

SUBMISSION

Therapeutic Products Bill

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HealthPost submission to Health Select Committee



www.healthpost.co.nz

info@healthpost.co.nz

HealthPost Limited, P O Box 9, Collingwood, Golden Bay 7054, New Zealand

NZ: 0800 148 148

AU: 1800 040 156

Executive Summary

HealthPost is Aotearoa New Zealand's largest online natural health retailer. We are strong proponents of Kiwis' right to access a broad range of safe, high-quality natural health products; contributing constructively and effectively to the development of these regulations is important to us.

HealthPost employs a team of 90 staff, making us the largest employer in our rural area. We stock over 6,000 products from more than 350 brands and have over 125,000 active customers in New Zealand. Hundreds of thousands of New Zealanders have shopped with us at least once.

We acknowledge the need to update regulations relating to natural health, as the *Dietary Supplements Act 1985* is outdated, however the new regulations need to be fit-for-purpose.

HealthPost opposes the *Therapeutic Products Bill* in its current form due to the likelihood that it would reduce consumer access to as wide a range of safe, high-quality natural health products as possible.

Our concerns are focused on the following priority matters, which we would encourage the Select Committee to investigate further:

- the establishment of a new Regulator within the Ministry of Health with minimal detail of the principles to be applied in regulating natural health products (NHPs), AND
- the Bill's silence regarding international harmonisation.

As such, HealthPost makes the following recommendations:

- **Recommendation 1:** That the regulatory functions as they relate to NHPs be separated from the responsibility of the Therapeutic Products Regulator, and a Natural Health Products Regulator takes sole charge for the regulatory functions relating to NHPs as outlined in this Bill.
- **Recommendation 2:** That that those NHP ingredients with a long history of safe use should be automatically recognised as approved NHP ingredients.
- **Recommendation 3:** That a black-listing approach to market authorisation and ingredient approval be adopted.
- **Recommendation 4:** That the proposed legislation should expressly make allowances for international harmonisation, particularly for automatic approval of NHP's already authorised by selected international regulators with equivalent or higher standards.
- **Recommendation 5:** That consumer interests remain at the heart of this Bill.

Introduction

1. HealthPost welcomes the opportunity to make a submission on the *Therapeutic Products Bill*, and we wish to appear before the Select Committee to speak to this submission.
2. While we support the intent of the Bill to update regulations relating to natural health products, we do not support the Bill in its current form.
3. The Bill proposes regulation that is not fit-for-purpose and may reduce the range of safe, high-quality natural health products available to consumers.
4. We recognise and support the need for a modern regulatory system for therapeutic products in Aotearoa, however we do not believe the Bill as it stands effectively responds to the needs of the natural health sector.
5. Modern regulations around natural health and natural health products (NHPs) must be fit-for-purpose, and relevant to the issue that the government is attempting to manage. In this circumstance, the Bill's intention is to improve consistency in product standards and to legally recognise the therapeutic value of natural health products, allowing for and regulating claims of benefit based on scientific evidence and traditional use. We support regulation that is risk proportionate and enables people to continue to access the natural products they know and trust.
6. However, we are concerned that the Bill in its current form could unnecessarily restrict consumer choice in NHPs. The 'catch all' approach to regulation appears to be founded on an assumption of harm caused by NHPs which hasn't been qualified.
7. HealthPost's concerns centre on two priority areas:
 - the establishment of a new Regulator within the Ministry of Health with minimal details of the principles to be applied in regulating NHPs, and
 - the Bill's silence regarding international harmonisation.
8. We encourage the Select Committee to investigate these areas in more depth.
9. The Select Committee will also be aware that a previous attempt to improve consistency in product standards regarding NHPs was made through the *Natural Health and Supplementary Products Bill 2011*.
10. 13 years on, despite our ongoing advocacy for improved quality assurances and standards for NHPs, we are disappointed that the inclusion of NHPs within this Bill appears to be a legislative shortcut to addressing a long-standing regulatory gap - without sufficient consideration of the real-world impacts it would have on both our sector and consumers.
11. A stand-alone Bill on NHPs would be preferable, as it would provide greater opportunity for the consumer voice to be considered and ensure that the regulation being placed on the sector does not unduly restrict access to NHPs.

