



NZ Health Trust

Protecting your Future

NZ Health Trust and New Health NZ Submissions on the Natural Health Products Bill 24 February 2012

Introduction and summary

1. New Zealand Health Trust (NZHT) is a charitable trust focused on health education and New Health (NH) is an incorporated society representing the interests of the New Zealand health consumer. Neither entity has any commercial interest in the subject matter of the Natural Health Products Bill (the Bill).
2. In the lead-up to the drafting of this Bill, and following the Health Committee Select Committee report of December 2003,¹ NZHT engaged in a lengthy process of consultation with the natural and traditional health products industry in order to co-ordinate a joint industry position as to how the industry should be regulated. NZHT estimates that during this process (which involved many meetings and work-shops attended by large number of industry representatives) it has engaged with around 95% of the natural and traditional health products industry. The result of this was the Joint Industry Proposal (the JIP) which was finalised in February 2009 (attached to the submission as Appendix 1).
3. Our submissions reflect the work of NZHT in reviewing the Bill for consistency with the JIP. The views expressed in this submission are those of NZHT and NH formed through the lens of the JIP (albeit without the benefit of further input from industry participants). We expect that various parties who participated in the JIP process will make their own submissions and that they may vary in some respects from the JIP and these submissions.
4. This summary provides an overview of our key concerns about the Bill cross-referenced to our substantive submission. The substantive submission is provided in a table form attached to this summary and sets a detailed clause by clause analysis of the Bill and suggested amendments.

¹ Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products;
http://www.parliament.nz/NR/rdonlyres/BC850BE7-8DD3-41B7-8CDC-47438279AF8F/14174/DBSCH_SCR_2633_2394.pdf

Workability

5. In general we support the Bill but have significant concerns about its processes and workability.² The Bill appears rushed and incomplete. It is significantly lacking processes that reflect the principles of natural justice to enable industry to engage with the regulator and/or many of the regulatory powers are too wide.³
6. In that sense the proposed regime is far from the Government's recent commitment to improving the quality of regulation. In August 2009 the Government stated that improvement of the quality of regulation was a priority and made the following commitment: "We will introduce new regulation only when we are satisfied that it is required, reasonable, and robust."

Purpose & principles

7. The workability problems are exacerbated by the inadequacy of the purpose and principles clauses.⁴ The purpose clause does no more than state the obvious (to establish a system for regulation of natural health products ...) The principles do not accurately reflect the object of the Act as stated in the RIS.
8. The purpose and principles must acknowledge that any regulation is risk-proportionate. That risk must be assessed against a background of a long history of safe use of natural and traditional health products in New Zealand (we prefer this term to "natural health product"). The principles should acknowledge that the consumption of natural and traditional health products is voluntary and in the small number of cases where such products cause an adverse reaction, it is usually reversible (ie it goes away when the product is no longer taken).
9. We support the principle that consumers should receive accurate and "true to label" information.

² There are many "workability" issues in the Bill but see in particular: clause 5 (definition of "food") page 2, (definition of "health benefit") page 3, (definition of "serious condition") page 5, (definition of "sponsor") page 3; clause 6 (definition of "natural health product") page 7; clause 12 (sponsor must be resident in New Zealand), p 11; clause 13 (product notification of natural health products required before distribution), p 12; clause 25 (export certificate), p 23; clause 35 (Authority may prescribe fees), p29.

³ See discussion in the submissions on the following clauses – clause 9 (Authority may declare recognised authorities), p 10; clause 16 (Authority may suspend or cancel product notification), p 15; clause 20(3)(a) (Authorities power to conduct a safety assessment), p 18; clause 21 (prohibited ingredients), p 19; clause 22 (new ingredients), p 19; clause 23 (safety assessment of new ingredient), p 21; clause 31 (Audits of manufacturing facilities), p 25; clause 34 (Authority may revoke or suspend licence), p 26; clause 41 (Appeals committee), p 31; clause 42 (Appeals), p 32; clause 45 (Delegation), p 33; Clause 47 (Regulations), p 34;

⁴ See detailed discussion on clauses 3 and 4 (Purpose and Principles), page 1.

Natural health products (NHPs)

10. The definition of an NHP is unworkable.⁵ It makes no accommodation for other ingredients currently used in NHPs such as excipients (used to bind and stabilise products) and traditional ingredients. The limits to the methods of administration are unnecessarily limited (for example, ear drops are excluded).
11. The bright-line drawn between a natural health product and a food means that many existing reliable natural health products will be excluded from being able to be provided by the natural health industry. There is no good reason why a product could not be both a NHP and a food (under the Food Act). Similarly, there is no good reason for a bright-line to be drawn between natural health products and prescription and pharmacy only medicines which will mean that many products (for example various plant extracts) cannot be used as natural health products.
12. The processes to determine the safety of NHPs will deal with any unsafe food or medicine and obviates the need for any such exclusions. The requirement for evidence to support claims of a health benefit will protect consumers from untrue claims.

