

The Regulation of Natural Health Products

Consultation document

Citation: Ministry of Health. 2015. *The Regulation of Natural Health Products: Consultation document*. Wellington: Ministry of Health.

Published in November 2015
by the Ministry of Health
PO Box 5013, Wellington 6145, New Zealand

ISBN 978-0-947491-41-3 (online)
HP 6303

This document is available at health.govt.nz



MANATŪ HAUORA



This work is licensed under the Creative Commons Attribution 4.0 International licence. In essence, you are free to: share ie, copy and redistribute the material in any medium or format; adapt ie, remix, transform and build upon the material. You must give appropriate credit, provide a link to the licence and indicate if changes were made.

Contents

How to have your say	v
Introduction	1
Overview	1
How the regulatory scheme will work	2
Ingredients	4
Permitted substances	4
Proprietary ingredients	5
Health benefit claims	7
Named conditions	7
Evidence	9
Relevance and representativeness of evidence	9
Traditional evidence	9
Scientific evidence	11
Manufacturing	13
The Code of Manufacturing Practice	13
Site audits	13
Manufacturing exemptions	14
Fees	15
Types of fees	15
Annual product notification fees	16
Types of fees and fee structure	16
Labelling	19
Minimum information requirements for labelling	19
Unique identifiers	20
Over-labels	20
Labelling exemptions	21
Notification	22
Information required	22
Notification exemptions	23

Recognised authorities	24
Determining if your product is a permitted natural health product	25
Consultation submission	27
Consultation questions	28
List of Tables	
Table 1: Fee structure	16
Table 2: Volume assumptions for fees	17

How to have your say

The Government is developing a new regulatory scheme for low-risk natural health products, and is interested in public feedback on the proposals outlined in this document.

Your feedback is important because it will help shape the final proposals, ensuring they are workable and that the purpose of the legislation is achieved. We appreciate you taking the time to make a submission.

The Ministry welcomes all feedback. However, there are questions throughout this document, which may help you to prepare your submission. At the back of this document there is a submission form, which includes a list of all the questions.

You can make a submission by sending an email to:

naturalhealthproducts@moh.govt.nz

or by posting your submission to:

Natural Health Products
Ministry of Health
PO Box 5013
Wellington 6145.

All submissions are due by **5 pm on Friday 5 February 2016**.

Your submission may be requested under the Official Information Act 1982. If this happens, the Ministry will normally release your submission to the person who asks for it. If you consider there are good reasons to withhold it, please clearly indicate these in your submission.

Introduction

Overview

The Natural Health Products Bill is intended to come into force by July 2016. The legislation establishes a new regulatory scheme, separate from food and medicines regulation, to control low-risk natural health products (NHPs) such as garlic capsules.

Much of the detail of the regulatory scheme will be in regulations and notices, rather than in the primary legislation.

The purpose of this document is to seek your feedback on a number of areas to help inform the Natural Health Products Regulations and associated notices, guidelines and documents. In particular, the regulations and notices will specify the labelling requirements, the fees associated with manufacturing and selling permitted NHPs, and the type and quality of evidence used to support health benefit claims. The Regulations are expected to come into force shortly after the Bill.

The full regulatory scheme will be phased in over three years after the legislation comes into force.

The regulatory scheme is intended to ensure that the natural products that consumers use to support their health and wellbeing are safe, that the health claims made are true, and that the products contain what the label claims.

NHP regulation is intended to cover over-the-counter sales. Products made by a practitioner for a patient following a consultation are exempt from the regime – this includes rongoā Māori and traditional Chinese medicine, **as traditionally practised**. Products containing less than 20 parts per million of the active ingredient are exempt from the regime as are homeopathic products.

You can find a copy of the Bill, along with all other current New Zealand legislation, on the Government's legislation website (www.legislation.govt.nz).

Throughout this document the Natural Health Products Bill is referred to as the Bill and the Natural Health Products Authority is called the Authority.

How the regulatory scheme will work

Overall

Because NHPs are generally low risk, the Government has established a light-handed regime that will address the risks without imposing unreasonable costs on consumers or sellers of NHPs.

The regulatory system will be web-based. Before a product is sold it must be notified to the Authority via an online form. Products will be listed on a publicly accessible website so that everyone will be able to see what is on the market and what evidence supports the claims made. Unlike medicines, there will be no pre-market review of individual products. People will be able to notify the Authority of what they are putting on the market then get on with selling it.

As with any regulatory scheme, the NHP regime addresses risk. There are three main risks associated with NHPs.

1. The ingredients in the product could be unsafe.
2. Consumers may delay seeking conventional medical treatment.
3. Products could be manufactured in an unsafe way.

These risks are addressed in these ways.

1. Ingredients must be selected from a list of permitted substances.
2. Controls will be imposed on health claims and labelling.
3. Robust manufacturing standards will be set.

On the same site as this document you will find drafts of the:

- permitted substances list
- list of conditions for which health claims may be made
- Code of Manufacturing Practice
- Guidelines for Natural Health Products Evidence Requirements.

For consumers

Consumers of NHPs buy them to support their health and wellbeing. As well as for safety reasons, and to ensure products contain what the label says they do, we think the claims made for these products are very important. One aim of the legislation is to help consumers make choices about the products they buy. We are particularly interested in your views on how information about claims should be presented (see pages 7 and 8).

For manufacturers and sellers

New Zealand-based manufacturers will need to be licensed and to comply with a Code of Manufacturing Practice. We talk more about manufacturing standards on pages 13 and 14. The aim is for an appropriate level of risk management. This will allow some very small-scale manufacturing to be exempt from licensing. We seek your views on how such exemptions might be made.

