

## Natural Health Products Bill and Regulations fact versus fiction

There is a lot of misunderstanding and misinformation about the Natural Health Products Bill and the associated Regulations. The questions and answers below will help you to sort the fact from the fiction.

### GENERAL QUESTIONS ABOUT THE BILL

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#### Key facts:

- *Natural Products NZ supports the Bill because we believe it will benefit consumers, the natural products sector and the wider New Zealand economy*

Click on the questions below to find out the facts:

[What is the difference between the Natural Health Products Bill \(Act\) and the Regulations?](#)

[Why is the Bill necessary? Doesn't other legislation already cover the areas it seeks to regulate?](#)

[Isn't the Bill overkill given that there's low risk of someone being harmed by natural products?](#)

[Is the Bill bad for complementary and integrative medicine?](#)

[Isn't the Bill imposing out-dated restrictions on health care, self-care, and preventive health care?](#)

[What can companies or individuals do if they are not happy with the Bill's provisions once it is enacted \(i.e. becomes law\)?](#)

[Is the Bill restricting the public's right to information and choice?](#)

#### **What is the difference between the Natural Health Products Bill (Act) and the Regulations?**

Note that the Bill (Act) is akin to a framework or policy for a regime. It must be debated and passed in Parliament before it becomes an Act and the regime can begin. Regulations are different, these cover the finer details about how to comply with the Bill (Act). For example, the Natural Health Products Bill (Act) would specify that there must be labelling for products, while the Regulations would specify what must be (or must not be) on the label.

The Natural Health Products Bill will become the Natural Health Products Act once it has undergone its third (and final) reading in Parliament. Regulations usually follow close behind a Bill's enactment so that the Act's requirements are clear for all concerned.

At this stage the Ministry of Health is in 'information gathering mode' on the Regulations, which are by no means finalised. Further consultation is planned and there will be plenty of opportunities to fine-tune the Regulations even after the Bill passes into law.

### **Why is the Bill necessary? Doesn't other legislation already cover the areas it seeks to regulate?**

The Bill is timely due to consumers' growing demand for alternative options to maintain health and assist disease prevention. New Zealand therefore needs regulations that recognise consumers' right to information about natural health products and their functions, and the right to access products that are safe and effective.

The new regulations will do this by providing all parties with a higher level of assurance that the natural health and supplementary products available here are safe, effective and contain what is stated on the label.

Increased transparency means that consumers will also be able to find out more about the products they are buying and therefore become better informed about how best to use them.

The new regulations will make it far more difficult for questionable products to be marketed and sold here. It will also make it much easier for New Zealand's natural health products manufacturers to export to a number of countries that have similar regulations to those associated with the Natural Health Products Bill.

### **Isn't the Bill overkill given that there's low risk of someone being harmed by natural products?**

Product safety is only one part of the equation. The Bill will provide consumers with a greater level of certainty that product ingredients are effective and it will also enable natural health product providers to tell consumers far more about their products than is currently the case. This will help consumers make a more informed choice. Also the Bill will make it easier for New Zealand companies to export natural health products into a number of important markets.

Our members' strong support for the Bill shows just how much we believe it will benefit consumers, the industry and New Zealand's wider economy.

### **Is the Bill bad for complementary and integrative medicine?**

The Bill is very good for complementary and integrative medicine because it will enable natural health product makers to give consumers more information about how their products can help. The Bill's regulations will also provide consumers with peace of mind because they can be sure that the product in the bottle is what the label says it is.

### **Isn't the Bill imposing outdated restrictions on health care, self-care, and preventive health care?**

Just the opposite! It will bring New Zealand more into line with international standards and our major export markets, which have had legislation and regulations covering natural health products, for many years. It will also benefit New Zealand consumers because they can be given better information about how natural health products can help them. Additionally, it will provide peace-of-mind because consumers can be sure that the product in the bottle is what the label says it is.

## **What can companies or individuals do if they are not happy with the Bill's provisions once it is enacted (i.e. becomes law)?**

The regulations are not set in concrete and there will be plenty of opportunities to fine-tune them even after the Bill passes into law.

## **Is the Bill restricting the public's right to information and choice?**

In fact the Bill will enable natural health product makers to give consumers much more information about how the product can help. For example, the current laws prohibit natural health product makers of arthritis relief products from using the word "arthritis" on labels or in advertising unless that product is registered as a medicine.

As a result, it is very difficult to tell consumers exactly what the product is for – at best the labels and ads can refer to "joint support". The Bill is very likely to enable the word "arthritis" to be used and more information given about how the product helps.

