**AN EXPLANATION OF WHY THE NATURAL HEALTH PRODUCTS BILL IS FLAWED REGULATION AND WILL DAMAGE THE INDUSTRY AND CONSUMERS**

**INFORMATION TO HELP YOU MAKE A SUBMISSION TO THE MINISTRY OF HEALTH BY 4th MARCH 2016**

**1. Summary**

The Natural Health Products Bill establishes a regulatory regime for natural health products separate from those in place for food and medicines. It preserves the existing restrictions and introduces many new restrictions and obligations that will impose significant new compliance costs.

The current regime regulates natural health products as foods. The Bill, however, takes a pharmaceutical-type approach to natural health products that is disproportionate to the de minimis risks they pose.

The effect of the Bill will be that consumers will completely stop buying New Zealand products and instead will buy online from companies such Amazon and Iherb.

The Bill was introduced into Parliament in September 2011. It has gone through the Select Committee process and is awaiting its third reading.

The Select Committee made several amendments to the draft Bill. Further substantial amendments are proposed in a Supplementary Order Paper dated 18 August 2015. This document is not a public document and has only been circulated to a small select group of consultees.

The Ministry of Health is consulting on various details of the proposed regime that are to be contained in regulations. Submissions are sought by **Friday 4 March 2016**.

If passed into law this Bill will deleteriously affect the manufacture, sale and supply of natural health products. In particular it will impose significant and unjustified obligations and compliance costs on the industry with no commensurate health benefit to consumers. In summary it will:

* Create a new regulatory body known as the Natural Health Products Regulatory Authority that is granted wide discretionary powers in relation to the manufacture, sale and supply of natural health products. **This is a new body that will be funded by fees and other charges paid by the industry.**
* Restrict the sale of products to only those containing permitted substances. This could mean a number of products will no longer be able to be lawfully sold. **This is a new restriction that doesn’t currently apply.**
* Restrict the sale of products to only those that have been notified to the Authority. **This is a new obligation and restriction that doesn’t currently exist.**
* Require as part of the notification process that evidence to support health benefit claims be included on the product notifier’s website. This means that if a product claims to support joint health there must be scientific or traditional evidence supporting that claim on the website. **This is a new obligation that doesn’t currently exist.**
* Restrict health benefit claims about any particular illness or condition to only those claims that have been approved by the Authority. This means that even if claims about a particular condition are substantiated by scientific and/or traditional evidence, they cannot be made unless pre-approved. **This is a new restriction that doesn’t currently exist.**
* Require manufacturers to be licensed and to comply with the Code of Practice and to be audited. **These are new obligations that don’t currently exist.**
* Require overseas manufacturers to comply with a new Code of Practice unless the manufacturer is a “recognised authority”. The proposed list of recognised authorities is proposed to include principally pharmaceutical medicines regulators including the Therapeutic Goods Agency in Australia. **This is a new obligation that doesn’t currently exist.**
* Prevent practitioners administering natural health products to individual clients from using non permitted substances. **This is a new restriction that doesn’t currently apply.**
* Impose significant new compliance costs on manufacturers and distributors of natural health products. These costs include:
	+ The cost of notifying each and every product offered for sale. The proposed fee is $195.50 per product and is to be an annual charge.
	+ The cost of providing information on a website about any health benefit claims made about a product. The level of information required is likely to be detailed and will take a reasonable amount of time to prepare and collate.
	+ The cost of applying to have a non-permitted substance approved. The proposed fee is $805 plus the cost to the industry member of obtaining and collating the necessary evidence to support an application. This could be at least $40,000 and could cost an additional $50,000 to $150,000 if toxicological data needs to be commissioned.
	+ The cost of applying to have a health benefit claim about a named condition approved. The proposed fee is $2300 or $5520 (for a new named condition where claims are restricted to a product or class of product). There will also be the cost to the industry member of obtaining and collating the necessary evidence to support an application.
	+ The cost of a licence to manufacture. This is proposed to be $667.
	+ The cost of complying with the Code of Manufacturing Practice.

**These are new costs that don’t currently apply.**

* Permit export certificates to be obtained at a proposed cost of $149.50 per product. **This is a new permission.**
* Stifle innovation.