12. However, HealthPost recognises that there is likely to be limited appetite across both the wider NHP sector and the Government to extend what has already been a long, protracted process.
13. Therefore, we ask the Select Committee to seek clarity from the Government as to why, after such a long time, the Bill fails to:
 - apply risk proportionate regulation
 - expressly outline the scope of powers to be held by the proposed regulator, and
 - speak to how our laws could align to other jurisdictions that have workable regulatory frameworks in place.
14. Our submission recognises the interests of our more than 125,000 active customers across Aotearoa, as well as the many New Zealand-based natural health brands and manufacturers with whom we work. It is also informed by our experience as a retailer of natural health products and consultation with our customers. It is supported by a significant amount of direct consumer feedback.

The role of the Regulator

HealthPost is concerned with the failure to expressly outline the scope of powers held by the new Therapeutic Products Regulator.

15. We are concerned with the sheer lack of detail and failure, so far in the process, to expressly outline the scope of powers regarding NHPs to be held by the proposed Regulator.
16. Currently the Bill states that the Therapeutic Products Regulator:
 - is appointed by the Chief Executive of the Ministry;
 - must be a public service employee;
 - is subject to any general policy directions given by the Minister that affect therapeutic products and are consistent with the purpose of the Act;
 - is accountable to the Chief Executive of the Ministry for the Regulator's performance of their functions and exercise of their powers.
17. We are not confident that the objective of the Regulator—which is “to foster and maintain an independent and effective system to regulate therapeutic products to achieve the purposes of this Act”—can be achieved if the Regulator is to be housed within the Ministry of Health, accountable to the Chief Executive, and required by law to act consistently with “directions given by the Minister”.
18. Effective regulatory systems contribute to positive social, economic and environmental outcomes. Without a robust regulatory framework that is grounded in best-practice, these systems will at best fail to adapt and respond to an ever-changing regulatory environment and, at worst, fail to perform their core duties, resulting in unnecessary harms, costs and loss of opportunity.

19. Many regulators in New Zealand are established outside the ministry or department responsible for policy creation, which helps ensure the purpose of the system is clear and provides assurance that the necessary capabilities are in place to deliver the intended outcomes. For example:
 - The Commerce Commission, responsible for competition, fair trading, consumer credit and economic regulation, is established through the *Commerce Act 1986*, and is an independent Crown entity.
 - The Financial Markets Authority, responsible for promoting and facilitating the development of fair, efficient, and transparent financial markets, is established through the *Financial Markets Authority Act 2011*, and is also an independent Crown entity.
 - Even the recently established Grocery Commissioner, responsible for providing general oversight of the grocery industry and ensuring compliance with the regulatory regime, is expected to be established within the Commerce Commission, with their functions, duties, and powers expressly provided for in legislation.
20. We submit that it is more appropriate for a Therapeutic Products Regulator to be established at arm's length from the Government and its agencies, as an independent Crown entity, in order to prevent undue influence and interference.
21. We are also concerned by the potential for regulatory overreach by the Regulator with respect to NHPs. There is next to no detail around:
 - what NHP ingredients will be permitted for use in New Zealand,
 - what claims of benefit can be made for NHP ingredients and products,
 - what process and principles will be applied to determine the above, and
 - what costs will be levied on the NHP industry.
22. If unnecessary discretionary power is ceded to the Regulator in its current form, we are concerned that the regime may take a restrictive approach to providing for the acceptable safety and quality of NHPs, meaning consumers will lose access to many NHPs that are of global acceptable quality, but may not meet the yet-to-be determined standards set by the Regulator.
23. We submit that the overarching priority of the new Regulator with regard to NHPs should be for the stakeholder perspective to be brought into its decision-making processes. Therefore, it is our view that for confidence in the system, the Regulatory functions as they relate to NHPs should be established outside the Ministry of Health, remaining at arms length of government policy.
24. The Bill also does not stipulate that the new Regulator must have appropriate expertise as it relates to NHPs, stating only that the appointing Chief Executive "must be satisfied

on reasonable grounds that the person has appropriate experience and expertise to perform the functions and exercise the powers of the Regulator”.