## **HOW THE BILL WILL AFFECT THE TYPE AND PRICE OF NATURAL HEALTH PRODUCTS**

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### **Key facts:**

- *You will still be able to buy the vast majority of your favourite natural products*
- *Prices should stay about the same*
- *You can be given better information about how the product can help you*
- *You can be sure that the product in the bottle is what the label says it is*

Click on the questions below to find out the facts:

[Will I still be able to buy my favourite natural health products \(e.g. dietary supplements, skin care, herbal remedies, homeopathic remedies, etc.\)?](#)

[Will the Bill make the prices go up?](#)

[Will it affect natural skin care products?](#)

### **Will I still be able to buy my favourite natural health products (e.g. dietary supplements, skin care, herbal remedies, homeopathic remedies, etc.)?**

Yes, you will still be able to buy the vast majority of natural health products.

### **Will the Bill make the prices go up?**

NPNZ is working closely with the Ministry of Health to make sure the regulations are fair, workable, and affordable for small and large companies alike so we are confident that the compliance costs will be low enough to prevent any significant price increases.

### **Will it affect natural skin care products?**

The Bill may affect topical skin products that make a therapeutic claim, e.g. chest rubs for colds.

### **Key facts:**

- *You should still be able to buy natural health products from the same places that you can today.*
- *You will still be able to buy the vast majority of natural health products.*

Click on the questions below to find out the facts:

[Will I still be able to buy natural health products on the Internet \(from NZ or off-shore suppliers\)?](#)

[How will it affect direct-to-consumer distributors who are selling products that have been sourced off-shore?](#)

[Will natural health practitioners still be able to dispense their own preparations?](#)

### **Will I still be able to buy natural health products on the Internet (from NZ or off-shore suppliers)?**

The Bill won't apply to products purchased from off-shore suppliers but it will apply to New Zealand-based suppliers. Under the Bill you should still be able to buy the vast majority of your favourite natural products via overseas websites but we always recommend you purchase your products from informed reputable retailer.

### **How will it affect direct-to-consumer distributors who are selling products that have been sourced off-shore?**

It will affect them in the same way that it affects all New Zealand-based natural health product suppliers and manufacturers, thus creating a level playing field for all.

### **Will natural health practitioners still be able to dispense their own preparations?**

The Bill supports consumer choice by allowing health practitioners to prescribe, dispense and/or administer natural health products or formulations that they deem appropriate to clients in the context of a one-to-one consultation – even if those ingredients are not included in the Approved Ingredients List and provided they are not on the Medicines List. This is the same situation that we have currently.

This exemption is designed to allow practitioners to utilise ingredients that, like certain pharmaceutical products, may not be suitable for 'over the counter' consumer purchase but can safely be taken under close health practitioner guidance. This type of exemption has been successfully applied for many years in other countries.

**Key facts:**

- You will still be able to buy the vast majority of traditional, cultural and herbal medicine products.
- The Bill will not apply to common kitchen foods such as herbs and spices when they are used in food preparation or on a non-commercial context.

Click on the questions below to find out the facts:

[Will the Bill discriminate against traditional / cultural / herbal / Rongoā Māori / preparations and ingredients?](#)

[Will the Bill allow for anecdotal evidence \(e.g. with long-used traditional remedies\)?](#)

[Will companies have to fund expensive research to prove that the ingredient works?](#)

[Will use of common kitchen foods and folk remedies \(e.g. aloe vera, cardamom, betel nut, neem, mustard, almond, tamarind, etc.\) be restricted under the new regulations?](#)

**Will the Bill discriminate against traditional / cultural / herbal / Rongoā Māori / preparations and ingredients?**

The Ministry of Health is working closely with the natural products sector to make sure that the Bill supports traditional, cultural, ethnic and herbal practises. The aim is to ensure that the regulations are fair, workable and affordable for everyone.

**Will the Bill allow for anecdotal evidence (e.g. with long-used traditional remedies)?**

Companies will be required to hold evidence to demonstrate that they are able to make the relevant claim about the relevant condition for the ingredients in the product that they are notifying. Traditional evidence will be accepted if it fits into the guidelines.

Will companies have to fund expensive research to prove that the ingredient works?

Companies will not have to fund expensive scientific research unless they wish to, and in that case it is likely that they would turn to the Medicines Act.

The Bill will clarify how traditional evidence can be used.

**Will use of common kitchen foods and folk remedies (e.g. aloe vera, cardamom, betel nut, neem, mustard, almond, tamarind, etc.) be restricted under the new regulations?**

The Bill does not apply to ingredients when they are used for food preparation or in a non-commercial context. However, it does apply to these ingredients when they are prepared and sold for health purposes and that is described on the packaging. For example, it will not stop someone from buying ginger in a supermarket to make themselves a ginger tea for preventing nausea. However, if someone wants to sell their ginger tea preparation as an anti-nausea preparation then they will be bound by the Bill's (Act's) regulations.

