New Zealand Health Trust[1] position paper

Natural Health & Supplementary Products Bill (as reported back by Select Committee 31 October 2012) - key changes, problems and unintended consequences[2]

Name of the Bill

- Logically the name of the Bill should be the Natural and Supplementary Health Products Bill.

Principles & purpose (clauses 3 & 4)

- The purpose clause states the obvious and does not refer to a "risk proportionate system for the regulation of NH&SPs
- The principles clause does not include principles that NH&SPs with a history of safe use should be considered safe until proven otherwise.

Interpretation (clause 5)

- "risk" is not defined. It should be defined to exclude the "risk" of consumers choosing NH&SPs instead of medicines.
- "health benefit" does not include "restoration".
- (There are a number of changes and additions to various definitions – discussed below where appropriate).

Definition of "natural health & supplementary product" (clause 6)

- The definition has now been changed to allow notifiers to choose whether a product is a NH&SP or a medicine (medicines consented under the Medicines Act are excluded from the definition).
- Whether a food is a NH&SP or a food (under the Food Act depends on whether it is presented as a food) so to that extent there is choice about whether a notifier notifies a product as a food or a NH&SP.

The Authority (clauses 8 to 11)

- The bill has not been amended to ensure that the NH&SP Authority is regulated separately from Medsafe.
- The bill has not had a schedule of recognised authorities added.
- The bill does not provide for consultation prior to the Authority making decisions about "recognised authorities"
- The Authority must now consult the Minister before making any appointment to the Advisory Committee (we submitted the Minister

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[2] Red arrows identify aspects of the Bill that need to be changed for NZHT to continue to support the Bill.

should make the appointment). There are more specific obligations in terms of the expertise of members (requirements for experience relevant to NH&SPs, manufacturing and science).

Product notifier (clauses 11A & 12)

- There is a new clause (11A) defining the product notifier (previously "sponsor") which clarifies the concept of notification. The product notifier is the manufacturer or if a manufacturer manufactures on behalf of someone else, the product notifier is the other person.

Health benefit claims (clauses 12A, 12B and 12C)

- This part of the bill has changed considerably introducing pre-approval processes for products that make claims about named conditions and giving the Authority the power to pre-approve lists of conditions for which health benefit claims could be made and approve particular claims about named conditions (in respect of a particular product or class of products).
- This must be changed to revert to a simple "notification" process for all NH&SPs (see detailed submission in key issues document).

Notification (clause 13)

- The confusion about "sponsor" (and particularly who is obliged to notify NH&SPs) has been fixed with the change from "sponsor" to "product notifier" and has provided more clarity through the definition of product notifier.
- There is a new sub-clause (13(2A)) that would require a product notifier to publish on the internet a summary of the evidence supporting a health benefit claim. This clause will result in a notifier incurring significant indirect compliance costs – particularly when considered in the context of new offence provisions. The bill now provides that it is an offence to knowingly provide information in the 13(2A) summary that contains any health benefit claim that relates to a named condition unless it is an "allowable" claim (see clause 40A(2)). This means that any evidence intended to be posted in order to comply with 13(2A) will need to be edited to ensure that it contains only claims in "allowable" form (ie in the wording approved by the Authority). It is not difficult to foresee a situation where, for example, a scientific paper could not be posted as evidence because the claims in the paper are not limited to the wording of the "allowable claim". This obligation is unworkable and will not achieve the object of allowing the public to make informed decisions. It should be deleted from the bill.
- There is now a specific definition of "scientific evidence" (evidence derived from empirical studies and/or repeatable experiments).

Exemptions (clauses 13A and 14)

- "Practitioner" remains undefined (for the purposes of the practitioner exemption). It should be defined to make clear that it is not limited to a registered health practitioner.
- An exemption for NH&SPs with active ingredients in low concentrations (20 parts per million) has been introduced.
- The practitioner exemption should be expanded to allow for small batch manufacture as occurs with pharmacists compounding pharmaceutical products (see Health & Disability Pharmacy Services Standards NZS 8134.7:2010.
- The re-draft includes matters the Authority must take into account when considering whether to exempt a product from notification (as recommended in the NZHT submission).

Audit (clause 15)

- No change

Suspension & cancellation of product notification

- The obligation to suspend ("must suspend") has been changed as per NZHT submission to "may suspend".
- The NZHT submission that suspension powers relate to the likelihood of "serious harm" rather than "harm" has not been actioned.
- There is now provision for notification of suspension however there is no provision for advance notice of suspension and the period of suspension is inflexible (21 days).
- The significance of the lack of advance warning of suspension is significant because new clause 16A obliges a notifier to "ensure a product [that has been suspended] is not sold by any person" when a notifier may have supplied product to many and varied re-sellers.
- There should be provision for variation of a product notification (as well as cancellation or re-instatement).

