it may be in the supplier's interest to have uncertainty about the regulatory regime that applies to a product, thus giving the supplier scope to select the regulatory regime that best suits their interests under different circumstances, eg, that is cheaper or that allows a higher level of therapeutic claims. To address such instances, the legislation will need to define who has the authority to declare a particular product to be a natural health product, a medicine, a food or a cosmetic. This work will be reported back to Cabinet as part of the draft Natural Health Products Bill.

[6] In many instances, a range of products with the same key or active ingredient will fall under different regulatory regimes depending on the potency and form (ie, liquid, powder or tablet) of the active ingredient(s).

It is anticipated that, together, these four regulatory regimes will cover the full range of cosmetic, nutritional and therapeutic products on the market.

Sub-option 3A: Ministry of Agriculture and Forestry (New Zealand Food Safety Authority) administers the legislation

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 responsibility for administration of the Dietary Supplements Regulations (after amendment to exclude food-type dietary supplements from coverage) has transferred from the NZFSA to the Ministry of Health.

In recent consultation, a number of submitters supported aspects of the proposed regulatory scheme being administered by NZFSA.

Sub-option 3B: A stand-alone regulator (ie, separate to the NZFSA and the Ministry of Health) administers the legislation

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 will therefore not administer the regulatory scheme appropriately.

The advantage of the model is that it would be more acceptable to those in the natural health products industry who do not consider that regulation administered by an existing regulator would be appropriate.

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 industry). When compared with the option of using a unit within the Ministry of Health, establishing a separate regulator would result in higher occupancy 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 with natural health products and other therapeutic products.

In recent consultation, a small number of submitters expressed a preference for this option, however, some of these recognised that it would be more cost-effective to have the regulator based within the Ministry of Health.

Sub-option 3C: A new regulatory unit within the Ministry of Health administers the legislation

This option would offer the benefits described in sub-option 3B, but without the cost disadvantages associated with a stand-alone regulator. It would, however, likely be more costly than sub-option 3D (placement within Medsafe), given that Medsafe has existing systems and expertise that could be applied to the administration of new natural health products legislation, without incurring the same level of start-up costs.

In recent consultation, this option was at least implicitly supported by the majority of submitters – the two-thirds of submitters who agreed in principle with the development of a natural health products bill (ie, submitters did not comment on or object to any of the options, including this one which was described as the preferred option).

This option is preferred by the majority of the industry, which has concerns that Medsafe would unnecessarily apply pharmaceutical-level controls.

Sub-option 3D: Medsafe administers the legislation

This option offers the benefits described in sub-option 3B, but without the cost disadvantages associated with a stand-alone regulator. Medsafe also has some expertise currently in the administration of natural health products regulations in that it administers the Dietary Supplements Regulations.

The majority of the industry has expressed a view that Medsafe should not be the regulator. The concern is that Medsafe, as the regulator of pharmaceuticals, would take a heavy hand to the regulation of natural health products and would not appreciate that, as natural health products are less risky than medicines, they warrant a lighter regulatory hand. However, it would be possible to design a regulatory scheme that ensured that was not the case.

Preferred option

The Ministry of Health considers that the choice of preferred option is between 3C and 3D. Establishing a separate regulatory scheme under a new piece of legislation will best enable the creation of a coherent framework across foods and therapeutic products, while emphasising the distinguishing characteristics of natural health products. NZFSA does not have the required expertise to take on regulation in this area, hence a recent decision to transfer regulation of therapeutic-type dietary supplements to the Ministry of Health.

There does not seem to be a compelling argument for setting up a new regulator outside of the existing agencies that regulate foods and therapeutic products, and this would likely be the most expensive option.

In choosing between options 3C and 3D, the key factors appear to be cost and perceptions about the lightness of the regulatory scheme. The Ministry is inclined to the view that a relatively light regulatory scheme specified in legislation could be equally well managed by Medsafe or a new unit of the Ministry, although other stakeholders do not necessarily share this view. However, there is likely to be a higher cost (to be borne by the industry and potentially consumers) involved in setting up a separate regulatory unit from Medsafe. On balance, option 3C is supported as it is likely to have considerably greater industry support.

[Redacted pursuant to sections 6(b)(i) and 9(2)(j) of the Official Information Act 1982]

Costs and benefits of the proposed regulatory scheme

Costs

The introduction of New Zealand-only risk-based regulation of natural health products will impose two types of costs – costs of complying with the regulatory requirements, and direct costs through fees and levies.

