

Confidential



Updated Regulatory Assessment of the Natural Health Products Bill

Report to New Zealand Health Trust

**September
2015**

Acronyms and Abbreviations

ICD-10	International Statistical Classification of Diseases and Related Health Problems
MoH	Ministry of Health
NHPs	Natural health products
NZHT	New Zealand Health Trust
SOP	Supplementary Order Paper
the Bill	The Natural Health Products Bill

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1 Summary and Introduction

The purpose of the Natural Health Products Bill (“the Bill”) is to ensure that natural health products (NHPs) are safe, true to claim, and true to label. The Bill proposes an approvals regime that requires firms selling NHPs to notify their products, ingredients, and health benefit claims to the regulator. The regulator controls the NHP market by regulating the allowed ingredients and the allowed health benefit claims.

Castalia was engaged in 2014 by the New Zealand Health Trust (NZHT) to evaluate the original Bill. We found that the Bill was a heavy-handed response to any problems of non-compliance with the existing legislation, and the low risk posed by NHPs.

A Supplementary Order Paper (SOP), with proposed amendments to the Bill, is intended to be presented to Cabinet in September 2015. NZHT has again engaged Castalia to review whether the proposed changes move the Bill closer to, or further away from, best practice regulation, as described in Treasury’s guidance.¹

NZHT also wants to understand whether the amended Bill is an appropriate response to the ‘problem’ being targeted by the regulation, and if the amendments help avoid the costs of the original Bill (identified by Castalia’s first regulatory assessment).²

The original Bill’s key problems are that it is neither proportionate, nor growth-focused regulation

We find that the Bill, without the proposed amendments, falls short of two criteria for Best Practice Regulation:

- **Proportionate:** The Bill does not use a risk or cost-benefit framework and the regime’s benefits are outweighed by the costs. The regime’s benefits are small because NHPs have a low risk profile, and there is existing legislation (such as the Fair Trading Act) that ensures that NHPs are true to claim and true to label. In contrast, the costs of the regime (administrative and compliance costs, and reduced innovation and competition) are significant (with preliminary estimates of ongoing costs in the order of \$3-4 million).³
- **Growth-focused:** The Bill pursues other objectives such as safety and consumer protection (despite these objectives being covered by other legislation). This discourages other economic objectives of maximising competition and innovation and minimising compliance costs.

Other areas of concern include the Bill’s ability to meet the principles of certainty and predictability, flexibility, and durability required of best practice regulation.

The changes to the Bill are minor and do not resolve the broader concerns

The amendments to the Bill do not help make the Bill more proportionate or growth-focused. The changes instead adjust details that have a relatively small impact, and do not mitigate the negative impacts of the initial Bill.

Our regulatory assessment of the amended Bill finds that it:

¹ Treasury. “The Best Practice Regulation Model: Principles and Assessments.” July 2012.

² Castalia. “Natural Health and Supplementary Products Bill: Regulatory Assessment.” March 2014.

³ Ministry of Health. “Regulatory Impact Statement: The Development of a Natural Health Products Bill.” June 2011.

- Still falls short of the criteria for best practice regulation (particularly the objectives for proportionate and growth-focussed regulation)
- Still fails to clearly define the problem it seeks to rectify
- Is now further away from best practice regulation as a result of the amendments

While the changes are minor, they continue to steer the Bill further away from meeting Best Practice Regulation criteria. For instance, the changes either do not support, or further contradict the principle of proportionate regulation. This is evident in the amendments that narrow the definition of natural health products, reduce the products exempt from product notification, and changes to the advertising rules for NHPs.

There are alternatives to the Bill that would meet best practice regulation

We find that there are also possible alternatives to the Bill that are comparatively low cost, and meet the criteria for proportionate and growth-focussed regulation.

The simplest solution is to do nothing and ensure that the regimes in existence are implemented to achieve their purpose. This is effectively regulating the products as a form of food. This would be a 'light touch' in respect to the regulatory apparatus required and impact on the market.

Our approach to this regulatory assessment

We assess the Bill in two steps. Firstly, we reiterate the problems of the original Natural Health Products Bill using Treasury's Best Practice Regulation framework (Section 2). Section 3 then evaluates the changes in the SOP on whether they address the problems with the original Bill, and whether they have a significant and positive economic impact.

In Section 4 we consider the key issues that have been overlooked by the Natural Health Products Bill, and suggest alternative ways to solve them that would be proportionate to the problems identified in the natural health products industry.