**2. Key features of the Natural Health Products Bill**

**2.1. Scheme of the Bill**

The Bill regulates the manufacture, sale and supply of natural health products. Only permitted natural health products that have been notified to the Authority may be sold, and manufacturers must be licensed and comply with the Code of Practice.

**2.2. Definitions of a natural health product, permitted natural health product, and permitted substance**

The Bill (as amended by the Supplementary Order Paper dated 18 August 2015) defines a “natural health product” as:

* represented for human use for the primary purpose of bringing about a health benefit
* contains only natural substances (defined in Schedule 1)
* not a food or not presented as a food
* does not contain a psychoactive substance
* does not contain a medicine listed in Schedule 1 of Medicines Regulations

A “permitted natural health” product is defined as one containing only permitted substances.

A “permitted substance” is defined as a substance declared by the Authority to be a permitted substance.

**2.3. Sale of natural health products**

Subject to certain limited exceptions, the Bill (eg practitioners administering to an individual) provides that only permitted natural health products that have been notified to the Authority can be legally sold.

If a product contains a non-permitted substance, an application must be made to the Authority and the product cannot be sold unless the Authority either does not raise any safety concern about the substance or approves the substance as a permitted substance.

**2.4. Notification of permitted natural health products by product notifier**

The Bill requires all permitted natural health products to be notified to the Authority by a New Zealand based product notifier.

For natural health products manufactured in New Zealand the product notifier is the manufacturer but if the manufacturer manufactures on behalf of another person, the notifier is that other person.

For natural health products manufactured overseas the product notifier is the importer but if the person imports the product on behalf of another person, the notifier is that other person.

This means that any foreign manufacturers intending to sell products in New Zealand will need to do so through a New Zealand-based person or company.

Products made by a practitioner for an individual patient are not required to be notified but must only contain permitted substances.

**2.5. Health benefits claims and allowable claims**

A health benefit claim is a claim about any 1 of the following benefits:

* the maintenance or promotion of health or wellness
* nutritional support
* vitamin or mineral supplementation
* affecting or maintaining the structure or function of the body
* relief of symptoms

When notifying a natural health product evidence the product notifier relies to support each health benefit claim must be made available on an internet site.

A health benefit claim cannot relate to a named condition (which is defined as a disease, disorder, conditions, ailment listed in the ICD) unless it is an allowable claim.

An allowable claim means a health benefit claim that the Authority has determined may relate to a named condition.

**2.6. New regulatory body**

A new regulatory body known as the Natural Health Products Regulatory Authority is established by the Bill and will have wide powers to:

* Determine the list of permitted substances and allowable claims
* Audit product notifications.
* Suspend or cancel product notifications.
* Charge fees for monitoring compliance on a user-pays basis.

**2.7. Other requirements**

* Manufacturers must have a licence and must comply with the Code of Practice. The Code of Practice requires a manufacturing facility to have a fully documented and well-defined quality assurance system that incorporates the principles of good manufacturing practice and the concepts of quality control and quality risk management. The Code of Practice requires systems and procedures to be implemented to cover the following areas: personnel, premises and equipment, production, quality management and quality control, complaints and recall.
* Overseas manufacturers licensed by an overseas body that is a “recognised authority” may be deemed to comply with the Code of Practice.
* Health practitioners administering a natural health product to an individual client following a consultation, will not need to notify the product, but any product must only contain permitted substances.
* All labelling requirements prescribed in the Regulations must be complied with.
* Advertising and labelling of products will be unable to make any health benefit claim in relation to a named condition unless it is an allowable claim
* An export certificate may be obtained for a permitted natural health product. An export certificate, however, is not a guarantee that the permitted natural health product necessarily meets the commercial requirements of the customer, or necessarily meets the specific requirements of overseas markets.
* Existing products have 1 year to complete notification, 2 years to comply with labelling requirements and 3 years to comply with manufacturing requirements.
* There are significant penalties for individuals or bodies corporate who breach the Bill. Fines can be ordered up to $500,000 for a body corporate and $100,000 for an individual and up to 5 years’ imprisonment.

**3. Summary of what the Bill means for participants in the industry**

**3.1. Who is a manufacturer?**

A preliminary issue arises as to who is a manufacturer. Manufacture, in relation to a product, means to make up, prepare, produce, or process the product for the purposes of sale, and includes the packaging of the product in a container for the purposes of sale.