Compliance costs

For suppliers, compliance costs would arise from the time taken to understand the new requirements, implement the systems required to meet the requirements of the manufacturing code, and gather the information necessary to complete the web-based notification process.

Regulatory costs would arise from fees (from audit, notification etc) and annual charges. The greatest impact would fall on small to medium-sized businesses, particularly those importing and distributing large ranges of products. There may also be some risks to exports, eg, where small companies produce for both the domestic and export markets, increased costs could price them out of the domestic market. In as much as this would also mean that it would be unviable to produce only for export, then exports would be at risk. Increased costs associated with additional regulatory hurdles could also adversely affect innovation within the industry.

These costs would be minimised through use of web-based applications with tools to minimise data entry. It is also proposed that there be a reduced fee for notifying low turnover products. Low turnover will need to be defined during the transitional period of the scheme and costings determined over its first two years of operation.

Costs would be incurred by manufacturers if they need to upgrade equipment or buildings, introduce a quality assurance system or begin testing starting materials and finished products in order to meet new manufacturing standards. For processors of animal products for export there are existing costs of having to meet the requirements of the Animal Products Act 1981.

If the export assurance system under the natural health products bill is not sufficiently robust and undermines confidence in the New Zealand official system there may be opportunity costs for exporters that currently gain market access with certification provided under the Animal Products Act. Significant resource (industry and Crown-funded) has been committed to negotiating such access over a considerable period of time. Returns on this investment could be threatened.

In addition, there is potential for similar products to be exported under different regimes: the proposed light-handed approach of the natural health products bill and the existing animal products exporting system. This could cause a two-tiered assurance system with associated levels of cost. This may create a market distortion for which, due to the risks identified in the paragraphs above, any potential benefits may not be sufficiently justified.

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) making other products such as cosmetics and these may need to cease manufacture of natural health products because they will 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 reformulate and package their products as foods or cosmetics and meet the relevant standards for these products.

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 are removed from the market, the impact on the range of ingredients available in the market place would be negligible.

Financial costs

At this stage, it is not possible to be clear about the cost of establishing this regulatory scheme, as we lack good information on the number and type of products in the market, and the likely demand for various regulatory activities. The Ministry of Health's preliminary estimate is that it could cost $1.100 million capital expenditure and $1.800 million of operating costs to set up the regulator, with ongoing costs of $3.640 million per annum.

The regulator will need to be funded for the following outputs:

a. regulatory policy advice
b. notification of products and new ingredients
c. standards setting
d. export certificates
e. compliance, audit, licensing manufacturers and monitoring
f. enforcement.

The consultation paper proposed full cost recovery (except for policy advice). There was strong opposition to this amongst submitters. Many considered that all post-market costs (compliance, audit, monitoring and enforcement) should be met by the Crown, while

others thought that the costs of the scheme should be met 50/50 by the Crown and industry.

It is proposed that the Crown meets the costs of regulatory policy advice and enforcement and that all other costs are paid for by the industry (including set up costs, which would need to be met up front by the Crown and recouped through fees). Both NZFSA and Medsafe recoup most of the cost of providing the outputs set out above from industry. The Ministry of Health provisionally estimates that this would amount to industry funding $3.750 million per annum. This includes a recovery over about six years of set-up costs of $1.800 million.

It is proposed that a memorandum account be established to recover the set-up costs. There are precedents for this as Medsafe operate a memorandum account which allows under/over recoveries of cost to be spread over future years. The following table illustrates the proposed funding model over the first four years, and the use of the memorandum account:

	$m			
	2011/12	2012/13	2013/14	2014/15
Total annual costs	1.800	3.640	3.640	3.640
Funded by:-				
Crown funding for "Public Good"	-	(0.500)	(0.500)	(0.500)
3rd Party levies/charges	-	(1.875)	(3.750)	(3.750)
Net Cost to Crown	1.800	1.265	(0.610)	(0.610)

	$m			
Memorandum Account	2011/12	2012/13	2013/14	2014/15
Opening Balance	-	(1.800)	(3.065)	(2.454)
Annual Change	(1.800)	(1.265)	0.610	0.610
Closing (Deficit) Balance[7]	(1.800)	(3.065)	(2.454)	(1.844)

The bill will need to allow for the setting of fees and levies following consultation with industry. Based on information submitted by a small number of businesses that there are upwards of 20,000 products on the market, it should be possible to fund the scheme at an average cost of under $200 per product, a level than many companies seem comfortable with. Consideration will be given to setting lower fees for products that already have approvals from trusted regulators, and to whether it is appropriate to charge a reduced fee for companies with a large number of low-turnover products to ensure that they can afford to continue in business.