2 What Were the Concerns with the Original Natural Health Products Bill?

The Natural Health Products Bill (as it stood in 2014) was a heavy handed response for the size of the problem identified, and imposed barriers to competition and innovation. The Bill proposes an approvals regime that requires firms selling NHPs to notify their products, ingredients, and health benefit claims to the regulator. The regulator controls the NHP market by regulating:





- **Ingredients:** The regulator creates a blacklist and a whitelist for ingredients. A new ingredient, that is not listed on either the blacklists or whitelists, must be reported to the regulator and receive written confirmation before progressing to product notification.
- **Health benefit claims:** Non-specific health claims must enter their claim on a database with a declaration of supportable evidence. Claims that refer to named conditions (any of the 14,500 conditions listed on the International Statistical Classification of Diseases and Related Health Problems (ICD-10)) are subject to an approval regime, where the regulator has a list of approved health benefit claims that producers can make.

The Bill failed against meeting multiple criteria for Best Practice Regulation, as defined by Treasury’s guidance. The only objective where we had no significant concerns was in transparency and accountability. Table 2.1 identifies which areas are of material concern, and the following sections describe the reasoning for these assessments.

Table 2.1: Evaluation of Natural Health Products Bill against Best Practice Regulation Criteria

Best Practice Regulation Principles						
Proportional	Growth-focused	Flexible	Durable	Certain and Predictable	Transparent and Accountable	Capable Regulators
						

Key

-  Strong indications of material concern
-  No significant concerns
-  Possible areas of material concern
-  Not known

Source: Criteria from Treasury, The Best Practice Regulation Model: Principles and Assessments, 2012

2.1 Proportionate and Growth Focussed Regulation are the Major Failings of the Bill

The areas of particular concern are where the Bill fails to meet the objectives for proportional and growth-focused regulation.

The Natural Health Products Bill is a heavy-handed response to a very small issue

Proportional regulation is where the “burden of rules and their enforcement [are] proportionate to the benefits that are expected to result”.⁴ This means that both the rules, and how they are enforced, are based on assessment of risk and on the assessment of costs and benefits. The Bill fails in meeting this objective because the costs imposed by the Bill will outweigh the benefits to consumers.

The reasons for the Bill’s shortcomings are largely a result of overstating the size of the problem to begin with, which in turn comes from not establishing an empirical basis for the problem definition (another aspect of proportionate regulation).⁵

The Ministry of Health (MoH) proposed that the current regulatory framework⁶ did not ensure that NHPs are safe, true to claim, and true to label. Currently, NHPs are prohibited from making therapeutic claims (treatment, diagnosis, and prevention of disease, or the modification of a physiological function).⁷ The exception to this is where NHPs have been approved as medicine. Firms wishing to sell medicine in New Zealand must submit an application to Medsafe, who then evaluates the evidence on the product’s claims, ingredients, and manufacturing process.⁸ However, this process is not commonly undertaken by NHPs.

The problems identified, however, are dealt with by existing legislation and practices, as Table 2.2 identifies. The remaining size of the problem left over is very small, and is largely a problem of non-compliance with the existing law, to the extent that it occurs.

Table 2.2: Existing Safeguards against the Concerns with the NHP Industry

Element of Problem Definition	Existing Safeguards	Evidence of the Effect of the Existing Regulatory Framework
Safety	<ul style="list-style-type: none"> ▪ Products must meet safety requirements under the Food Act 1981 ▪ Manufacturers must comply with the Food Hygiene Regulations 1974 	<ul style="list-style-type: none"> ▪ No coroner reports have linked deaths in NZ to NHPs ▪ Rate of adverse events is low⁹ ▪ Risk of deferring visits to medical professionals is equal to that of any other food, dietary supplement or lifestyle change

⁴ Treasury. “The Best Practice Regulation Model: Principles and Assessments.” p.9.

⁵ See footnote 4.

⁶ NHPs produced for oral consumption are regulated under the Dietary Supplements Regulations 1985, made under the Food Act 1981.

⁷ Clause 11, Part 1, Dietary Supplements Regulations 1985.

⁸ Medicines, Introductory Regulatory Guidance. Updated 19 June 2015. Available at <http://www.medsafe.govt.nz/regulatory/regguidance.asp#sell>.

⁹ Between 1992 and March 2009, only 344 reports of suspected adverse reactions from NHPs were made to the Centre for Adverse Reaction Monitoring. See Medsafe. “Complementary Medicine Corner: Reporting adverse reactions.” Prescriber Update, November 2009. Available at <http://www.medsafe.govt.nz/profs/PUArticles/PDF/Prescriber%20Update%20Nov%202009.pdf>.