This definition means that in relation to a product there could be a number of manufacturers. For example, if the person who prepares the product is different to the person who packages it or labels it, then both conceivably may be manufacturers.

This is important because if a person is a manufacturer there are obligations on them in their capacity as a manufacturer, and hefty penalties in the event of breach of these obligations.

**3.2. What the Bill means for manufacturers**

* Subject to some limited exceptions, eg practitioners administering to an individual, all manufacturers will need to be licensed by the Authority.
* Manufacturers will need to comply with the Code of Practice. This means they will need to ensure that their systems and procedures comply with the requirements of the Code.
* Manufacturers will need to notify each product to the Authority. This is expected to be an annual obligation.
* Manufacturers may not manufacture natural health products that contain non-permitted substances unless the substance is approved by the Authority.
* Manufacturers must be able to provide evidence to support health benefit claims and may only make health benefit claims in relation to approved named conditions.
* Manufacturers who knowingly manufacture a natural health product without a licence are liable for a fine up to $250,000 if a body corporate, and up to $50,000 if an individual.
* Product notifiers who knowingly make a claim that relates to a named condition that is not an allowable claim are liable for a fine up to $250,000 if a body corporate, and up to $50,000 if an individual.
* It is an offence to sell or offer to sell natural health products that contain non-permitted substances and or have not been notified to the Authority. A person liable for a fine up to $250,000 if a body corporate, and up to $50,000 if an individual.

**3.3. What the Bill means for foreign manufacturers who intend to sell products in New Zealand**

* Foreign manufacturers will need to comply with the Code of Practice unless they are already licensed by a “recognised authority”. A recognised authority is proposed to include the organisations recognised by Medsafe for the purposes of the Medicines Act.
* Foreign manufacturers may not manufacture for the New Zealand market natural health products that contain non-permitted substances unless the substance is approved by the Authority.
* Products manufactured overseas must be notified by the importer or the person on behalf of whom a product is imported. If foreign manufacturers wish to sell products to New Zealand they will need to make arrangements with a New Zealand-based company or individual.
* Foreign manufacturers of natural health products that do not comply with the New Zealand regime could make them available over the internet rather than sell them **in** New Zealand.

**3.4. What the Bill means for importers**

* Importers must notify each product to the Authority.
* Importers must publish on the Internet the evidence to support any health benefit claims made.
* Importers may only make allowable claims.
* Importers may only import for sale natural health products that contain permitted substances.
* Importers may not import natural health products that contain non-permitted substances unless that substance is approved by the Authority.
* Importers will need to comply with labelling requirements.
* Product notifiers who knowingly make a claim that relates to a named condition that is not an allowable claim are liable for a fine up to $250,000 if a body corporate, and up to $50,000 if an individual.
* It is an offence to sell or offer to sell natural health products that contain non-permitted substances and or have not been notified to the Authority. A person is liable for a fine up to $250,000 if a body corporate, and up to $50,000 if an individual.

**3.5. What the Bill means for exporters**

* Exporters may only export products containing permitted substances and products that have been notified to the Authority.
* Exporters may obtain an export certificate. However, an export certificate is not a guarantee that the permitted natural health product necessarily meets the commercial requirements of the customer, or necessarily meets the specific requirements of overseas markets.
* It is an offence to export natural health products that contain non-permitted substances and or have not been notified to the Authority and a person is liable for a fine up to $250,000 if a body corporate, and up to $50,000 if an individual.

**3.6. What the Bill means for retailers**

* Retailers must only sell products that contain permitted substances and that have been notified to the Natural Health Products Regulatory Authority.
* Retailers must only make health benefit claims in relation to named conditions that have been approved.
* It is an offence to sell or offer to sell natural health products that contain non-permitted substances and or have not been notified to the Authority and a person is liable for a fine up to $250,000 if a body corporate, and up to $50,000 if an individual.

**3.7. What the Bill means for consumers**

* Consumers can only buy in New Zealand natural health products that contain permitted substances.
* Consumers may buy for their own use on the internet overseas products that do not comply with the Bill.