It is proposed that the costs of export certification, audit and issuing of manufacturing licences and product notification be met by companies via a fee for service and that other costs be met by industry as a whole based on an annual levy to be charged on a per product-line basis.

Because we currently do not know exactly what, and how many, products are in the market, it is proposed that in the first two years of the scheme, the levy be based on a conservative estimate of the number of products and low-turnover products on the market. A funding review would be undertaken after two years to determine whether the fees and levies charged matched the actual costs of providing the regulatory services.

[7] The deficit balance in the memorandum account would be cleared by 2018/19.

Treasury's *Guidelines for Setting Charges in the Public Sector* identify three types of 'goods' that determine the appropriate source of funding: public goods, private goods and industry or club goods which 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 those whose actions create the risk if applicable).
- Industry Good: an industry 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 people 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.

Cost recovery (pre-market and partial post-market) through fees paid by the industry is proposed and would be consistent with Treasury and Audit Office principles and guidelines for charging for government services.

Table 2: Assessment of elements of scheme against Treasury guidelines

Output	**Type of Good**	**Recommendation**
Policy advice	Public – to maintain independence of advice to the Minister, these outputs should be regarded as public goods and funded by the taxpayer	Crown pays
Notification	Private – as the benefits can be directly attributed to those persons wanting to market their product	Industry pays, fee for service
Standards setting	Industry – as use by one industry participant does not impose a loss of benefit on others	Industry pays, levies
Export certificates	Private – as the benefits can be directly attributed to those persons wanting to market their product	Industry pays, fee for service
Compliance, audit, surveillance and monitoring	Industry – as use by one industry participant does not impose a loss of benefit on others	Industry pays, levies
Enforcement (investigations, sanctions and prosecutions)	Public – charging fees could be counterproductive (eg, if a party would incur costs if they reported non-compliance) and compromise the independence and integrity of the regulator	Crown pays

Under this model, the Crown would fund the costs of policy advice and enforcement; all other costs would be recovered from industry.

It is proposed that the costs of audit and licensing of manufacturing facilities, export certification and product notification (including the information technology costs) be recovered by fees charged to the applicant company and that the level of fee should match actual costs.

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 ingredient, the cost could be spread across all product approval holders and recovered through an annual 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 which there is no history of safe use. However, most of the costs would be recovered through an annual charge paid by all product sponsors.

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. Similarly, Australian companies operating in both markets will face two sets of costs. The impact of this on the detailed design of the scheme will need to be carefully assessed to ensure it does not impact negatively on competition, the single economic market objective or reducing the burden of regulatory compliance.

The cost per product line is difficult to estimate at this stage due to a lack of market information. Earlier in this RIS, it was indicated that there were an estimated 6,600 products in the market, however, in the absence of any register of products we have no way of knowing whether this is an accurate estimate. One submission in the recent consultation considered that there were over 20,000 products in the New Zealand market. Assuming that there would be ongoing annual costs to be recovered of $3.750 million and given that the majority of these costs would be spread across the number of product lines in the market, whether it is 6,600 or 20,000 or some other number is material. At 6,600, the annual cost per product would be $568, whereas at 20,000 the annual cost per product would be $188. It is also possible that the estimated cost could be higher if the number of product lines is substantively higher, depending on the additional number of staff and other resources required by the regulator. At the higher end of the cost estimates, it is unlikely that the scheme would be viable as industry would be unable to sustain the costs. In such a scenario, the elements of the scheme would have to be revisited.

For this reason, it is proposed that initial fees be based on a conservative best-estimate of the products on the market and that the Crown initially meet any shortfall, which would subsequently be recovered from industry. The latter approach would provide an incentive for companies to make early business decisions on whether to position their products in the natural health product, food or medicine arena (ie, whether to make therapeutic claims about them).

Benefits

Consumers will benefit from increased assurance of the safety and quality 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 for government assurance about the safety, efficacy and

quality of the products will facilitate uptake of natural health products within the primary healthcare setting.