True to claim	<ul style="list-style-type: none"> ▪ Fair Trading Act 2013 prohibits unsubstantiated claims ▪ Commerce Commission can prosecute firms for breaching these rules 	Companies making unsubstantiated claims about health and the nutritional content of their products have been prosecuted in the past ¹⁰
True to label	<p>Consumers are protected from false and misleading claims under the:</p> <ul style="list-style-type: none"> ▪ Fair Trading Act ▪ Consumer Guarantees Act ▪ Advertising code and guidance¹¹ 	Current rules have been used to penalise firms that have made misleading advertising claims about NHPs e.g. Zenith Corporation was fined \$792,000 for false claims about its Body Enhancer product

Because the problem definition (net of the impact of existing legislation) is small, the benefits of the regulatory regime are also marginal. These benefits are then easily outweighed by the costs of the proposed regime:

- **Administrative costs:** The NHP industry will meet the costs of establishing, and the operation of, the regulator (except regulatory policy advice and enforcement) which is expected to be \$3.75 million per year.¹² The final fee structure will be determined in the regulations, but there is a risk that some possible designs will disproportionately impact smaller operators.
- **Compliance costs:** The costs associated with meeting the regulatory requirements (outside of fees) include the time delay to notify or approve a product or ingredient, the systems and process change for producers, such as upgrading capital or relabelling products, management costs to understand new regulation, and labour costs in order to manage compliance issues.
- **Efficiency losses:** There will be less market transactions due to reduced competition and innovation, which lead to increased prices and less consumer choice. Barriers to market entry will affect smaller producers and those with wide product ranges. Existing suppliers will reduce product ranges and avoid future expansion. The regime discourages applications for new claims or ingredients (as one firm will bear the costs, while its competitors will benefit from having the claim or ingredient added to the approved list).

The regime also duplicates the roles of the existing legislation in Table 2.2, which is inefficient law-making, as well as confusing and costly for consumers and businesses.

The Bill fails to support the growth of an emerging industry, and instead risks reducing competition and innovation

Growth-focused regulation gives economic objectives (competition, innovation, exports, compliance costs, and trade and investment openness) appropriate weighting relative to other objectives (which, for NHP could be health, safety, and consumer protection).¹³

¹⁰ See <http://www.comcom.govt.nz/fair-trading/fair-trading-act-fact-sheets/health-and-nutrition-claims/>.

¹¹ See http://www.anza.co.nz/Section?Action=View&Section_id=33.

¹² Ministry of Health. "Regulatory Impact Statement: The Development of a Natural Health Products Bill." June 2011, p. 20.

¹³ Treasury. "The Best Practice Regulation Model: Principles and Assessments." pp.9-10.

The impacts of the Bill undermine the ability to achieve economic objectives in the NHP industry—namely, maximising competition and innovation and minimising compliance costs. The ‘other’ objectives are largely dealt with under existing legislation listed in Table 2.2.

The process of having a whitelist will limit the introduction of new products, which will limit innovation and lead to standardised products rather than a wide consumer range to answer to a wide range of consumer health and wellbeing issues.

The MoH has identified that regulatory costs will have the greatest impact on small to medium businesses, particularly those with wide product ranges.¹⁴ These new costs will force existing small operators from the market, and prevent the entry of small new players. These market changes reduce competition, consumer choice, and the downward pressure on prices.

2.2 Other Concerns with the Bill

The most concerning aspects of the Bill are that the regulatory regime is disproportionate to the problem, and it inhibits economic growth. However, there are also other concerns with the Bill that need to be addressed in order to meet best practice principles.

The Bill lacks flexibility to deal with minor concerns in a low cost manner

A flexible regime is one that is principles or performance-based, is designed to be administered flexibly, and uses non-regulatory measures, including self-regulation, whenever possible. Our previous report identified that the Bill did not meet this objective and a notification regime (only using a ‘blacklist’ ingredients list) would be a more appropriate and proportionate response to the identified problem. If evidence of a greater problem existed, then stricter regulation could be looked into. However, this kind of approach has not been adopted by MoH.

The imposition of a whitelist undermines the Bill’s durability

Durable regulation can evolve and respond to new information and changing circumstances. The Bill risks not meeting this objective through the whitelist for ingredients, particularly if there are cost barriers to amending the list.

Over time, the whitelist creates barriers to using ingredients that are discovered, or become fashionable as the industry evolves. In particular, maintaining a whitelist of approved health products imposes a time lag and a cost that will impact on the ability to get new products to consumers.

The regulation amounts to a ‘trust us’ approach to approvals. This creates the risk that the combination of broad regulator discretion and poor implementation could, over time, lead to a narrow list of approved ingredients that bears no reflection to what would be used without the whitelist, without an empirical basis for these restrictions.