**3.8. What the Bill means for practitioners**

* Practitioners administering to individuals do not need to notify the product, but the product must only contain permitted substances and also cannot contain medicines. The Ministry in the consultation document has stated that practitioner-made products are not limited to permitted ingredients, but cannot contain substances listing in Schedule 1 of the Medicines Regulations. However New Zealand Health Trust’s interpretation of Supplementary Order Paper is that a practitioner cannot supply a product containing non-permitted substances. While a practitioner may be exempt for product notification requirements, the requirement to only sell permitted natural health products applies. Further the exemption in s 28 of the Medicines Act relating to herbal remedies is to be repealed.
* It is an offence to sell or offer to sell natural health products that contain non-permitted substances and a person is liable for a fine up to $250,000 if a body corporate, and up to $50,000 if an individual.

**4. Some of the problems with the Bill**

**4.1. The Bill is a solution to a non-existent problem**

The stated drivers for the Bill are to ensure that natural health products are safe, true to claim and true to label.

However, there is no evidence that the current regulatory regime is defective in these respects.

There is no evidence that significant safety risks exist. Products sold for human consumption must already meet risk-based manufacturing standards, be fit for purpose, and be true to label. Consumers are well-protected by existing legislation (eg Fair Trading Act 1986) that prevents misleading claims.

There is no evidence that any coroner’s report in New Zealand has ever attributed a cause of death to a natural health product.

**4.2. The Bill fails to take a risk proportionate approach, or apply common sense**

Measures taken to protect human health must be proportional. Such measures should not erode consumer choice, stifle innovation, or result in obstacles to free movement of goods that are entirely disproportionate to the pursued aim of protecting health.

The Bill is not a proportional response.

Industrially produced natural health products are inherently safe. The Bill fails to recognise this by requiring all ingredients, including common foods and ingredients with a generally recognised safe history of use to be individually and formally approved again. At present a number of hitherto “safe” substances may no longer be able to be legally sold because they contain substances that are not permitted substances.

The principal risk the Ministry of Health appears to be concerned about is the risk that a person will elect to use a natural health product rather than go to a doctor and be prescribed a medicine.

There is no evidence that this is a legitimate risk and properly prescribed medicines pose a significantly higher risk of harm. At present there are commonly warnings on labels to the effect that if symptoms persist see a doctor. This is an adequate means of dealing with any concerns of the Ministry and doesn’t justify the Bill.

**4.3. The regime is a pre-approval regime (when the Government expressly assured the industry it would not be)**

Only pre-approved ingredients can be used. Only pre-approved claims about named conditions can be made.

Even if traditional and/or scientific evidence exists to support a particular health benefit claim about a condition, that claim cannot be made unless the Authority has approved it.

**4.4. Permitted substances list is flawed**

At present the draft list prepared by the Ministry of Health contains more than 5000 ingredients, including things like potable water. However, there are literally hundreds of thousands of ingredients in nature.

Requiring everyday foods and common ingredients such as water to be approved is bureaucratic micromanagement that is unjustified for this low-risk industry.

A preferable solution is to have a blacklist of ingredients. This would be a permissive regime, ie unless prohibited it is permitted, rather than the “it’s prohibited unless it’s allowed” approach proposed by the Bill.

Under the current law, natural health products cannot contain substances listed in the Schedule to the Medicines Regulations unless they are regulated as related products under the Medicines Act. This prohibition is continued under the Bill.

This is objectionable because a number of these substances are not unsafe. The Bill continues the ability for Medsafe to add substances to the Medicines Regulations Schedule and to prevent the use of those substances by the natural products industry.

**4.5. Inability to make therapeutic claims**

Under the current law, natural health products cannot make therapeutic claims (eg that they treat and prevent disease) unless they are regulated as related products under the Medicines Act.

Under the Bill natural health products will not be able to make therapeutic claims, nor can they be related products under the Medicines Act. Related products are cosmetics, dentifrices and foods making a therapeutic claim. However, a natural health product is not a food and consequently could not be a related product.

It is objectionable that health benefit claims are defined narrowly and do not permit natural health products to make substantiatable therapeutic claims.

Pharmaceuticals should not have a monopoly over the use of the expression “therapeutic purpose”.

Some natural health products have the ability to prevent, treat and cure disease. An obvious example is Vitamin C to cure scurvy. Where the appropriate evidence exists to justify a therapeutic claim, such claims should be permissible.

**4.6. Significant new compliance costs are imposed on industry**

The industry will bear significant and unjustified **new** costs, including:

* Product notification costs. Every product sold must be notified. This is expected to be an annual cost.
* Costs of providing information on the website about health benefit claims.
* Costs of applications to have new ingredients and claims about named conditions approved.
* Costs to achieve direct and indirect compliance with the Code of Practice.