The benefits for industry will be the ability to:

- lawfully promote their products with natural health product claims
- obtain export certification that attests to the regulated environment in New Zealand (at present export certification provides no guarantees about the standard of products because the regulator has no information on which to base such guarantees).

Consultation

The Ministry received around 1,500 submissions on the consultation paper *The Development of a Natural Health Products Bill*. Eighty five percent of submissions were from individual consumers, practitioners and others with an interest. Fifteen percent of submissions were from organisations, eg, practitioner bodies, industry umbrella groups, individual businesses and consumer groups.

Two-thirds of submitters expressed support for the need to regulate the natural health products sector and for the general purpose of the proposal. However, many of these submitters sought changes to the proposal including:

- having only a list of prohibited ingredients and not also a list of permitted ingredients
- allowing any new ingredient to be marketed in a product without having to go through a safety pre-assessment
- allowing any therapeutic claim, provided it is based on evidence (with traditional evidence being acceptable)
- recognising a range of risk management programmes (including food-based ones), along with use of third-party auditors and/or self-certification of compliance against international standards
- a government contribution to cover the cost of post-market activities, which were strongly considered to be public goods.

A minority of submitters sought a more rigorous scheme, expressing concern that the proposal was inadequate, and not in line with international best practice. Particular concerns were that it would not be sufficiently robust to guarantee that products were 'safe, true to claim and label' and that it would not be recognised by key trading partners, particularly Australia and the European Union.

A few submitters gave unqualified support to the proposal.

Others considered that adequate controls were in place through consumer protection legislation or they expressed a preference for industry self-regulation or the implementation of a draft bill presented to Ministers in 2009 by an industry group[8]. These submitters generally held a strong view that natural health products were no or very low risk.

While many concerns were expressed about the proposal, the most common were:

- consumers would lose access to valued health products through price increases or rationalisation of product lines
- people should be free in a country like New Zealand to determine for themselves how best to care for their own health
- it is not a truly independent New Zealand proposal, but based on models in other countries, particularly Australia and/or it is effectively the trans-Tasman model that was previously rejected

[8] Accessed at www.healthtrust.co.nz/pdf/Joint_Industry_NTHPs_Bill_Feb_2009.pdf on 24 June 2010.

- it is driven by or aimed at supporting large multinationals and, in particular, pharmaceutical companies
- it will increase public health costs
- it will damage industry, exports and the economy.

While initially expressing outright opposition, many of these submissions then went on to address specific components of the proposal.

In consultation with Māori (particularly representatives of the WAI 262 indigenous flora and fauna claim, rongoā Māori practitioners providers and consumers), a very strong view was expressed that this bill should not proceed until the WAI 262 claim is settled. The main concern was that the bill would pre-empt the conditions of any settlement and that the bill should address issues to do with indigenous flora and fauna, including intellectual and cultural property rights – issues which are, at least at present, outside the scope of the bill.

Much of the detail of the scheme has yet to be developed, eg:

- a precise definition of natural health product, and clarification of the interface with medicines, food and cosmetics legislation
- a list of ingredients that will be prohibited for use in natural health products
- a list of ingredients suitable for use in natural health products
- identification of overseas regulators whose approvals will be recognised by the New Zealand regulator
- labelling requirements.

The Ministry of Health will appoint an interim technical expert advisory group to advise on this level of detail. As this work progresses, further consultation will be undertaken with industry and other regulators. The priority will be the definition, which is required for the bill; the other issues will be set out in secondary and tertiary legislation. When the bill is enacted, the interim advisory group will be replaced by a technical expert advisory group to be established under the Act.

Conclusions and recommendations

In summary, the introduction of the scheme would place additional costs on industry – costs of complying with the regulatory requirements, and direct costs through fees and levies. The greatest impact would likely fall on small to medium-sized businesses, particularly those importing and distributing large ranges of products. To minimise the impact on industry, the scheme is intended to have a low regulatory impost and, consequently, low costs. There would also be additional costs for manufacturers if they need to upgrade equipment or buildings, introduce a quality assurance system or begin testing starting materials or finished products to meet new manufacturing standards. These costs will be kept to a minimum through the recognition of manufacturing licenses issued and audits undertaken by trusted overseas regulators. The main impact will be on manufacturers who are not licensed by overseas regulators.

There will also be costs for auditors and third party verifiers to come up to speed with the requirements of the new regime, and to be recognised as competent auditors. If these costs are prohibitive, or are not economic for auditors in some parts of the country, there may be a market failure. Consideration will need to be given to providing an ‘auditor of last resort’ in cases of market failure.