Some products will be exempt from notification, such as those where the active ingredient is in a very low concentration and those made by a practitioner for an individual patient. Some exemptions are set out in clause 18 of the Bill. Clause 19 of the Bill allows the Authority to make other exemptions if notification would be impractical or unfeasible. We seek your views on how such exemptions could be managed (see pages 22 and 23 of this document).

All health claims made must be supported by evidence. We set out preliminary standards for evidence in this document. We are particularly interested in your views on how traditional evidence should be managed.

What happens next?

After the consultation period closes on 5 February 2016, the Ministry of Health will analyse the submissions with a view to finding the best way to limit risk to the public without imposing unnecessary restrictions, including costs on industry. The Ministry will provide the Minister of Health with a summary of the submissions, and our analysis, to decide on the outcome.

We intend to continue accepting submissions on the permitted substances list until May 2016. The Ministry will convene a panel of experts to consider the suitability of these substances. Not all submissions may be able to be considered before the Bill takes effect, but any submissions made before the cut-off date will still be considered, free of charge.

Your feedback on the Code of Manufacturing Practice will allow the Authority to finalise the Code by the time the Bill takes effect.

The Regulations will be available on www.legislation.govt.nz. On www.health.govt.nz you will be able to read:

- a summary of the submissions made in response to this consultation
- the finalised permitted substances list
- the list of named conditions about which a health benefit claim can be made
- the Code of Manufacturing Practice and Guidelines for Natural Health Products Evidence Requirements.

Ingredients

Permitted substances

Under the new regulatory scheme, NHPs sold over the counter may only contain permitted substances. The Authority must publish a list of permitted substances on its website. When deciding whether to add a substance, the Authority must take into account whether trusted regulators allow it, whether it is recognised as an ingredient in a traditional medicine system, and any other relevant information. We seek your views on what other relevant information might be.

The Ministry has prepared a draft list of permitted substances. It is a combination of the lists of substances allowed by Australian and Canadian regulators of similar products. The list also includes additional ingredients that were considered by a panel of experts to be suitable. Some substances approved by other regulators, such as datura or gamma-aminobutyric acid, have not been included, as they are controlled under other regulatory schemes in New Zealand.

We intend to continue accepting submissions on the permitted substances list until May 2016.

Adding substances to the permitted substances list

We expect substances to be added to the draft list before it is finalised, published and comes into effect. We are seeking your views on what those additional substances might be.

New substances can be added at any time after the draft list takes effect, but notifiers will need to apply for the substance to be added and pay a fee.

The Bill requires the Authority to establish a Natural Health Products Advisory Committee. The role of the Committee is to provide expert advice to the Authority on matters referred to it by the Authority, which will include advice on substances to be used in NHPs.

When determining whether substances should be added to the draft or finalised permitted substances list, we propose the Committee considers:

- the toxicity of the ingredient (in the quantities likely to be used)
- 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.

Names of permitted substances

Most, if not all, permitted substances have both scientific and common names. For example, lemon, which is included in the permitted substances list, is also known by the scientific name citrus limon. However, common names often don't make important distinctions. For example, comfrey may be common comfrey (*Symphytum officinale*) or Russian comfrey (*Symphytum x uplandicum*), which have different levels of alkaloids. To avoid confusion, and to make the notification process easier, the scientific name will be the unique name in our database. Notified sellers of NHPs will, however, be able to use common names on labels and in advertising.

A proprietary name is the protected brand name or trademark under which a manufacturer markets a substance. Consumers are unlikely to know what substance is indicated by the use of a proprietary name. Therefore, to avoid confusion and to make the notification process easier, we propose the permitted substances list will not include proprietary names.

Restrictions on permitted substances

The Bill allows the Authority to place conditions on the use of a substance. The draft permitted substances list includes restrictions on certain substances. Here are some examples of restrictions.

- The substance may be restricted to topical use only.
- The total amount allowed per pack may be limited.
- Warning statements may have to be added to the labels.

This is to ensure that the substances are of an acceptably low level of risk when used in NHPs.

Proprietary ingredients

Proprietary ingredients are a mixture of ingredients where the manufacturer wants to keep the exact details of the formula and/or the manufacturing process a secret from their competitors. The term proprietary ingredient could apply to an entire product, the blend of active ingredients, or the colours and flavours, for example.

Proprietary ingredients pose a number of challenges to the NHP regulatory scheme.

- Keeping the formulation details confidential while ensuring the proprietary ingredient contains only permitted ingredients may result in additional costs to the Authority (and therefore industry) while depriving consumers of the information required to decide if the product is safe, effective or otherwise suitable.
- The manufacturing process of permitted ingredients within an NHP poses a potential risk to consumers.

For these reasons, we propose that full formulation details of proprietary ingredients must be disclosed to both the Authority and consumers, and that their manufacture must meet the manufacturing requirements of the Bill. Proprietary ingredients must only contain permitted substances.

Consultation questions

1. Are there other criteria that the Committee should consider when adding a substance to the permitted substances list?
2. Of the criteria proposed, are there any that you think should not be considered by the Committee when adding a substance to the permitted substances list, and why?
3. Should the criteria to be considered by the Committee be weighted or ranked in some way?
4. Do you agree that full formulation details of proprietary ingredients should be disclosed? If not, what alternatives do you suggest?
5. Are there substances that could be added to or should be removed from the draft permitted substances list?

Health benefit claims

The term 'health benefit' is defined in clause 5 of the Bill. It means any one 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.

Any health benefit claim must be supported by evidence of a suitable standard. The requirements of the Fair Trading Act 1986 will continue to apply to health claims for NHPs.

Named conditions

A named condition is any disease, disorder, condition, ailment or defect that is listed or described in the most current version of the International Statistical Classification of Diseases and Related Health Problems (ICD), published by the World Health Organization. The current version is the 10th revision. The ICD is a tool to help medical practitioners, researchers, patient organisations and others to classify diseases and health problems. A copy of the ICD can be found at <http://apps.who.int/classifications/icd10>.