25. We are not confident that NHPs would be given due consideration within a regulatory system dominated by medicines and medical devices.
26. HealthPost considers well-established natural health professionals—such as naturopaths and medical herbalists—as being those with the appropriate experience and expertise to fulfil the legislative objective as required for NHPs.
27. Domain specific expertise is essential, and natural health professionals with recognised, degree-level qualifications in Naturopathy and Medical Herbalism would be best placed to draft, implement and enforce a statement of principles that guide how the Regulator will determine which ingredients are recognised and the legitimacy of health benefit claims.
28. Therefore, we recommend that the regulatory functions as they relate to NHPs be separated from the responsibility of the Therapeutic Products Regulator, and a Natural Health Products Regulator takes sole charge for the regulatory functions relating to NHPs as outlined in this Bill.
29. This approach would give greater certainty to our sector that regulatory oversight for low-risk, natural form products will be led from a consumer-first perspective, with priority placed on access to high-quality products, value for money and ensuring health benefit claims are legitimate.
30. We also remain concerned about the lack of detail in the Bill regarding the costs that will be levied on the NHP industry due to these changes - these are factors left to the new Regulator to implement as they see fit.

Recommendation 1: *That the regulatory functions as they relate to NHPs be separated from the responsibility of the Therapeutic Products Regulator, and a Natural Health Products Regulator takes sole charge for the regulatory functions relating to NHPs as outlined in this Bill.*

Risk-proportionate regulation

HealthPost is concerned that the proposed white-list approach in the approval of NHPs in line with medicines and medical devices, rather than the current blacklist approach is excessive.

31. With respect to NHPs, this Bill appears to be taking a sledgehammer to a walnut, with all the associated costs and complexity, both for industry and the Regulator. It is doing so to ‘solve’ a problem of assumed harm from NHPs that has never been quantified. Ministry of Health themselves acknowledge the lower risk factor associated with NHPs.
32. The definition of NHPs in this Bill is overly broad. NHP ingredients are defined as anything intended for a ‘therapeutic purpose’, in turn defining a therapeutic purpose as

anything used for 'supporting or sustaining human life'. With such a broad definition, it will be difficult to both effectively implement NHPs as part of a regulatory framework, and to create a clear scope of operation for manufacturers and retailers of NHPs.

33. For example, this broad definition of NHPs would, in practice, class many foods (such as seed and nut oils, simple dried herbs, berry and fruit powders) as NHPs. It is unclear how the regulation of NHPs as opposed to the regulation of food would effectively be put into practice.
34. The Bill also fails to take into consideration the long history of safe use of NHPs and the extensive research undertaken regarding many NHP ingredients.

Recommendation 2: *That those NHP ingredients with a long history of safe use should be automatically recognised as approved NHP ingredients.*

35. At present, a market authorisation is not required for low-risk NHPs, with a relatively simple regime in place for other NHPs. This is a sensible approach to take, given the low overall risk profile for NHPs.
36. We are concerned that the green-listing—or 'approved list'—approach proposed in this Bill is unnecessarily restrictive, by only permitting the use of those ingredients explicitly approved by the Regulator in NHPs.
37. There are thousands of ingredients that go into different NHPs across the globe, and the need to check that every item in a product line is approved creates an additional administrative burden on manufacturers and suppliers, and a huge and unnecessary workload for the Regulator to manage.
38. We instead recommend that a black-listing—or 'banned-list'—approach would be more appropriate and would significantly reduce the administrative burden on importers, manufacturers and retailers, as well as the regulator itself. Given the low overall risk profile of NHPs, the number of ingredients likely to be black-listed from use in New Zealand is low and would make compliance far simpler for all involved in the process.

Recommendation 3: *That a black-listing approach to market authorisation and ingredient approval be adopted.*

International harmonisation

HealthPost is concerned by the Bill's silence regarding international harmonisation.

39. The harmonisation of our legislation with that of other countries provides far more clarity for our sector. For example, if a product or ingredient is approved in those countries with stricter regulation, by automatically accepting these there would be far less need to reinvent the wheel - as this Bill appears to be doing.

40. We submit that the most appropriate course of action is to model our regulation of NHPs on those countries whose regimes are well-established and effective. Particular consideration should be given to those jurisdictions with whom we routinely compare ourselves, such as:
- Australia - which has a risk-based approach with a two-tiered system for the regulation of all medicines, including “complementary medicines” (complementary medicines being the Australian equivalent of NHPs), and
 - Canada - where NHPs must be safe to use and sold without a prescription. Products requiring a prescription are regulated under the Food and Drug Regulations.