Consumers would, however, benefit from increased assurance about 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 the products contain the

correct ingredients in the stated amounts. For industry, the key benefits would be an ability to legally make therapeutic claims for natural health products and to obtain export certification that attests to the quality of products.

In conclusion, the scheme should proceed with some changes to the proposal set out in the consultation paper,as follows:

- a standard should be developed setting out levels of evidence required for making specific health claims (rather than, or in addition to, a list of allowable claims)
- a two year transitional period (rather than the proposed one year period) to complete product notification; three years (rather than two) to meet manufacturing standards; and the addition of a one year period to enable products containing ingredients not on the initial ingredients list to remain in the market pending an assessment of those ingredients.

The Ministry's recommendations are:

- The natural health products bill should regulate the manufacture, supply and promotion of low-risk natural health products, with higher-risk products requiring approval under the Medicines Act.
- Natural health products should be notified to the regulator via an online database which would automatically check products' suitability against in-built criteria.
- There should be exemptions from product notification for:
  - products prepared by a practitioner for a patient
  - certain products or categories of products declared exempt by the Director-General of Health, eg, aromatherapy and homeopathic remedies similar to the Australian system (as developed jointly by the New Zealand and Australian industries)
  - export-only products (except where businesses require the regulator to issue export certification).
- There should be a prohibited ingredients list.
- There should be an open-ended ingredients list and a new ingredients assessment process (where the regulator has concerns about the proposed new ingredient).
- There should be a standard setting out the levels of evidence required to make specific health claims.
- That manufacturers or distributors should hold evidence to support any health claims that are made about a product.
- The Act should contain regulation-making powers to set out:
  - labelling requirements
  - advertising requirements
  - fees/levies
  - administrative processes
  - manufacturing requirements.
- Manufacturing standards should be specified either in a code developed specifically for New Zealand's natural health products industry or in guidance to the application of internationally accepted good manufacturing practice.
- The regulator should unilaterally recognise manufacturing licences issued by trusted overseas regulators.

- The Act should contain sanctions and penalties commensurate with other recent relevant legislation, such as the Food Bill, the Wine Act 2003 and the Animal Products Act 1999.
- Appeals should be made in the first instance to the Director-General of Health and subsequently to a review committee.
- The regulator should establish a technical expert advisory committee.
- The regulator should regularly consult with stakeholders to obtain feedback on its performance.
- The Act should contain transitional periods of:
  - one year to allow products containing ingredients not on the initial ingredients list to remain in the market while those ingredients are assessed
  - two years for product notification
  - three years to meet manufacturing standards.
- The Crown should fund the costs of policy advice and enforcement; all other costs should be recovered from industry.
- Costs to be recovered from industry should be conservatively estimated and charged as a levy in the first two years in order to collect market information to enable the level of fees and levies, including reduced levels for low turnover products, to be determined.
- Any shortfall in funding in the first two years should be met by the Crown, but subsequently recovered from industry.
- The scheme should be reviewed after 5 years to determine whether it is meeting the Government's objectives.

Implementation

It is anticipated that the bill would be enacted in 2011. There would be a transition period of two years for product approvals, three years for meeting manufacturing standards and one year for products in the New Zealand market that contain ingredients that are not on the initial ingredients list. Once the bill was enacted, the Dietary Supplements Regulations 1985 would be revoked.

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

There would be a public education campaign prior to enactment of the bill and more focused assistance for industry to assist them to understand and comply with the new requirements. Following commencement, the Ministry would continue to run a 'helpdesk' 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 begin to provide early advice on any upgrades that would be needed by the end of the proposed three year transition period.

Monitoring, evaluation and review

As noted earlier in this RIS, there is relatively little accurate information available about the natural health products industry and the products available in the market. One of the advantages of having a register of products will be improved information. Over time, we will be able to see how many products there are, by product category. This information will help to monitor, evaluate and review the regulatory scheme. For example, we will be able to investigate whether numbers and types of products change over time, and whether there is

any change in the composition of the industry. We will also be able to identify particular types of products or companies that are associated with adverse events, in order to focus the efforts of the regulator more appropriately.

A review of the scheme is proposed after 5 years to determine whether it is meeting the Government's objectives, or whether an alternative approach would be more efficient and effective.