The Bill allows the Authority to decide whether health benefit claims can be made in relation to a named condition. Such claims are then known as allowable claims.

For example, hayfever (as 'seasonal rhinitis') is on the draft list of named conditions about which allowable claims can be made. This means that anyone is permitted to say that their product can relieve the symptoms of hayfever, as long as they can produce evidence to support that claim. Claims referring to hayfever are thus 'allowable claims' in the terms of the Bill.

The Ministry has prepared a draft list of conditions that may be used in allowable claims. This list can be found at www.health.govt.nz.

The draft list of conditions that may be used in allowable claims was compiled by selecting conditions from the ICD10 and considering whether they are:

- 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 list of factors is not a checklist, where anything that fails any of the tests can't be on the list, but rather a list of factors that must each be considered to ensure safety. For example, anaemia related to iron deficiency can be serious, it is not self-limiting, and it cannot be self-diagnosed, but is nonetheless on the draft list of conditions. That is because if caused by a lack of dietary iron, it can be easily treated (self-managed) by appropriate supplementation.

Health benefit claims cannot be made in respect of any disease, disorder, condition, ailment or defect that is not on the draft list of named conditions for which allowable claims can be made.

Consultation questions

6. Are the following factors the right ones to consider when deciding if claims may be made about named conditions:
 - non-serious
 - self-limiting
 - suitable for self-management
 - suitable for self-diagnosis
 - likely to cause serious consequences without health practitioner consultation?
7. Should other factors be considered?
8. Should the factors be weighted or ranked in some way?
9. Are there conditions you think should be added to or removed from the draft list of conditions about which health claims may be made?

Evidence

All health claims for NHPs must be supported by evidence. Product notifications will need to include a reference to a website with a summary of the evidence supporting the health claims for a product so that consumers can easily see the basis for the claims. This summary is described later in this section.

The Authority has prepared draft guidelines outlining the general requirements for scientific evidence to assist product notifiers to meet their obligations. A copy of the draft guidelines on evidence can be found at www.health.govt.nz.

Below is a brief outline of the guidelines.

Relevance and representativeness of evidence

In order to be useful, evidence must be relevant to the claim being made about the product and reasonably representative of the wider body of evidence. We propose that 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.

Consultation question

10. Are there other criteria that should be included, or should any of the listed criteria be excluded, and if so, why?

All health benefit claims must be backed by appropriate scientific or traditional evidence.

Traditional evidence

The Bill establishes that health claims may be made based on evidence of traditional use, which is referred to as 'traditional evidence'. These claims will take the form 'traditionally used for X', or words to that effect.

In order to be able to use traditional evidence, the extraction method or method of manufacture must be the same as described traditionally, as other methods may produce different effects from the release of different compounds.

Traditional evidence supports claims that a particular substance was used within the relevant tradition. For example, a claim might be that kawakawa was traditionally used by Māori to relieve upset stomachs. A product notifier would need to have evidence available to demonstrate that the claim is true. In this case, the claim has been taken from *Te Ara: The Encyclopedia of New Zealand*, published by the Ministry for Culture and Heritage, at www.teara.govt.nz/en/rongoa-medicinal-use-of-plants, so a link to that page might be sufficient.

There are several possible sources of traditional evidence. Schedule 2 of the Bill lists approved pharmacopoeia. A pharmacopoeia is a book, usually published under the jurisdiction of the government that contains a list of products and ingredients, their formulas, methods for making medicinal preparations, requirements and tests for their strength and purity, and other related information. In the context of the Bill, the term ‘approved pharmacopoeia’ is used to describe any pharmacopoeia, monograph, treatise, text or similar that the Authority has approved for use as such. The Bill establishes that the Authority must accept a reference to one of these as evidence of traditional use.

Other forms of evidence of traditional use may also be acceptable. For example, an individual recognised within a specific culture as having the authority to speak on such matters, may confirm that an ingredient or product has been traditionally used in the manner being claimed. Published studies detailing traditional use and treatises on traditional medicine could also be considered to be forms of evidence of traditional use.

We seek your views on what other sources of traditional evidence should be accepted.

Another aspect of traditional use is the ambiguity of the word ‘tradition’. It involves something happening over time, and between generations, but the actual time required varies. Our present thinking is that three generations or 75 years (25 years per generation) is sufficient to establish a tradition. This is in line with the Australian Therapeutic Goods Authority, but other regulators use different figures.

Consultation questions

11. Are these appropriate sources of traditional evidence and if not, why not?
12. Are there other sources of traditional evidence that should be accepted and why?
13. Do you think 75 years is an appropriate minimum period of use for something to be considered to be traditionally used? If not, what would be an appropriate minimum period and why?

Scientific evidence

The Bill establishes that health claims may be made based on scientific evidence.

Evidence must be directly linked to the active ingredient and should take into account different dose forms, and possible interactions with other active ingredients. **Evidence needs to show effectiveness in humans.**

A number of factors must be considered when determining what types of scientific studies might be acceptable. The minimum level of study that we currently consider to be acceptable:

- must be proportionate to the low risk posed by these products (as dictated through only allowing permitted substances and by the Code of Manufacturing Practice)
- should be sufficient for the NHP regime to command a respectable reputation, both domestically and internationally
- should not be beyond the reach of the average product notifier.

We are proposing that the following types of studies are acceptable forms of scientific evidence, provided they are well-designed, appropriately sized and critically analysed:

- systematic reviews
- critically appraised topics
- critically appraised individual articles
- randomised controlled trials
- cohort studies.