## QUESTIONS ABOUT THE BILL'S EFFECT ON NATURAL HEALTH MANUFACTURERS, SUPPLIERS AND PRACTITIONERS

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### **Key facts:**

- *NPNZ is working closely with the Ministry of Health to make sure the regulations are fair, workable, and affordable for small and large companies alike*
- *The Bill will help, rather than hinder, natural products businesses.*

Click on the questions below to find out the facts:

[Will it put natural health practitioners / small companies out of business?](#)

[Are big pharmaceutical companies pushing for the Bill so as to try get rid of competition from natural health products companies?](#)

[Won't the Bill make it prohibitively expensive for businesses to gather the level of proof necessary for an ingredient to be added to the Permitted Ingredients List?](#)

[Will the Bill be amended to include safeguards and clauses that cover and define all of the legislation's substantive intentions?](#)

[Will the Bill restrict the application of scientific advancements in plant-based preventive healthcare?](#)

[Is it true that the Natural Health Products Bill will result in the rule of confusion rather than the rule of law because the overlapping definitions of a 'food', a 'health benefit' and a 'natural health product' will render the Bill's clauses to be contradictory?](#)

[Doesn't the Bill confuse foods, natural products, and medicines, and their effects?](#)

[Why does the Bill class synthetic chemicals under the term 'natural'? Won't this confuse people?](#)

### **Will it put natural health practitioners / small companies out of business?**

The Bill will ultimately help rather than hinder natural health practitioners and small natural health companies because it will create a level playing field for everyone. Natural health practitioners' and small companies' needs are very much being taken into account and Natural Products NZ is working closely with the Ministry of Health to make sure the Regulations are fair, workable and affordable for all.

Nobody wants to see small enterprises go under so a lot of effort is going into ensuring that compliance costs are kept low.

### **Are big pharmaceutical companies pushing for the Bill so as to try get rid of competition from natural health products companies?**

It's the natural products industry itself (rather than big pharmaceutical companies) that is pushing for the Bill. Most (around 80%) of NZ's natural product providers belong to Natural Products NZ.

Our members' strong support for the Bill shows just how much we believe it will benefit consumers, the industry and New Zealand's wider economy.

**Won't the Bill make it prohibitively expensive for businesses to gather the level of proof necessary for an ingredient to be added to the Permitted Ingredients List?**

NPNZ is working closely with the Ministry of Health to make sure the regulations are fair, workable, and affordable and this includes ensuring that there are reasonable and inexpensive processes and costs associated with adding new ingredients to the list.

At present there is no charge to apply for products to be included on this list (although a small fee will apply once the Bill is enacted and the regulations come into force). This presents a great opportunity for companies to get their current ingredients listed at no cost before the Bill passes into law.

The PSL (Permitted Substances List) is likely to be the largest of its type amongst OECD countries that have similar legislation to us.

**Will the Bill be amended to include safeguards and clauses that cover and define all of the legislation's substantive intentions?**

The Ministry of Health advises that it takes many different things into account when drafting Regulations, including ensuring that they are free of conflicting processes. The Ministry is also required to make sure that Regulations do not go further than the Act allows.

Note that even though it has undertaken extensive consultation with all parts of the natural health products sector, the Ministry is still in 'information gathering mode' on the Regulations, which are by no means finalised. Further consultation is planned and there will be plenty of opportunities to fine-tune the Regulations even after the Bill passes into law.

**Will the Bill restrict the application of scientific advancements in plant-based preventive healthcare?**

Not at all. In fact the Bill will make it easier for companies to tell consumers how new products (that contain permitted ingredients) can help them.

**Is it true that the Natural Health Products Bill will result in the rule of confusion rather than the rule of law because the overlapping definitions of a 'food', a 'health benefit' and a 'natural health product' will render the Bill's clauses to be contradictory?**

The Ministry of Health have worked closely with their colleagues who have written the recent Food regulations and we believe that there will be minimal conflict and that any conflict will be sorted out. The Ministry is also required to make sure that Regulations do not go further than the Act allows.

**Doesn't the Bill confuse foods, natural products, and medicines, and their effects?**

No. The Bill is about therapeutic natural products only, not food or medicine.

**Why does the Bill class synthetic chemicals under the term 'natural'?**

The Permitted Substances List will allow certain ingredients that are synthetically produced using a validated method and to exactly the same chemical compound make-up as found in nature (e.g. Ascorbic Acid, Vitamin C).