Serious adverse reactions

- The definition of a "serious adverse reaction" should be defined consistent with the WHO definition of serious adverse event (also consistent with the approach to medicines and vaccines). In particular the reference to "allergic reaction" must be deleted.

New product notifications (clause 18)

- Clause 18 requires withdrawal and re-notification of a product notification in certain circumstances (including change of manufacture).
- A change in manufacture should be able to be amended or added to a product notification (to accommodate batch manufacturing and/or a change of manufacturer) rather than withdrawal and re-notification.

Cancellation of product notification (clause 19A)

- This clause has been amended to set out a process for the Authority to undertake before cancelling a product notification (including giving the product notifier notice that it is considering cancellation and an opportunity to be heard).

Prohibited methods of administration (clause 19B)

- Prohibited methods of administration have been shifted to a stand-alone clause (from the definition of natural health and supplementary product).
- NZHT submitted that administration to the ear should be allowed and this has been removed from the prohibited methods.

Permitted ingredients (clause 20)

- NZHT submitted that the ingredients in NH&SPs currently legally able to be sold and ingredients in identified Pharmacopeia and various other jurisdictions (to be added as a schedule to the bill) should be automatically be permitted ingredients. No amendments along these lines have been made.

Prohibited ingredients (clause 21)

- NZHT submitted that when considering prohibiting ingredients, the Authority must have regard to benefits associated with an ingredients use (as well as the risk of any harm arising) and whether any risks associated with the use of an ingredient could be dealt with by placing restrictions on an ingredient's use. No amendments along these lines have been made.

New ingredients (clauses 22 and 23)

- The only substantial change to the provisions for notification of a new ingredient is a requirement for the Authority to have regard to the same criteria as those applied to permitted ingredients.
- NZHT submitted that there must be a process for a prohibited ingredient to become a "new ingredient" (a blanket prohibition does not allow for a change in understanding or circumstances in respect of a particular ingredient). No amendment has been made.
- NZHT submitted that a 90 day notice period for new ingredients was too long (and suggested 30 days notice would be appropriate). The 90 day notice period remains in the bill.
- NZHT submitted that when determining whether an ingredient may be used in a NH&SP following a safety assessment, the appropriate criteria are those in clause 21(2). No amendment has been made in that regard.

- Clause 23 (safety assessment) is unchanged. NZHT submitted that the Authority must have grounds for concern as to the safety of a product before an assessment may be carried out. When carrying out a safety assessment the Authority should have regard to any information provided by the notifier and the criteria for prohibition (as per clause 21(2)).

Dietary supplements (clause 24A)

- This clause clarifies that a NH&SP that is a dietary supplement must contain only permitted ingredients (which appears to have been added to the definition section because of its inclusion in the definition of NH&SP).

Labelling (clause 24)

- NZHT submitted a "label" should be defined (as per the Food Bill) and that a provision should be inserted setting out certain criteria the Authority must take into account when regulating labelling. No amendments have been made in response to those submissions.

Exports (clause 25)

- Clause 25(4) has been deleted (as per NZHT's submission). The new clause 25(4) is consistent with NZHT's submissions (ie the ability to obtain an export certificate is no longer limited to the manufacturer).
- NZHT submitted that clause 25(6) should record the effect of an export certificate (ie what it "does" do as opposed to what it "does not" do). That sub-clause has not been amended.

NH&SPs that are animal products (clause 26)

- NZHT submitted that animal products that are also NH&SPs should require an export certificate under the NH&SP Act as well as the Animal Products Act (because different issues will arise under each of those Acts). The clause has not been amended.

Code of practice for manufacture of NH&SPs (clause 27)

- This clause has been amended so that it comes into force no later than 1 year after the commencement of the clause.
- In line with NZHT submissions, clause 27(2)(aa) has been added so that when developing the code the Authority must be guided by the principles of the Act.
- A consultation provision has been added ("persons the Authority considers to be representative of persons likely to be affected by the Code"). NZHT's position is that this must revert to an obligation to consult parties likely to be affected.
- NZHT submitted that this clause should reference the possibility of the Code cross-referencing to provisions of the APA, Food Act or

Medicines Act or regulations or food safety programmes under those Acts. No amendment has been made.