We appreciate that many product notifiers will not be familiar with this sort of approach. Further information can be found in the draft guidelines on evidence.

Consultation questions

14. Are there other factors we should consider when determining if a type of study is acceptable?
15. Are the types of studies that are acceptable clear?
16. Should other types of studies be considered acceptable? If so, which ones and why?

Summary of evidence

At the time of notification, notifiers will be expected to have a summary of evidence available on a website accessible to the public.

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 the 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 (such as traditional Chinese medicine).

Assistance on how to write a summary of evidence can also be found in the draft guidelines on evidence.

Consultation questions

17. Are the evidence guidelines clear?
18. Are there other evidence-related topics that should be included in these guidelines?

Manufacturing

Safe manufacturing is an important objective of the Bill. To achieve this objective, the Bill requires that the Authority must be satisfied that the product is manufactured in a facility that meets the requirements of the Code of Manufacturing Practice. 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 for sale. Any site performing any of these activities must do so in a way that meets the requirements of the Code.

Compliance with the Code will be monitored through regular site audits, either by the Authority or other recognised authorities (see page 25 for an explanation of recognised authorities). For imported products, the Authority would generally look for evidence that the facility is audited by a local trusted regulator.

The Code of Manufacturing Practice

The Bill provides that the Authority must issue a Code of Manufacturing Practice, to come into force no later than one year after the legislation. The Authority has prepared a draft Code, which is based on the internationally recognised principles of good manufacturing practice, revised to incorporate the Bill's principle of proportionality. In other words, the regulation of NHPs should be proportionate to the risks of their use. The draft Code details minimum standards for personnel, premises and equipment, production, quality control, and complaints and recalls.

In this consultation we seek your views on the proposed Code. A copy of the Code can be found at www.health.govt.nz.

The Bill provides that manufacturers have three years after the legislation takes effect to comply with the Code.

Consultation questions

19. Do you agree with the proposed Code of Manufacturing Practice? If not, why not?

Site audits

Auditing is important to assure safety, but auditing requirements should be proportionate to risk. Auditing will be necessary for some manufacturers as part of meeting the quality assurance requirements of the Code. The nature and extent of that auditing will depend entirely on the risk of the manufacture. The level and frequency of auditing should be the minimum necessary.

This level will vary between different manufacturers with different levels of risk. For example, a high-risk manufacturer might need a detailed site audit every two years, while a low-risk manufacturer might be audited only once every five years, or not need to be audited at all (though they would still be required to meet the standards).

The Bill allows the Authority to recognise audits from other authorities. For example, a manufacturer that passed an audit by Medsafe could be reasonably expected to meet the standards of the Code. We are aware that multiple audits are a significant issue for manufacturers and will minimise the requirement as much as is consistent with safety.

Manufacturing exemptions

Certain very small-scale and very low-risk manufacturers might be reasonably exempted from the scheme. For example, someone making 50 bottles of a lavender hand cream to be sold at a local farmers market is unlikely to pose a significant risk to public health.

Such an exemption could apply to manufacture below a certain number of units, or below a certain amount of revenue.

Consultation questions

20. How frequently should audits be required? Should this differ for different levels of risk?
21. Do you think there should be exemptions from manufacturing licensing? If so, on what grounds and within what thresholds?

Fees

The Bill provides for the costs of the Authority to be recovered from the industry through fees. The Bill further provides that these fees be specified in Notices published by the Authority.

The NHP regulatory environment and the Authority are being designed to keep costs as low as possible, in line with ensuring appropriate levels of safety and accuracy for low-risk products.

The bulk of costs are expected to be recovered via the product notification fee, which will cover the general cost of running the Authority. Fees for other services will be based on the estimated average cost incurred by the Authority in providing those services.

The fees are based on a conservative estimate of the number of notifications expected. We have assumed 10,000 products requiring notification. The notification fee is likely to vary depending on the number of notifications actually received.

The Bill requires the fees and fee structure to be reviewed no more than three years after the Bill comes into effect.

Types of fees

It is proposed that there will be charges for:

- product notifications (charged annually in advance)
- applications for new permitted substances
- applications for changes to conditions for existing permitted substances
- applications for new named conditions to be used in health benefit claims
- applications to restrict a health benefit claim to a product or class of products
- export certificates
- licences to manufacture
- appeals against decisions of the Authority.

Product notification will be via an easy-to-use online system. Detailed lists of permitted ingredients and conditions that claims can be linked to (with evidence) will be provided, minimising the need for notifiers to apply for consideration of ingredients and claims.

A manufacturing licence will be granted for up to five years. It is proposed that the fee be a one-off fee to cover processing and assessing the application. It is also proposed that manufacturers directly commission any third-party work that is needed to comply with their requirements under the Code. An example of this is audit for high-risk manufacturers.

Annual product notification fees

We propose that the product notification fee be an annual amount charged at the time of initial notification and annual renewal. There is little marginal cost to the Authority for processing a standard notification. The bulk of the cost, which is ongoing, is in providing and maintaining the notification system (both the online electronic system and its supporting non-electronic infrastructure).

For products already on the market when the Bill takes effect there will be a transition period of one year before they need to be notified. We propose there will be no notification fee for this period. We encourage notifiers not to leave it to the last minute to notify their product to avoid any technical issues caused by large numbers of people trying to access the database at the same time. Spreading initial notifications over that transition period also allows the Authority to provide more help to notifiers during the process.

After the initial 12-month transition period, it is proposed that the annual notification fee will cover the 12 months from the start of July to the end of June. This is more efficient administratively for the Authority than staggering notification periods and will help to keep costs down. Regardless of when a product is notified during any 12-month period, the full notification fee is payable.

Types of fees and fee structure

The types of fees and amounts proposed for these charges are shown in Table 1. These include recovering the relevant portion of establishment costs over five years.