The Bill does not support certainty and predictability in NHP industry

The regulatory system should be predictable to provide certainty to regulated entities and be consistent with other policies.

¹⁴ Ministry of Health. “Regulatory Impact Statement: The Development of a Natural Health Products Bill.” June 2011, p. 18.

The Bill replicates parts of other legislation, which is inefficient. The overlaps with food, advertising, and medicine create difficulties in drafting and defining exactly what the Bill is regulating and why. This will result in uncertainty for producers with products with products or ingredients from different regimes (food, NHPs, or medicine).

The fee structure to pass on the costs of the regime is also largely unknown. This undermines the predictability of the impact of the regime, creating uncertainty for smaller operations and their ability to enter or stay in the market.

The appointed regulator should be capable of a balanced approach to regulation

A capable regulator has the people and systems necessary to operate an efficient and effective regulatory regime. We are unable to judge whether the regulator of NHPs is capable because the Natural Health Products Regulatory Authority has yet to be established and choose the members of the advisory committee.

However, there is a risk that a regulator could issue rules with a conservative mind-set. Such a mind-set is suitable when applied to medicines by Medsafe under the Medicines Act, but is inappropriate for NHPs, given their low risk profile.

3 What Impact do the Changes in the SOP have?

Of the several amendments to the Bill proposed in the SOP, the key changes are:

- Altering the definition of a natural health product
- Removing the exemption from product notification for certain products
- Allowing the Minister to make the rules for claims on labels and in advertising.

To evaluate the impact of these changes, we examine whether each change addressed the concerns with the original Bill (in meeting best practice regulation principles). We also consider whether the change's economic impact will be significant or not, and positive or negative.

We find that the changes to the Bill are relatively minor and simply tinker with a regulatory regime that is largely not justified. The changes fail to improve on the problems identified with the Bill in Section 2, and in fact, steer the Bill further away from the principles of best practice regulation. The changes also fail to improve the Bill's ability to solve the initially identified problem.

Changes to the definition of a natural health product fail to provide certainty and predictability

The definition of a NHP has been changed in the current version so that a NHP is defined as one that “contains only natural health product ingredients”.¹⁵ The definition also prevents a NHP from containing a medicine on Schedule 1 of the Medicines Regulations 1984. Natural health ingredients are considered to be ones that are derived from nature, with minimal processing and no chemical transformation.¹⁶

This change was intended to prevent “non-compliant natural health products being automatically regulated as medicines or food”.¹⁷ However, those regimes might be more appropriate responses to the ‘risk’ posed by NHPs than the proposed NHP regulatory regime.

This change creates uncertainty as the interpretation of natural health product ingredients could cover multiple items, which would impose the regulatory regime on producers of a wide variety of products, not intended as NHPs. This contradicts the concept of proportionate regulation.

The prevention of medicines being in NHPs is particularly concerning as it restricts the ability for NHP producers to avoid the medical regime (of which the costs and barriers of entry and operation are disproportionate to the risks posed by NHPs). This fails to support growth by:

- **Duplicating administrative and compliance costs** for producers using medical and NHPs in one product, who will bear the costs of multiple regimes, despite no change in the products' risk profile
- **Reducing innovation and standardising product ranges** by producers with wide products ranges change their behaviour in order to avoid regulatory costs. This in turn will restrict consumer choice for NHPs.

¹⁵ Ministry of Health. “Table of Changes by SOP.” August 2015.

¹⁶ A list of such ingredients is provided in Schedule 1 in the Bill.

¹⁷ Ministry of Health. “Table of Changes by SOP.” August 2015.

Changes to exemptions from product notification contradict best practice principles, and have little impact

The previous version of the Bill allowed for NHPs that were intended for export-only, to be exempt from the process of product notification. This exemption would not apply if exporters were seeking an export certificate. NHPs where the active ingredient was in concentration of less than 20 parts per million were also exempt from product notification.

The current version of the Bill removes the exemption for export-only products, which has an impact on the costs faced by NHP producers who do not currently require an export certificate. However, this group is expected to be small. Therefore, while creating these barriers to exports contradicts the growth-focused objective of best practice regulation, the effect will be marginal.

The current version also requires more NHPs to notify their products by reducing the threshold for product notification. The threshold to be exempt from notification was for products with active ingredients of concentrations up to 20 parts per million, and the new Bill reduces this threshold to 10 parts per million. This change was made in order to match the Medicines Act.¹⁸ This change counteracts the concept of proportionate regulation, as a Bill designed to regulate NHPs should not be based off a regime designed for products that are potentially high risk.