The costs are not simply the application fees to be paid to the Ministry of Health but will include the time and cost to do the research, obtain the necessary reports (including a toxicology report if required), prepare the necessary documentation, create a website etc.

NZHT research shows that in Australia, it can cost approximately $40,000 to prepare the necessary information required to support an application for a new substance to be approved by the TGA. This will include various literature searches and a toxicological report analysing the data. However, if there is an absence of toxicological data it could cost $50,000 to $150,000 to obtain that information. There is no guarantee that an application will be approved and there may be the additional cost of an appeal (including legal advice and representation).

The cost in New Zealand is likely to be similar because the criteria for assessing substances is similar.

Another factor to be borne in mind is that if the substance is approved, any other person can then supply a product with that substance in it. No exclusivity over the substance is granted to the applicant.

The fees proposed to be charged by the Ministry are set out in section 7.6 below. These fees do not seem to be set at a rate that will recover what are expected to be significant administrative costs, and it is likely they will be significantly increased in the future.

**4.7. The Bill creates a new regulator with wide arbitrary powers**

The Bill will be administered by an Authority which will sit in the Ministry of Health.

The Bill confers significant regulatory powers on the Authority to approve/disapprove permitted substances, approve/disapprove what claims can be made in relation to products, set fees, suspend product notifications, and suspend licences etc. While principles are expressed to guide decision making, eg that regulation of natural health products should be proportionate to the risks associated with their use, these principles are stated in the Bill as being not enforceable.

The Authority is proposed by the Ministry of Health to be Medsafe. This is directly contrary to the assurances given by the Government to the Select Committee that the Authority would not be Medsafe.

Medsafe regulates medicines and is likely to take a pharmaceutical (high-risk) mind-set to a sector which poses no significant risk to the public.

**4.8. Maori health practitioners disadvantaged**

Maori health practitioners and others using traditional herbal and other remedies to administer to an individual will be unable to use non-permitted ingredients.

**4.9. Innovation is stifled**

The Bill will reduce competition by potentially removing products from the market for no risk-based reason, and placing barriers in front of innovators. Consumers will suffer as a consequence.

**4.10. The Bill advantages those large firms with a small number of products with high turnover, and disadvantages smaller enterprises with a high number of low turnover products**

Using over-regulation to eliminate competition from small to medium enterprises is a well-known technique.

It is acknowledged that the Bill could benefit those who seek to create a monopoly and reduce competition to expand their market share. The Bill advantages those large firms selling large numbers of a limited number of products.

Small to medium enterprises (who are believed to largely oppose the Bill) that sell a high number of low volume products will be unfairly disadvantaged with high direct and indirect compliance costs.

**4.11. Export-only products now need to be notified**

The Supplementary Order Paper has removed the exemption for export-only products from being notified.

A product can only be exported if it has a valid product notification and contains only permitted substances. There is no justification for these restrictions to be imposed on export-only products. Exporters have to comply with the rules of the country of destination and New Zealand rules are not relevant.

A product notifier can apply for an export certificate under the Bill. The benefits of obtaining a certificate are unclear as the Bill provides that such a certificate is not a guarantee that the product meets the commercial requirements of the customer or the specific requirements of overseas markets.

**4.12. Minister believes the Bill will promote phenomenal export growth**

The Ministry of Health has advised the Minister that based on industry estimates the natural health products industry contributes exports of over $1 billion per year and that exports could grow to $5 billion per annum by 2025.

The implication is that the Bill will cause this five-fold increase in exports.

New Zealand already has a good export market as evidenced by the claimed $1 billion of annual exports under the current regime.

The New Zealand Health Trust is not aware of any credible information/evidence that explains how the Bill could cause such spectacular export growth over a 10 year period.

The opposite is more likely to be the result as the Bill firstly, restricts the products that can be exported to only products containing permitted substances (that have also been notified) and secondly, imposes high compliance costs.

An exporter has to manufacture and comply with the overseas country’s rules. New Zealand’s rules are irrelevant.

Currently amongst importing nations, NZHT understand that New Zealand’s system of regulation of these products is regarded more favourably than Australia’s. Why would we want to jeopardise that reputation.