Table 1: Fee structure

Fee	Amount (excl. GST)	Amount (incl. GST)	Activity
Product notification (per year)	\$170	\$195.50	Establishing and ongoing operation of the notification system
Application for a new permitted substance or change to an existing condition	\$700	\$805	Processing the application, assessing the substance's safety and preparing advice for the Advisory Committee
Application for a new named condition about which a claim can be made	\$2,000	\$2,300	Processing the application, preparing advice for the Advisory Committee and convening the Committee
Application for a new named condition where claims are restricted to a product or class of product	\$4,800	\$5,520	Processing the application, preparing advice for the Advisory Committee and convening the Committee
Export certificate (per application, per product, per country)	\$130	\$149.50	Processing the application and issuing certificate
Application for licence to manufacture (New Zealand-based manufacturers only – valid for five years)	\$580	\$667	Processing the application, assessing whether the manufacturer meets the requirements of the Code of Manufacturing Practice and the 'fit and proper' tests
Appeal against Authority decision (per appeal)	\$200	\$230	

These fee estimates are based on assumptions around the annual volume of work for each type as shown in Table 2.

Table 2: Volume assumptions for fees

Fee	Number (annually)
Product notifications	10,000
Applications for new permitted substances and changes to existing conditions	20
Applications for a new named condition about which a claim can be made	6
Applications to restrict a claim to a product or class of product	6
Export certificate	500
Applications for licence to manufacture	40
Appeals	6

Consultation questions

22. Are these the right things for the Authority to charge for? Are there other things for which the Authority should charge?
23. Are the charges structured appropriately?
24. Do you have any comment on the proposal that notification be for a July–June financial year, and/or the proposals to handle the transition period?
25. Do you have any comment on the level of the charges?
26. Do you have any comment on the assumptions around volumes each year? Would you expect higher volumes in the first year?
27. How many products do you anticipate notifying initially, and in the next two to three years?
28. Do you agree that manufacturers are best placed to commission any quality control activities, such as audit, that might be required by the Code of Manufacturing Practice?
29. Are there additional issues relating to fees and charges that you would like us to consider?

Very low-volume products

If only very low volumes of products are sold, notification charges and other regulatory costs might result in the loss of those products from the market. Examples of such situations include:

- large ranges of catalogue products, where each is sold in very small numbers
- unprofitable service products, where supply is maintained for small numbers of long-term consumers.

It may be beneficial to reduce fees or exempt notifiers from fees in such situations.

An exemption or reduction in fees for very low-volume products could be seen as a cross-subsidy from larger businesses, who would then bear an undue proportion of the scheme costs. The extent of this would depend on the design of the exemption or reduction, as fees will not be paid for products exiting the market.

Consultation questions

30. Do you see a case for reducing fees for very low-volume products?
31. How would you define very low-volume products?
32. Do you have suggestions for the design of any provisions, including:
 - limits on the number of products that any notifier can have fee exemptions for
 - administrative efficiency
 - any other issues that might be associated with low-volume products?

Labelling

The Bill allows labelling detail to be set in Regulations. Labels are an important way to support informed consumer choice. Appropriate labels allow consumers to get accurate and helpful information. Labels need to reflect what is in the product and provide enough information for consumers to weigh up the risks and benefits of using the product.

Labelling will also need to reflect and support the other parts of the scheme, including permitted ingredients and health benefit claims. The definition of 'label' in the Bill covers the label attached to the container (such as a bottle, tube or blister pack), the primary pack (such as a carton) and any printed information supplied with the container or inside the packaging.

Regulations will set out minimum information requirements. This will not prevent labels containing other information (as long as it is not misleading or contrary to other requirements of the scheme).

We are conscious of the fact that many products are sold in multiple countries, whose requirements differ. The labelling requirements are intended to minimise the need for relabelling products, although it can't be avoided entirely. For example, we do not intend to specify that ingredients must be listed in a particular order (such as by volume or alphabetically) as those requirements differ worldwide and pose no safety concern.

Product notifiers will have two years from when the Bill comes into effect to comply with labelling requirements in regulations.

We propose that regulations require that a label be:

- clearly visible
- written in English
- in lettering that is clear, distinct and legible
- durable and not readily damaged by normal handling.

Minimum information requirements for labelling

We propose the following minimum information requirements for the **outer packaging labels** (the part that consumers can see when the product is on the shelf) of NHPs:

- the product name
- intended purpose of the product (linked to the health benefit claim)
- the scientific names of **all** ingredients (common names can be used as well, but not instead of)
- the quantity or proportion of all active ingredients
- applicable warning statements – for example, the regulations may require a general warning on all products such as 'see a healthcare professional if symptoms persist', and specific warnings on certain products (for example, on products that contain an ingredient known to be commonly allergenic, such as bee products)

- any restriction from the permitted ingredients list (such as an upper limit of the amount that can safely be consumed over a period of time)
- batch number
- storage conditions, if relevant
- expiry date
- statement of the net weight, volume or number of capsules
- a description of the dose form (such as tablet) and presentation (such as oral)
- directions for use, including the dose and frequency of dose or the maximum daily dose (for an adult or child, as relevant).

We propose the following information must also be included somewhere on the labelling (so it could be on the outer packaging or on any information that accompanies the product when sold):

- the name and address of the manufacturer (if it is different from the product notifier)
- the name and address of the product notifier, including their website address
- if the product is imported, the name and address of the importer and/or product notifier.

We are aware that many notifiers may have concerns that these labelling requirements prevent notifiers from protecting what they consider to be trade secrets. We are currently of the opinion that, because products will not be pre-approved by the Authority, and in the interests of consumer safety and choice, this information must be made public. We welcome your thoughts on this proposal.