- NZHT submitted that this clause should contain criteria to be considered in developing the Code (similar to clause 24). No amendment has been made.
- NZHT also submitted that there should be an obligation to publish the Code on the Authority's internet site (as opposed to "an internet site"). No amendment has been made.

Licence to manufacture NH&SPs (clause 28)

- NZHT submitted that this clause needed amendment to clarify that it did not intend to require a person manufacturing a NH&SP for personal use (and for those purposes suggested that "manufacture" and "practitioner" be defined). No amendment has been made.

Application for licence to manufacture (clause 29)

- NZHT submitted that this clause should allow for persons to be licensed in New Zealand based on compliance with other regimes (either in New Zealand or overseas). There has been no amendment to provide for this.
- NZHT submitted that licences should be able to be granted for periods longer than three years (recognising long term compliance). Clause 29(4) has been amended so that licences remain in force for up to five years.
- NZHT also submitted that there was no need for "fit and proper person" criteria because compliance with the code should suffice. No amendment has been made to delete that test (other than a minor amendment to the criteria by which a "fit and proper person" is determined).

Conditions of licence (clause 30)

- NZHT suggested an amendment to clause 30 consequent on the submission that licences from other regulatory regimes should be recognised (change to clause 29). That suggestion was not adopted. This clause remains unchanged.

Audits of manufacturing facilities (clause 31 and 31A)

- NZHT submitted that audits should be regular (ie every three years) or because the Authority had reasonable grounds to believe the manufacturer was not complying with licence conditions. Those submissions were not adopted.
- Audit powers have been extended from licence holders to include manufacturers who have applied for a licence.
- Audits may be undertaken at any time.

- A new provision has been added allowing the Authority to recognise audits undertaken by another person under another Act for another purpose.
- Clause 31A is new and provides the Authority with the power to enter manufacturer's premises during normal business hours. It sets out in detail what the Authority may do at the manufacturer's premises (open containers, secure evidence, inspect documents etc).

Compliance notice (clause 32)

- No meaningful change.
- NZHT suggested this clause could be included with clause 34 (as part of a toolbox of regulatory responses to non-compliance) and that a clause be inserted requiring non-compliance to be managed in a risk-proportionate manner.

Deemed compliance with code (clause 33)

- NZHT submitted that this clause should be clarified to ensure that the two following scenarios were covered by this clause:
  - A NZ manufacturing facility granted a licence by a foreign recognised authority; or
  - A foreign manufacturing facility in which a NH&SP is manufactured under a licence granted by a recognised Authority.
- No significant change has been made and this clause remains unclear.

Revocation/suspension of licence for non-compliance (clause 34)

- This clause has been amended so that revocation or suspension of a licence could only occur after an audit has been conducted.
- This amendment does not deal with NZHT's submission that the clause should contain guidance to the Authority in the exercise of these powers. NZHT suggested a limit on suspension (3 months) and grounds for suspension including repeated non-compliance or where non-compliance has led to serious safety concerns that cannot be dealt with by product recalls or compliance notices.
- NZHT also submitted that clause 34 should set out a process whereby the manufacturer has an opportunity to respond to concerns or allegations before suspension/revocation takes place. No amendment has been made.

Fees (clause 35)

- NZHT submitted that fees should be set by regulation (therefore requiring cabinet approval and review by the Regulations Review Committee). The power to prescribe fees by Gazette notice remains in the bill.

- In submissions NZHT expressed concern that this clause should provide the ability to both impose charges and/or a turnover levy in order to fund the Authority.

➡ Consistent with NZHT submissions, a consultation clause has been added (although NZHT considers it should not be limited to consultation with persons or organisations the Authority considers "representative" of the interests of persons likely to be substantially affected by the proposed fee but should simply be "persons likely to be substantially affected").

- Consistent with NZHT submissions, criteria have been added to guide the Authority in determining the appropriate method of cost recovery. It has been made clear that a strict apportionment of costs is not required and that fees may be set by averaging costs and taking into account costs of indirect services.

Offences – Deception (clause 36)

- NZHT submitted that the penalties under clause 36 should be commensurate with similar low risk industries. The penalties have been halved to maximum penalties of $250,000 (body corporate) and $50,000 (individuals).
- A number of offences have been added to clause 36 (destroying/failing to provide documents required by the Act, altering a label so it no longer complies with labelling requirements).

Offences – sale of NH&SP that have not been notified/do not meet standards (clause 37)

➡ This clause has been amended so that it is no longer limited to the "sponsor" of a NH&SP and applies to any "person". NZHT submits that "product notifier" should replace the reference to "person" so that the incentive to ensure a product is notified rests with the notifier.