**Key facts:**

- *NPNZ is working closely with the Ministry of Health to make sure the regulations are fair, workable, and affordable for small and large companies alike*
- *The regulations are NOT set in concrete and there will be plenty of opportunities to fine-tune them even after the Bill passes into law*
- *The Bill will ultimately help rather than hinder natural products businesses*
- *The Bill will greatly benefit anyone who is exporting natural products*

Click on the questions below to find out the facts:

[Will the Bill allow Medsafe to increase its control over natural health products?](#)

[Most supplements have multiple ingredients so is it true that if any one ingredient in a product exceeds a specified dose, then won't the entire product will be outlawed in NZ?](#)

[What recourse do companies have if the regulators decide against adding their ingredient/s to the Permitted Substances List? Will companies end up having expensive legal battles to get their ingredients listed?](#)

[Will the Bill undermine companies' intellectual property rights?](#)

[How big is the Permitted Substances List and can it be added to?](#)

[Won't this just open the way for an Australian-style TGA system?](#)

[Isn't shifting the onus from proving harm \(i.e. a black list\), to providing benefit \(i.e. a white list\) simply forcing unnecessary compliance costs on the sector?](#)

[Won't the costs of making permitted claims be very expensive?](#)

[Won't the Bill make it harder to export products?](#)

[What is happening in relation to herbal extracts?](#)

[How much will it cost to comply with the Regulations?](#)

**Will the Bill allow Medsafe to increase its control over natural health products?**

No, there will be a separate entity within the Ministry of Health to run the natural health product regulations.

**Most supplements have multiple ingredients so is it true that if any one ingredient in a product exceeds a specified dose, then won't the entire product will be outlawed in NZ?**

All products sold in NZ will need to be notified and fit into the regulations. This applies to all companies and all products.

**What recourse do companies have if the regulators decide against adding their ingredient/s to the Permitted Substances List? Will companies end up having expensive legal battles to get their ingredients listed?**

If an ingredient is declined then companies will be able to re-apply to have their ingredient added. In most cases ingredients will be declined because more information is needed about their -safety, so the applicant will need to be able to provide this information.

**Will the Bill undermine companies' intellectual property rights?**

The Ministry of Health advises that it has noted the feedback concerning divulging intellectual property and is designing regulations that will not require any company to reveal their intellectual property or commercially-sensitive information.

**How big is the Permitted Substances List and can it be added to?**

At present the Permitted Substances List contains around 5500 ingredients and it is still being added to. Processes will be put in place to enable new ingredients to be added to the list, as well as allowing companies to resubmit ingredients that were not initially accepted.

**Won't this just open the way for an Australian-style TGA system?**

No, the NHP Bill is substantially different to the TGA system because it proposes a lighter regulatory approach, and is designed for low risk products. The TGA does have a route for low risk products, but it is still more stringent than our scheme.

**Isn't shifting the onus from proving harm (i.e. a black list), to providing benefit (i.e. a white list) simply forcing unnecessary compliance costs on the sector?**

Having a white list approach will benefit the industry and consumers because it goes beyond simply black listing questionable ingredients. The white list approach provides consumers with a greater level of certainty that the ingredient is actually safe. It will also reassure consumers that what is in the bottle is the same as what is stated on the label. Importantly, the white list approach (which incorporates permitted statements) will enable natural health product providers to tell consumers far more about their product than is currently the case.

**Won't the costs of making permitted claims be very expensive?**

There will be a list of permitted claims to be able to be made about that condition and those ingredients. The cost of making a permitted claim is very small in relation to the cost of developing, distributing and marketing products. Being able to tell consumers more about what their product does will make it much easier to effectively market a product.

A company will notify their product by listing the permitted ingredients and listing a condition for those ingredients. Most companies already hold the evidence to make those claims (especially those who sell in Canada and Australia). If a company wishes to have a new claim or condition added to the list then there will be a process for that.

### **Won't the Bill make it harder to export products?**

The Ministry of Health advises that a system will be put in place to allow ingredients in export products to either be included on the permitted substances list with an export only note, or to be considered in some way that allows exporters to continue current trade and grow trade in new products. The Ministry is designing this system and will be consulting on it again.

### **What is happening in relation to herbal extracts?**

The Ministry of Health has advised that it plans to address this matter in a way that works for notifiers and resolves the proprietary ingredients issues.

### **How much will it cost to comply with the Regulations?**

NPNZ is committed to ensuring that that all compliance costs are affordable for large and small companies alike. It is too soon to say what the Ministry of Health will end up charging for the following activities these fees are still under discussion and review:

- To notify a product (annual cost)
- To apply to have a new ingredient added after the date of 31 October 2016 (one-off cost)
- To apply to have a new named condition accepted about which a claim can be made (one-off cost)
- To apply for an Export Certificate (one-off cost)
- To apply for a new named condition with claims restricted to a product or class of product (one-off cost)