Unique identifiers

Unique identifiers will be created by the NHP database. In any database every entry has a unique key to ensure the system can never mistake one item for another. Requiring unique identifiers to be printed on labels could be useful for consumers to distinguish between products with a similar name or to indicate that a product has been notified to the Authority. We are interested in hearing your views on whether unique identifiers should be on labels.

Over-labels

Over-labels are labels that can be stuck over the top of an existing label (for example, on a product manufactured outside of New Zealand) to ensure the product complies with local labelling requirements. Over-labels are permitted for medicines, and we propose that they should be permitted for NHPs.

Labelling exemptions

Blister strips, sachets and any other presentation that is sold in an outer carton, bag or similar, do not need to meet the full labelling requirements, as long the outer packaging does.

Consultation questions

33. Do you agree that labels should meet the proposed presentation requirements? If not, why not?
34. Are the proposed minimum labelling requirements the right ones? If not, what should be included or excluded and why?
35. Should product labels include unique identifiers? If not, why not?
36. Is there any other information that should be included, or should any of the listed information be excluded, and if so, why?

Notification

Before being sold, products must be notified to the Authority. This will be done via a form on the Authority's website. The website will use the government log-on service RealMe. Product notifiers will need to obtain a RealMe ID to verify that they are legitimate entities for the purposes of product notification.

Information required

The Bill requires information relating to the name of the product, the product details, the product notifier, the manufacturer and any health benefit claims made for the product to be notified to the Authority. We interpret this to mean the following details:

- product name
- health benefit claim
- name and quantity of active ingredients
- name and quantity of all other ingredients
- dose form (such as tablet, cream, solution)
- dose presentation (for example, oral, topical)
- name and contact details of product notifier
- name and address of all manufacturers (including all sites that make up, prepare, produce or process the product, and package the product in a container for the purposes of sale)
- name and contact details of the contact person (for example, the company manager or a regulatory affairs consultant)
- name and address of importer(s), finished product testers, retailers(s)
- link to the summary of evidence
- manufacturing licence status (for example, granted by whom, when and expiry day, or licence not required and why)
- compliance with the Code of Manufacturing Practice (including audited by whom, when and expiry date, or audit not required and why).

The Bill requires that the Authority must publish a list of notified permitted NHPs. We are proposing that all of the notified information will be made publicly available to ensure that the public are able to make an informed decision about which product to use and why.

Consultation questions

37. Is there information that you think should be included in or excluded from the notification process and why?
38. What information that we are proposing be notified do you think should **not** be made publicly available and why?

Notification exemptions

Certain products are exempt from notification. If a product is made by a natural health practitioner, to be administered to an individual patient as the result of a consultation, then it does not need to be notified. Products that contain less than 20 parts per million of the active ingredient (homeopathic products) are also exempt.

Practitioner-made products

An NHP made by a practitioner, to be administered to an individual who has sought the practitioner's advice, is exempt from notification. These products are not limited to permitted ingredients, but cannot contain substances included in Schedule 1 of the Medicines Regulations 1984 (prescription or pharmacy medicines).

When a product is manufactured by a third party and supplied to a natural health practitioner for sale to an individual under their care, it is not necessarily exempt. If the product is in its final form, it is not exempt from notification. If it requires further compounding, mixing or otherwise altering, it is effectively an ingredient, rather than a product and not subject to notification requirements.

Other exemptions

The Bill allows the Authority to make other exemptions if warranted. The grounds on which the Authority may make exemptions are set out in clause 19 of the Bill. The Authority may only exempt products from notification if it would be impractical or unreasonable to require notification, bearing in mind that regulation must be proportionate. The Authority can only exempt a product if it is satisfied that the exemption does not pose a risk to public health.

There may be a case for exempting certain low-volume products. If someone is selling a very small number of low-risk products, then notification may be unnecessary. We are interested in your views on how this could be managed.

There are several ways that an exemption could be managed. The Ministry thinks it would be unreasonable to require people making low-volume products to apply for an exemption individually, so we seek your views on how we might make a general exemption. It might be done on volume of sales, or by revenue.

Consultation questions

39. Should products that sell in less than a certain quantity per year be exempt from notification? If so, what should this quantity be?
40. Should products for which the annual sales amount is less than a certain figure per year be exempt from notification? If so, what should this figure be?
41. Should exemptions on other grounds be considered? If so, what would these grounds be?
42. To be fair to all product notifiers, how should requests for exemptions be verified to ensure they actually qualify?