**4.13. The Bill perpetuates and exacerbates key problems with the current regime**

The principal disadvantages with the current regime (under the Dietary Supplements Regulations 1985) are:

* Supportable therapeutic claims cannot be made (unless a costly related-product approval is sought under the Medicines Act); and
* A number of ingredients, eg those listed in the Schedule of the Medicines Regulations (which is used as a means of banning often safe substance), cannot be used.

While the Bill permits the Authority to approve some claims this is expected to be limited and not wide enough to include all evidence based health claims. The prohibition on the use of Medicines Regulations ingredients is continued in the Bill. This will maintain the status quo regarding prohibiting many safe ingredients or levels of ingredients for no risk-based reason.

In other words, natural health products will continue to be regulated as poor cousins of pharmaceutical drugs.

**5. The solution is ….**

A regime that permits natural health products to use a full range of natural ingredients and make verifiable therapeutic claims. This will ensure true competition between pharmaceuticals, foods, and natural health products.

The key features of a fair natural health products regime are:

* Any ingredient can be used unless included on a blacklist. Ingredients proved to be unsafe would be banned rather than all ingredients being banned unless they are proven to be safe.
* Any verifiable therapeutic claim can be made unless included on a blacklist.
* Products must comply with current food manufacturing standards.
* Labels to include ingredients and appropriate warnings.

Any regime should also be regulated by the Ministry of Primary Industries and not Medsafe or the Ministry of Health. A pharmaceutical approach to these low-risk products is inappropriate and as noted above, the Ministry of Health is not a suitable regulator.

**6. Overview of the Ministry of Health consultation process**

In December 2015 the Ministry of Health issued a consultation document entitled The Regulation of Natural Health Products. The Ministry is consulting on various aspects of the regime that are to be dealt with by regulations including:

* The permitted substances list.
* The list of named conditions for which health benefit claims may be made.
* The evidence required to support health benefit claims.
* The details of the Code of Manufacturing Practice.
* Labelling requirements.
* Notification requirements
* Recognised authorities.

A link to the consultation documents is set out below:

<http://www.health.govt.nz/publication/regulation-natural-health-products-consultation>

The consultation document contains a list of 47 questions and a “consultation submission” can be filled out online.

Submissions are due by **5 pm on Friday 4th March 2016**.

A submission can be made by sending an email to: naturalhealthproducts@moh.govt.nz

Or by posting a submission to:

 Natural Health Products

 Ministry of Health

 P O Box 5013

 Wellington 6145

**7. Summary of the consultation questions**

A summary of the issues raised and the questions posed for feedback is set out below.

NZHT recommends that the questions should not be answered because the regime is fundamentally flawed and engaging in the detail implicitly validates this unsuitable regulatory model.

**7.1. Permitted substances**

The Ministry has proposed the following criteria to determine whether substances should be approved as permitted substances:

* The toxicity of the ingredient
* The risk of inadvertent overdose
* The risk of adverse effects from prolonged or inappropriate use
* The need for advice from a health practitioner
* Known side effects
* Whether any concerns can be managed by a condition of use.

The Ministry is seeking feedback on whether these criteria are appropriate and what other criteria might apply.

**7.2. Health benefit claims in relation to named conditions**

The Ministry has proposed the following criteria to assess whether a named condition can be the subject of a health benefit claim. Is the condition:

* Non-serious
* Self-limiting (will resolve itself over time without treatment)
* Suitable for self-management
* Suitable for self-diagnosis
* Likely to cause serious consequences without health practitioner consultation.

The Ministry is seeking feedback on whether those factors are the right ones.

**7.3. Evidence**

The Ministry is consulting on the evidence to support a health benefit claim, the sources of traditional evidence, the types of scientific evidence that might be acceptable and what the evidence on the website must include.

The Ministry is proposing that the evidence to support a health benefit claim must be relevant to the claim being made about the product and reasonably representative of the wider body of evidence and that the evidence must:

* Relate to the same method of administration, active ingredient, dose and formulation as the product
* Be relevant to the target population
* Directly measure the claimed health benefit
* Not conflict with a wider body of evidence

The Ministry is seeking feedback on whether these are the right criteria.