Recommendation 4: *that the proposed legislation should expressly make allowances for international harmonisation, particularly for automatic approval of NHP's already authorised by selected international regulators with equivalent or higher standards.*

Putting consumers at the heart of natural health products

41. For the reasons outlined above, HealthPost submits that the passage of this Bill will make it more difficult for New Zealand-based consumers to access a wide range of high-quality NHPs at reasonable prices.
42. Kiwi consumers should have access to as wide of a range as possible of NHPs from local retailers. In buying locally, they will have all of the rights and protections afforded to them under both this Bill and relevant consumer law, including the *Fair Trading Act* and the *Consumer Guarantees Act* (with these protections not extended to consumers purchasing NHPs from overseas websites).
43. Our focus on consumer centred NHPs prioritises the needs and preferences of the people who use them. Our perspective reflects the 35 years of continuous consumer feedback on NHPs which has in turn informed the rigorous independent product standards regarding quality, efficacy, transparency and ethics on which our business is built.
44. By prioritising the consumer, NHP manufacturers and retailers can create products that not only improve the health and well-being of individuals, but also foster trust and loyalty among their customer base.
45. The previous, standalone *Natural Health and Supplementary Products Bill 2011* was far superior in this respect, as it provided both industry and consumers much more detail as to the likely impact of the bill, instead of taking a ‘just trust us’ approach.
46. HealthPost submits this Bill should expressly consider the way NHPs are used in people's lives and trust that appropriate choices will be made. To the best of our knowledge, there are comparatively far fewer reported adverse effects resulting from

NHPs compared to medicines - with the lower risk profile of NHPs acknowledged in the Bill, but not reflected in the regulatory approach.

47. There must be a common-sense middle ground between the necessary oversight of higher-risk pharmaceuticals and regulation of low-risk NHPs.
48. HealthPost have received well over 150 emails from our customers about the Therapeutic Products Bill to date. Without exception these have expressed concern or outright opposition to the Bill in its current form. While some of these individuals will have made their own submissions, we assume many will not.
49. We are confident that we speak alongside a great many of our customers in expressing our concern that consumer interests regarding NHPs are inadequately reflected and protected in the Bill as it stands.

Recommendation 5: *That consumer interests remain at the heart of this Bill.*

Conclusion

50. In summary, the Bill as it stands is not fit-for-purpose.
51. With regard to NHPs, the Bill takes an approach to regulation that is based on an assumption that these products are harmful without any evidence to prove those assumptions. It also does not sufficiently take into account the disparity in risk profile between low-risk, natural form NHPs and pharmaceutical ingredients.
52. The incorporation of NHPs into a regulatory scheme that is designed for medicines and medical devices is fundamentally disproportionate to the problems which the Bill seeks to address.
53. We have an opportunity to adopt world-leading regulation of NHPs which acknowledges the important role they play in supporting health and nourishment, empowering people to make positive choices about their own wellbeing. This Bill fails to do so.

About HealthPost

HealthPost is Aotearoa New Zealand's largest and longest-established independent (non-pharmacy or grocery) online retailer of natural health products. We are a family-owned company, established in Golden Bay in 1988 to improve Kiwi's access to quality NHPs by offering nationwide delivery. Initially operating a mail-order catalogue model, we began selling online and delivering worldwide in 2002, which continues to this day.

Since our inception, we have sold many millions of individual units of NHPs across several million individual customer orders. The majority of products we sell are New Zealand made from a wide range of Kiwi brands, both large and small. Some of our products are imported in their fully-finished and labelled form – primarily from Australia and the USA.

We also operate our own-label brand of NHPs called 'BioBalance'. This range contains approximately 30 products made to our specifications by GMP accredited, New Zealand contract manufacturers, and another half dozen which are imported as finished products from the USA, labelled to our specifications.

Our founding and ongoing purpose is to help our customers live naturally healthy lives. Our mission is to make a lasting, positive impact on the wellbeing of people and our planet. We consider ourselves to be a highly responsible retailer, and 'NZ's leaders in ethical natural health retail', delivered through:

- strict ingredient and supplier standards, which we continuously review
- charitable gifting and the 'HealthPost Nature Trust' (over \$1.5M donated to date)
- B Corp, Zero Carbon & Living Wage Certification
- Natural Health Products NZ industry body membership
- strong attention to regulatory affairs, with very few compliance events ever raised, and
- on-staff natural health professionals, record kept of any customer reported adverse events.

More information can be found at www.healthpost.co.nz/about-us.