Recognised authorities

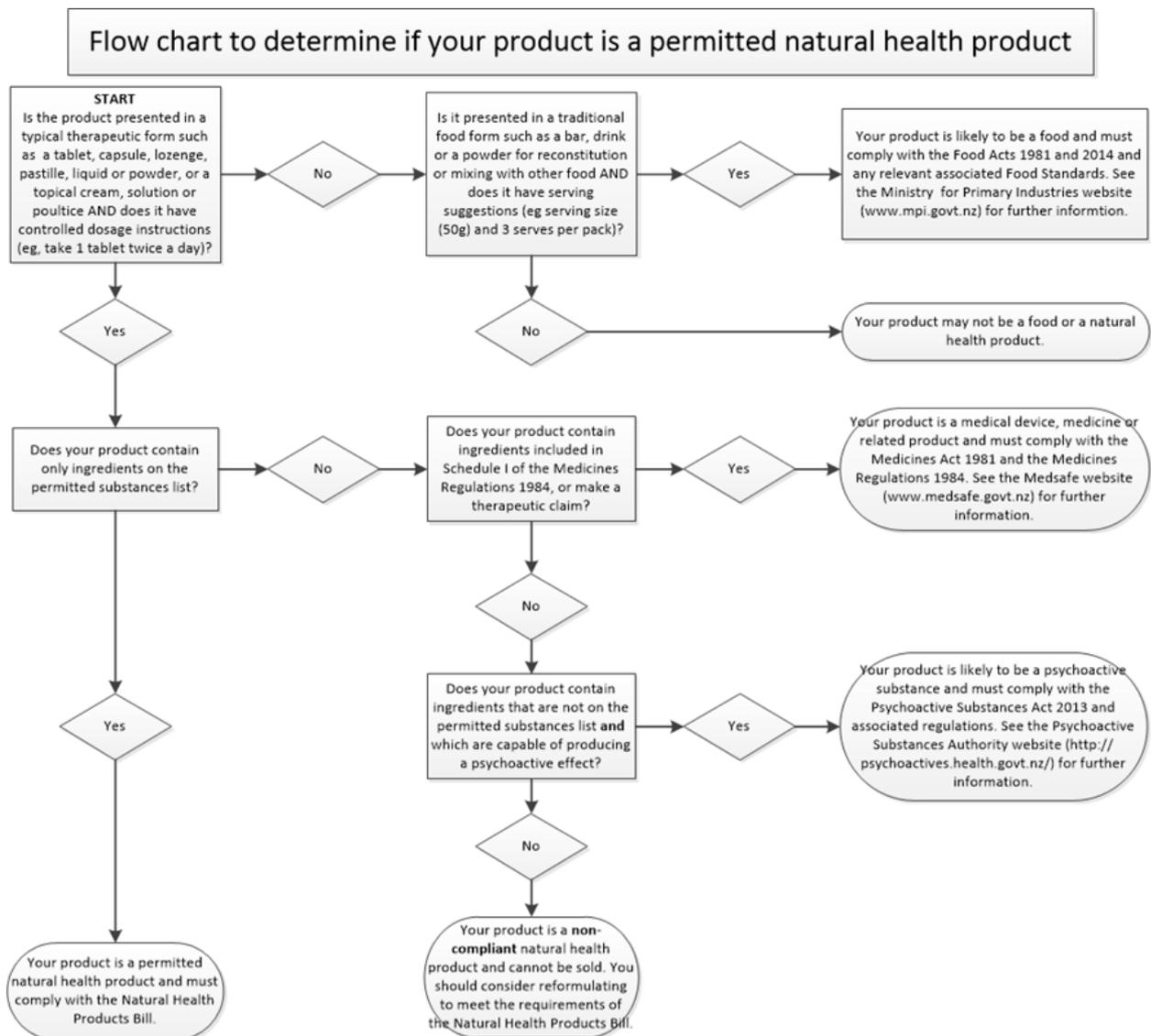
In keeping with the Government's commitment to minimising compliance costs for industry, the Bill allows the Authority to recognise other authorities for a specific purpose. Currently, we are proposing that these specific purposes be to conduct manufacturing audits. All products, whether they are manufactured domestically or overseas, must meet the requirements of the Code of Manufacturing Practice. Recognising local inspection bodies or regulatory authorities will minimise the costs associated with meeting these requirements.

Before it recognises another authority, the Authority must be satisfied that it assesses compliance against standards that are at least as robust as those observed under our legislation. As a starting point, we propose that Medsafe, and all authorities recognised by Medsafe for the purposes of GMP auditing should also be considered recognised authorities for the purposes of the Bill. You can find a list of authorities recognised by Medsafe in Part 4 of the GRTPNZ: Manufacture of Medicines (<http://www.medsafe.govt.nz/regulatory/current-guidelines.asp>).

Consultation questions

43. Are there any additional purposes for which you think the Authority should also consider recognising other authorities?
44. Are there any purposes for which you think the Authority should **not** consider recognising other authorities?
45. What other authorities do you think the Authority should recognise and for what purpose?

Determining if your product is a permitted natural health product



Consultation questions

46. Does the flow chart to determine if your product is a permitted natural health product make sense to you?
47. Are there other considerations that we should take into account?

Consultation submission

Details

Name and designation: _____

Company organisation name
and address: _____

Contact phone number and
email address: _____

Confidentiality

Please keep my comments confidential: *(reasons including identity of specific comments if applicable)* Yes

This request can only be actioned if your reasons satisfy Official Information Act criteria

Company organisation name and address: Yes

Contact phone number and email address: Yes

Additional information

I am, or I represent, an organisation that is based in:

New Zealand Australia Other *(please specify):*

I am, or I represent, a: *(tick all that apply)*

- | | | |
|--|--|---|
| <input type="checkbox"/> Overseas manufacturer | <input type="checkbox"/> NZ based manufacturer | <input type="checkbox"/> Importer |
| <input type="checkbox"/> Exporter | <input type="checkbox"/> Retailer | <input type="checkbox"/> Government |
| <input type="checkbox"/> Wholesaler | <input type="checkbox"/> Institution (e.g. university, hospital) | <input type="checkbox"/> Member of the public |
| <input type="checkbox"/> Natural Health Practitioner | <input type="checkbox"/> Product notifier | |

Please return this form to:

Email: [mailto: naturalhealthproducts@moh.govt.nz](mailto:naturalhealthproducts@moh.govt.nz)

or post to: Natural Health Products, Ministry of Health, PO Box 5013, Wellington 6145

Consultation questions

The Natural Health Products Advisory Committee will be seeking comments on:

Ingredients

- 1 Are there other criteria that the Committee should consider when adding a substance to the permitted substances list?

Yes

No

If yes, please describe these.

- 2 Of the criteria proposed, are there any that you think should not be considered by the Committee when adding a substance to the permitted substances list?

Yes

No

If yes, please outline your reasons.

- 3 Should the criteria to be considered by the Committee be weighted or ranked in some way?

Yes

No

Please outline your reasons below.