The Ministry is seeking feedback on the sources of traditional evidence (eg Te Ara: The Encyclopedia of New Zealand, pharmacopeia) and the minimum period of use for something to be considered to be traditionally used

The Ministry has identified that scientific evidence would require the following types of studies provided they are well-designed, appropriately sized and critically analysed:

* Systematic reviews
* Critically appraised topics
* Critically appraised individual articles
* Randomised controlled trials
* Cohort studies

The Ministry is seeking feedback as to whether these are the appropriate type of studies.

The Ministry has identified that a summary of scientific evidence must include:

* The claim made in respect of the product
* The source(s) of the evidence
* The objective and method of experiment
* Key findings and conclusions

A summary of traditional evidence must include:

* The claim made in respect of the product
* The source(s) of the evidence (such as approved pharmacopoeia)
* The traditional model that supports the claim

The Ministry is seeking feedback on whether the guidelines are clear.

**7.4. Code of Manufacturing Practice**

The Ministry has prepared a draft Code. The Code of Practice requires a manufacturing facility to have a fully documented and well-defined quality assurance system that incorporates the principles of good manufacturing practice and the concepts of quality control and quality risk management. The Code of Practice requires systems and procedures to be implemented to cover the following areas: personnel, premises and equipment, production, quality management and quality control, complaints and recall.

Feedback is sought from submitters as to whether they agree with the Code. Feedback is also sought on how frequently audits should be required and whether there should be exemptions from licensing.

**7.5. Fees**

The Ministry has identified the types of fees that will be charge and fee structure and is seeking feedback on whether the charges are appropriate. Proposed fees include:

* Product notification (annual fee) - $190 per product
* Application for new permitted substance or change to an existing condition - $700
* Application for new named condition - $2300
* Application for licence to manufacture - $667

**7.6. Labelling**

The Ministry is proposing that a label be clearly visible, written in English, have clear distinct and legible lettering and be durable and not readily damaged by normal handling.

The minimum information requirements for labelling include:

* The product name
* The intended purpose of the product (linked to the health benefit claim)
* The scientific name of **all** ingredients
* The quantity or proportion of all active ingredients
* Applicable warning statements
* Any restriction from the permitted ingredient list
* Batch number
* Storage conditions
* Expiry date

Feedback is sought on the requirements and also whether unique identifiers should be used.

**7.7. Notification**

The Ministry has identified the type of information that is to be provided by the product notifier and includes:

* Product name
* Health benefit claim
* Name and quantity of active ingredients
* Name and quantity of all other ingredients
* Dose form
* Dose presentation
* Name and contact of product notifier
* Name and address of all manufacturers
* Name and contact details of the contact person
* Link to the summary of evidence
* Manufacturing licence status
* Compliance with the Code of Practice

The Ministry is seeking feedback as to whether this the right information. Feedback is also sought on whether certain products should be exempt from notification.

**7.8. Recognised authorities**

The Ministry is proposing that all authorities recognised by Medsafe for the purposes of GMP auditing should be recognised authorities under the Bill.

Feedback is sought on other authorities that could be recognised and other purposes they could be recognised for.

**8. Make your own submission on the Govt website**

NZHT recommends that the questions should not be answered because the regime is fundamentally flawed and engaging in the detail is unhelpful and potentially legitimises the proposed scheme.

However, for those wanting to respond to each question, the template is found in the consultation document below. Individual submitters could explain how they personally are affected by the Bill.

<http://www.health.govt.nz/publication/regulation-natural-health-products-consultation>

**9. Or Email a pre-prepared submission**

**For those who have limited time to prepare a submission and wish to oppose the Bill in principle, click the below link for a short pre-prepared submission.**
<http://www.nzhealthtrust.co.nz/nhp_prepared_submission.html>

**SEND** submission to naturalhealthproducts@moh.govt.nz

**10. List of Substances**

**Below is a link to download the latest draft substances list as a XL Spread Sheet; you can enter any substance and check if it is on the pre-approved list as at 18th Dec 2015**

<http://www.nzhealthtrust.co.nz/pdf/nhp/Permitted_substances_list-as_at_18_Dec_2015.xls>

**11. Supplementary Order Paper**

The Ministry of Health’s proposed changes to the Bill are contained in a draft Supplementary Order Paper (SOP) dated 18 August 2015.  The SOP is presented as a revised bill.  [**Click here**](http://www.nzhealthtrust.co.nz/SOP.html)

If you require additional time to make a submission, you should request an extension of time from the Ministry.