Changes to the rules for claims on labels and advertising duplicates existing legislation

A new addition to the Bill allows changes to rules about claims, on labels and in advertising, to be made by the Minister. This change undermines the potential predictability and certainty of the regulatory regime by introducing a discretionary element to market rules which are typically operated by independent government agencies.¹⁹

Consumer protection legislation—specifically the revised Fair Trading Act—is sufficient protection for the risk posed by NHPs. There is no evidence for how an additional regulatory regime would deliver benefits to consumers over and above the existing legislation, and is therefore unnecessary, duplicative, and costly.

This change may impose some administrative costs (passing on the costs of a duplicative regime to NHP producers) and compliance costs (if the regulatory regime differs to existing legislation) on NHP producers, without delivering benefits that justify these costs.

The size of these costs will also depend on the use of Ministerial discretion. One possibility is that the change could undermine certainty by providing an opportunity for regulatory creep—where the Minister could narrow the claims advertised by NHPs or impose inappropriate compliance costs through labelling requirements.

¹⁸ Ministry of Health. “Table of Changes by SOP.” August 2015.

¹⁹ Treasury. “The Best Practice Regulation Model: Principles and Assessments.” p.9.

4 What are the Options to Solve the Original Problem?

The changes to the Bill fail to address its key weaknesses and the Bill remains a heavy handed response to a relatively insignificant, ill-defined problem. As it stands the Bill will impose compliance costs that will reduce competition and innovation, to the detriment of consumers.

However, there are potential alternatives to the current Bill that would avoid these negative outcomes.

Option 1: Do nothing and regulate natural health products as foods

In regards to claims of health benefits, it is difficult to distinguish NHPs from food products.²⁰ NHPs will often contain calories or provide other nutritional benefits while food products will often make claims about well-being, without necessarily providing nutritional benefit. At best, the distinction is obscure, at worst: no distinction at all.

Food regulations, including labelling requirements, already aim to ensure that products are true to label and safe for human consumption. This is further supported by consumer protection legislation such as the Fair Trading Act, which prevents substantiated claims being made by products. The Medicines Act regulates products that make therapeutic claims.²¹

Based on the intersection of these regulatory regimes, we think that NHPs must:

- Be fit for human consumption
- Be true to label
- Not make unsubstantiated claims without sanctions

In addition, high risk products or ingredients are subject to the Medicines Act.

It has not been conclusively shown that the combination of food, advertising, and Medicine regulations, cannot deal with claims made by NHPs. In this environment, there is little possibility that a significant market or regulatory failure could exist, or persist. Indeed, this is what we observe in the NHP industry: no evidence of safety risks from the consumption of NHPs.

A simple solution then is to do nothing and simply ensure that the regimes in existence are implemented to achieve their purpose. This is effectively regulating the products as a form of food. This would be a 'light touch' in respect to the regulatory apparatus required and impact on the market.

Option 2: Change the existing state of the Bill to introduce a risk-proportionate regime

This stage of the development of the Bill could be used to alter the regime so that it is proportionate to the problem it is trying to solve, and that it supports economic objectives. For instance, a notifications regime would be a low-cost alternative,

²⁰ The official guidance for determining whether a product is a supplemented food or dietary supplement (the classification for NHPs without therapeutic claims) is whether a product is presented in a therapeutic type dose form, such as tablets, capsules and controlled amounts of oral liquids or powders. See <http://www.medsafe.govt.nz/regulatory/categorisation-of-products.asp>.

²¹ Therapeutic claims include the treatment, diagnosis and prevention of disease, or the modification of a physiological function.

proportionate to the risk posed by NHPs, and enables the regulator to monitor this risk over time.

A notifications regime would require that NHP firms notify their products, ingredient, and their health benefit claims, and the regulator would develop a list of prohibited ingredients and health benefit claims. Notifications would include declarations of supportive evidence from traditional or approved sources. The regulator would be able to delay the marketing of the product by raising concerns with the product, conducting a safety assessment, or prevent the products sale by placing an included ingredient on the 'blacklist'.

This regime would ensure that known risks of products or ingredients are known before products are marketed. The risk-based criteria would have to be well-defined in order to avoid becoming increasingly conservative over time. This option would be low-cost for the industry while managing the risk posed by certain products, ingredients, or claims.

This option would allow for the regulator and interested parties (such as the Ministry of Health) to collect better data on the contents and use of NHPs. This would enable a future assessment of whether the level of regulation needs to be increased or decreased. A notifications regime would allow such a judgement to be based on an empirical judgement on the risks posed by NHPs.



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