- "sale" has been defined.
- NZHT submitted that the offence provision should not capture sale of a product that claimed <u>less</u> than the notified claim (ie a product that has been notified with a claim that does not include that claim on its label). An amendment clarifies that this provision is intended to capture claims <u>not</u> included in the product notification.
- NZHT also submitted that the wording of this provision was confusing. It is an offence to sell a product that does not meet the appropriate standards of evidence required for the claims made for the product. NZHT suggested that it is not the product that needs to meet the evidential standard but the claims for that product. No amendment has been made to this aspect of the provision.

Manufacturing without a licence (clause 38) & obstruction of an authorised person (clause 39)

- These clauses have been amended by deleting sub-paragraph 2 ("an offence against this section may be proceeded with either summarily or by indictment").

Endangerment of human health (clause 40)

- In line with NZHT's submissions this clause is now clearer about the distinction between a product notifier and a manufacturer (both are captured by this offence provision).

Specified offences relating to natural health and supplementary products (clause 40A)

- This is an entirely new clause providing for a number of new offences relating to health benefit claims.
- Clause 40A(1) provides it is an offence to knowingly manufacture or sell a NH&SP that contains a prohibited ingredient.
- Clause 40A(2) provides it is an offence to knowingly contravene section 12A(1)(to knowingly include a claim in a notification that relates to a named condition unless it is an "allowable" claim) or 12A(2) (to knowingly include or attach to the summary of evidence required under section 13(2A) any health benefit claim unless it is an allowable claim). (see notes on clauses 13(2A) and 40C)
- Clause 40A(3) provides it is an offence to knowingly contravene section 12A(3) (a prohibition on including anything other than an allowable claim on a label or in advertising where the health benefit claim relates to a named condition). (The limitation on advertising raises similar issues to clause 40C).
- Clause 40A(4) provides it is an offence to knowingly sell a NH&SP in contravention of section 19B (prohibited methods of administration).

NH&SPs that are dietary supplements (clause 40B)

- Clause 40B is new and provides that it is an offence to knowingly manufacture or sell a NH&SP that is a dietary supplement that does not contain only "permitted ingredients".

Publication of certain advertisements (clause 40C)

- Clause 40C is new and provides that it is an offence to publish any advertisement that suggests a NH&SP can be administered by a prohibited method or includes any health benefit claim suggesting a NH&SP can assist in the treatment of a named condition (unless it is an allowable claim). It is inconsistent and disproportionate when considered in the context of similar provisions for medicines under the Medicines Act.

- There is no exception for information provided to either NH&SP practitioners (or for that matter medical practitioners). In a similar provision in the Medicines Act an exception is specifically provided for information about medicines provided to medical practitioners. If enacted this would result in the anomalous situation of there being more restrictions on the provision of information to medical practitioners about NH&SPs than there is for medicines. This clause must be amended to provide for an exception in relation to information provided to practitioners (both medical and NH&SP practitioners – many of whom although not "registered" belong to standards based professional bodies).
- Another inconsistency with the Medicines Act is that the Medicines Act provides for a defence of "truth" to certain contraventions of advertising restrictions. There should be an equivalent defence in the NH&SP bill.
- Arguably this clause will capture the news media. Public interest stories that contains "health benefit claims" that are not in the form of "allowable claims" could arguably be prosecuted for a breach of this section.
- This clause should be deleted. Any false or misleading claims could be dealt with under the Fair Trading Act.

Appeals (clauses 41 and 42)

- NZHT submitted that the number of committee members in the appeals committee (clause 41) should be increased from three to six, with requirements for particular expertise of committee members (including expertise in the NH&SP industry). NZHT also submitted that the committee should be chaired by a lawyer and that there should be provision for deputies to be appointed and/or the committee operate via sub-committees. No amendments have been made.
- Clause 42 has been amended to provide more detail of the appeals process and outcomes. Consistent with NZHT submissions a sub-clause has been added providing that the committee may "confirm, reverse, or modify the decision appealed against".
- NZHT also submitted that there should be an internal review process prior to a right of appeal. No amendment has been made in that regard.
- NZHT also expressed concern about the lack of clarity inherent in the right of appeal being vested in a "person who is a party to a decision of the Authority" and submitted this should be amended to a person "adversely affected by a decision". No amendment has been made.