Natural health product ingredients

13. Because of the history of safe use, natural and traditional health product ingredients currently on the market should automatically qualify as natural and traditional health product ingredients but the Bill does not provide for this.⁶
14. The transitional provision provides for grandfathering of natural health products but we don't think this goes far enough (it only includes products and not ingredients)⁷ - there should be a process to automatically include on the database (via clause 20(3)) ingredients that are already available on the market in New Zealand or are specified in sources such as various Pharmacopoeia and similar lists as well as ingredients that meet the description set out in the transitional provisions in clause 46(1).⁸
15. We support the policy of having a prohibited list of ingredients but there should be a requirement for consideration to be given to risk management options (eg labelling or use restrictions) before prohibiting an ingredient.⁹ There is no mechanism in the Bill to remove an ingredient from the prohibited list should new evidence of safe use become available. We suggest a prohibited ingredient should be able to be notified as a "new

⁵ See clause 6 (Definition of a natural health product), p 7

⁶ See discussion on clause 20 (Authority may declare substances to be natural health product ingredients), p 18

⁷ See discussion on clause 46, p 36

⁸ See discussion on clause 20(3), p18 proposed schedule 3, p42, clause 46, p36

⁹ See discussion on clause 21, p 20

ingredient” and the prohibition reviewed via the process we suggest is included in clause 22.¹⁰

16. The process for adding a new ingredient is unclear in some respects (for example, it is unclear how a person who intends to product an NHP for export would get a product on the list given the provision is limited to products intended for distribution in New Zealand).¹¹ The requirement to notify a new ingredient 90 working days before notifying a product is too long. It should be possible to conduct any necessary safety assessment within 30 working days. The process for conducting a safety assessment currently does not require the Authority to consider any evidence provided about the ingredient by the notifier but should.¹²

Health benefit and health benefit claim

17. The “health benefit” definition is a crucial consideration in determining whether a product is a NHP. The definition is flawed. It does not cover all the characteristics of a natural and traditional health product. Such products do more than maintain and promote health – they can prevent illness (for example, vitamin C will prevent scurvy) and actively assist in treating conditions, restoring health or wellness and preventing illness (for example, iron tablets may restore the health of an iron-deficient person).¹³ The definition should be amended to include “the prevention of illness” and “the restoration, maintenance, or promotion of health or wellness”.
18. Also, the definition includes “relief of symptoms of any condition that is not a serious condition”. We can see no policy reason for excluding products that relieve symptoms of a serious condition and note that it will be difficult to draw the line between “condition” and “serious condition”. For example, arnica is commonly used as temporary pain relief from the symptoms of arthritis – which could be considered a “serious” condition.¹⁴ We suggest that “serious” be deleted from the definition and note that any concerns about the accuracy of claims will be dealt with by the requirement to back-up any claims with evidence to support those claims.

Product notification

19. The product notification process is far from clear. The definition of “sponsor” doesn’t work because as drafted it could mean that a number of people in the chain from production to sale of an NHP are obliged to notify a particular NHP.¹⁵ The extent of the

¹⁰ See discussion on clause 22, p 20

¹¹ See discussion on clause 22, p 21

¹² See discussion on clause 23, p 22

¹³ See discussion on clause 5 “health benefit” definition, p 3

¹⁴ See discussion on clause 5 “health benefit” definition, p 4

¹⁵ See discussion on “sponsor”, p 7; clause 12, p11

obligations to notify are also not clear - for example is it intended that a product that has been notified would need to be notified again if an identical product is being imported by someone else? Also, the principles as currently drafted imply a positive obligation to provide information about the risks and benefits of a product when we understood the intention was to simply ensure that health benefit information provided about a product (voluntarily) is accurate.¹⁶

20. We suggest an opt-in approach where a registered “product notifier” notifies the natural health product and therefore takes responsibility for the notification obligations.¹⁷
21. As drafted it is unclear whether the notification process requires a health benefit claim to be made. It should be made clear that there is no requirement to make a claim.¹⁸
22. In addition, more clarity is needed around the types of evidence required to support a health benefit claim. A further provision should be added providing guidance as to the types of evidence that would be appropriate in relation to different types of claims. We suggest that the level of evidence required must be proportionate to the health benefits claimed. There should also be a list of accepted claims (eg. For example folic acid taken during pregnancy will prevent neural tube defects) which could be sourced from our proposed Schedule 3 (listing various internationally recognised Pharmacopoeia/Standards).¹⁹

Suspension/cancellation of a product notification

23. The powers of suspension/cancellation are too broad and the Bill does not provide for any sort of process for the industry to have a say about whether a product notification should be suspended or ultimately cancelled. Suspension/cancellation of a product notification has the potential to have a significant impact on a natural health business. For a small to medium sized business it may sound the death knell.
24. The suspension/cancellation process should only commence in cases where the Authority has reasonable grounds to believe a product is causing or likely to cause “serious” harm and there must be a process incorporating natural justice requirements so that the product notifier is given an opportunity to be heard before any decision is made.²⁰