- 4 Do you agree that full formulation details of proprietary ingredients should be disclosed?

Yes

No

If not, what alternatives do you suggest?

5 Are there substances that could be added to or should be removed from the draft permitted substances list?

Yes

No

If yes, please detail below.

Health benefit claims

6 Are the following factors the right ones to consider when deciding if claims may be made about named conditions:

	Yes	No
• non-serious	<input type="checkbox"/>	<input type="checkbox"/>
• self-limiting	<input type="checkbox"/>	<input type="checkbox"/>
• suitable for self-management	<input type="checkbox"/>	<input type="checkbox"/>
• suitable for self-diagnosis	<input type="checkbox"/>	<input type="checkbox"/>
• likely to cause serious consequences without health practitioner consultation?	<input type="checkbox"/>	<input type="checkbox"/>

7 Should other factors be considered?

Yes

No

If yes, please detail below.

8 Should the factors be weighted or ranked in some way?

Yes

No

Please outline your reasons below.

9 Are there conditions you think should be added to or removed from the draft list of conditions about which health claims may be made?

Yes

No

If yes, please detail below.

Evidence

Relevance and representativeness of evidence

10 Are there other criteria that should be included, or should any of the listed criteria be excluded?

Yes

No

If yes, please detail below.

Included	Excluded	Reasons

Traditional evidence

11 Are these appropriate sources of traditional evidence?

Yes

No

If not, why not?

12 Are there other sources of traditional evidence that should be accepted?

Yes

No

If yes, please detail below.

13 Do you think 75 years is an appropriate minimum period of use for something to be considered to be traditionally used?

Yes

No

If not, what would be an appropriate minimum period and why?

Appropriate minimum period	Reasons

Scientific evidence

14 Are there other factors we should consider when determining if a type of study is acceptable?

Yes

No

If yes, please detail below.

--

15 Are the types of studies that are acceptable clear?

Yes

No

16 Should other types of studies be considered acceptable?

Yes

No

If yes, which ones and why?

Other acceptable types of studies	Reasons

Summary of evidence

17 Are the evidence guidelines clear?

Yes

No

18 Are there other evidence-related topics that should be included in these guidelines?

Yes

No

If yes, which ones and why?

Evidence-related topics	Reasons

Manufacturing

The Code of Manufacturing Practice

19 Do you agree with the proposed Code of Manufacturing Practice?

Yes

No

If not, why not?

--

Manufacturing exemptions

20 How frequently should audits be required?

Should this differ for different levels of risk?

Yes

No

Please outline your reasons below.

--

21 Do you think there should be exemptions from manufacturing licensing?

Yes

No

If yes, on what grounds and within what thresholds?

Grounds	Thresholds

Fees

22 Are these the right things for the Authority to charge for?

Yes

No

Are there other things for which the Authority should charge?

Yes

No

If yes, please outline below.

23 Are the charges structured appropriately?

Yes

No

If yes, please outline below.

24 Do you have any comment on the proposal that notification be for a July–June financial year, and/or the proposals to handle the transition period?

Yes

No

If yes, please outline below.

25 Do you have any comment on the level of the charges?

Yes

No

If yes, please outline below.

26 Do you have any comment on the assumptions around volumes each year?

Yes

No

If yes, please outline below.

Would you expect higher volumes in the first year?

Yes

No

If yes, please outline your reasons below.

27 How many products do you anticipate notifying initially, and in the next two to three years?

Initially	Next two to three years

28 Do you agree that manufacturers are best placed to commission any quality control activities, such as audit, that might be required by the Code of Manufacturing Practice?

Yes

No

If no, please give your reasons below.

29 Are there additional issues relating to fees and charges that you would like us to consider?

Yes

No

If yes, please outline below.

Very low-volume products

30 Do you see a case for reducing fees for very low-volume products?

Yes

No

31 How would you define very low-volume products?

32 Do you have any suggestions for the design of any provisions, including:

- limits on the number of products that any notifier can have fee exemptions for
- administrative efficiency
- any other issues that might be associated with low-volume products?

Yes

No

If yes, please outline below.

Labelling

33 Do you agree that labels should meet the proposed presentation requirements?

Yes

No

If not, why not?

34 Are the proposed minimum labelling requirements the right ones?

Yes

No

If not, what should be included or excluded and why?

35 Should product labels include unique identifiers?

Yes

No

If not, why not?

--

36 Is there any other information that should be included, or should any of the listed information be excluded?

Yes

No

If yes, please detail below.

Included	Excluded	Reasons

Notification

37 Is there information that you think should be included in, or excluded from the notification process?

Yes

No

If yes, please give reasons below.

Included	Excluded	Reasons

38 What information that we are proposing be notified do you think should **not** be made publicly available and why?

--

39 Should products that sell in less than a certain quantity per year be exempt from notification?

Yes

No

If yes, what should this quantity be?

40 Should products for which the annual sales amount is less than a certain figure per year be exempt from notification?

Yes

No

If yes, what should this figure be?

41 Should exemptions on other grounds be considered?

Yes

No

If yes, what would these grounds be?

42 To be fair to all product notifiers, how should requests for exemptions be verified to ensure they actually qualify?

Recognised authorities

43 Are there any additional purposes for which you think the Authority should also consider recognising other authorities?

Yes

No

If yes, please outline below.

44 Are there any purposes for which you think the Authority should **not** consider recognising other authorities?

Yes

No

If yes, please outline below.

45 What other authorities do you think the Authority should recognise and for what purpose?

Determining if your product is a permitted natural health product flowchart

46 Does the flow chart to determine if your product is a permitted natural health product make sense to you?

Yes

No

If no, please outline your reasons below.

47 Are there other considerations that we should take into account?

Yes

No

If yes, please outline below.