¹⁶ See discussion on principles, p 1

¹⁷ See discussion on clause 12, p 11

¹⁸ See discussion on clause 13(3), p 13

¹⁹ See discussion on clause 13(3), p 13

²⁰ See discussion on clause 16, p 16

Recall

25. The recall provision requires the sponsor to arrange for recall and dispose of the product if the Authority has good reason to believe the product is not fit for purpose or is mislabelled. The requirement to dispose of products does not allow for the possibility of any other appropriate response, for example, relabeling products.²¹

Manufacturing code, licences and auditing

26. There should be a requirement that the manufacturing code be developed in compliance with the principles of the Act (in particular the principle of risk-proportionate regulation). The code should be consistent with internationally recognised manufacturing practice for NHPs.²²
27. To promote efficiency and reduce compliance costs, clause 27 should be amended to provide explicitly for cross-referencing to risk management programmes under the Animal Products Act or food safety programmes under the Food Act so that for certain purposes those programmes may be deemed part of the code.
28. Similarly, the provisions regarding to the granting of licences should allow licences to be issued based on compliance with equivalent or superior manufacturing standards under another Act (such as the Animal Products Act, Food Act or Medicines Act) or a foreign regime administered by a registered authority (rather than an audit against the requirements of the code). This would ensure the safety of products while limiting compliance costs.²³ Licence conditions should be “reasonable”.²⁴
29. We accept that it is appropriate for the Authority to have the power to revoke or suspend licences or export certificates but the power as drafted is too wide, gives no guidance as to the appropriateness of suspension or revocation and does not meet the requirements of natural justice for a process that will affect the rights and livelihoods of manufacturers.
30. Suspension should only be allowed in circumstances where non-compliance has been repeated or has led to serious safety concerns. There should be a time limit on suspension (we say three months), manufacturers should be given the opportunity to comment before suspension and/or revocation and be provided with reasons for any decision to suspend/revoke. In the competitive NHP industry, a licence suspension would likely be the death knell of a company. Revocation should only be allowed in circumstances of

²¹ See discussion on clause 44, p 34

²² See discussion on clause 27, p24

²³ See discussion clause 29, p 25

²⁴ See discussion clause 30, p 26

repeated suspensions or there has been such a serious failure to comply with the code as to cast doubt on the fitness of the product manufactured.²⁵

31. We do not see the need for manufacturers to be subject to a fit and proper person test. So long as the manufacturer complies with the code (which will be audited) there should be no safety concerns.
32. We agree that there should be an audit power but say that audits should be conducted regularly or where the Authority has reasonable grounds for concern about compliance with licence conditions (rather than “at any time”).²⁶

Fees

33. The provision for prescription of fees by the Authority is unusual and completely inappropriate. Cost recovery should be provided for by way of regulation as it is in most other Acts (requiring Cabinet approval and scrutiny by the Regulations Review Committee). We do not understand why this provision has limited cost recovery to the imposition of fees when the RIS has acknowledged that further work is required to consider whether fees, charges or levies would be an appropriate cost recovery mechanism and there have been strong and varied submissions from within the industry as to the appropriate mechanism.
34. The provision should be amended to provide for a wider range of cost recovery mechanisms (fees, charges and levies) and there should be an obligation to consult with affected parties in determining the appropriate costs recovery regime.²⁷

Appeals

35. We support appeals being available but the appeal process should be after an internal review by the Authority of any decisions made under delegation. The appeal provision gives a right of appeal to a “party” to a decision but what this means needs clarification. For example, given the lack of process around suspension of a manufacturing licence, would a manufacturer be a “party” to a decision? We say the correct threshold should be a person who is adversely affected by a decision.²⁸

²⁵ See discussion clause 34, p27

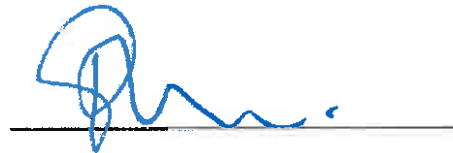
²⁶ See discussion clause 31, p26

²⁷ See discussion on clause 35, p 29

²⁸ See discussion on clause 42, p34

Delegations

36. Unusually, the delegation provision allows the Authority to delegate its powers and functions to “any person” (under the State Sector Act the Director-General as the Authority may delegate within the public sector).
37. We are concerned that this power could be used to delegate the powers under this Act to the proposed Australia New Zealand Therapeutic Products Agency and thereby undermine the aim of separate regulation for the industry in New Zealand.
38. The power to delegate outside the public sector should be limited to the power in clause 31 (the audit power) and there should be an additional “fit and proper person” requirement.²⁹



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Health NZ**

²⁹ See discussion on clause 45, p 35