Statement by Authority (clause 43)

- There has been no substantive change to this clause. NZHT submitted that the power to make public statements for the purpose of protecting the public would be better situated with clause 44 (power to recall) and clause 16 (suspension or cancellation of notification) as part of a tool-box of remedies.

Recall of NH&SPs (clause 44)

- In line with NZHT submissions this clause has been amended so that the Authority may order relabeling of recalled products (instead of being restricted to ordering disposal of recalled products).
- NZHT also suggested that any recall obligation should be in accordance with the product notifier's recall plan. No amendments have been made.

Delegation (clause 45)

- This has not been amended. NZHT submitted that delegation powers should be restricted to the power to audit and be subject to a fit and proper person test.

Power to declare a product or class of products a NH&SP (clause 45A)

- This is a new clause. It provides the Authority with the power to make a declaration that a particular product or a class of product is/are a NH&SP/s. The Authority must be satisfied that the product falls within the definition of a NH&SP and that the declaration is necessary to provide clarity to the applicant and any affected industry. Before making a decision the Authority must refer the matter to the advisory committee and take into account any advice received from that committee. Declarations are published in the Gazette and on the internet.
- NZHT supports the addition of this clause.

Transitional provisions (clause 46)

- This clause has not been substantively amended (the drafting has been amended to reflect changes to the definition of NH&SP (clause 6)).
- NZHT's concern that products containing excipients would not be captured by this transitional provision has been dealt with by including additive and formulation aids to Schedule 1.

➡ NZHT's main concern is that the bill must provide a mechanism to ensure that products currently legally able to be sold will continue to be able to be sold. NZHT suggested this could be achieved through a similar grandfathering mechanism that was adopted for the Hazardous Substances and New Organisms Act. No amendments have been made in that regard.

➡ Given the changes from a notification regime to a notification/pre-approval regime, we note that the one year transitional period (products must be notified within one year of commencement of the section) is much less realistic, given that any approval process may take a significant time to process. NZHT submits that a 2 year transition is more realistic.

Regulations (clause 47)

- Clause 47 has been significantly amended. The power to amend the Schedule by regulation has been more carefully defined and extended to include new Schedule 2 (see clause 47(1)(a) – (ad)).
- There is a new power to make regulations to provide requirements or restrictions on health benefit claims on product labels or advertisements (clause 47(1)(ae)).
- The new consultation process requires notification of the proposed regulation, the ability for anyone to make submissions and requires the Minister to consider those submissions.
- In making recommendations under clause 47(1)(ae) (health benefit claims on labels or in advertisements) the Minister is required to have particular regard to the principle of risk-proportionate regulation (clause 47(2C)).

➡ NZHT supports the inclusion of a requirement for the Minister to have particular regard to the principle of risk-proportionate regulation but submits that this should apply to all regulation making powers.

➡ The consultation obligation for the remainder of the clause (sub-clause 2) has been limited to an obligation to consult with any person or organisation the Minister considers "to be representative of the interests of persons likely to be substantially affected". NZHT submits this should revert back to an obligation to consult any person who has "an interest in or will be substantially affected by the regulations."

- NZHT remains of the view that fees should be set by regulation not by Gazette notice.

Review of the Act (clause 48)

- The obligation to review the Act has been extended from a policy review to a policy and operational review.

➡ NZHT submitted that any review of the Act should be an "operational" review rather than a "policy review" and that any review should commence five years after the transitional period for notification has elapsed.

➡ NZHT says that any review that is conducted should be conducted by the Minister not the Ministry of Health, should contain specific guidelines for the review and should include an obligation to consult interested parties.

Amendments to other Acts (clauses 50 to 56B)

- Clause 51 amends the Medicines Act so that a NH&SP is excluded from the definition of a medicine in section 3(1) of that Act. However the intention of clause 5 of the Medicines Amendment Bill is to repeal section 3 sub-sections (1) and (2) of the Medicines Act and substitute new sub-sections. The Medicines Amendment Bill does not carry on the intent of the amendment proposed by clause 51 of the NH&SP Bill. In particular it does not include a NH&SP on the list of particular

exclusions from the definition of a “medicine” in the proposed new section 3(1).

- A new section has been added (clauses 56A and 56B) providing that the Trans Tasman Mutual Recognition Act 1997 does not affect the operation of the NH&SP Act.

Schedule 1 suitable substances

- Schedule 1 has been amended to include additives and formulation aids.
- Pre-biotics have been deleted from the schedule.
- See also paragraph 2 – which now includes electrolysis as one of the allowed processes.

- There is no change to the list of amino acids (paragraph 8). This list must be a complete list of known amino acids.
- NZHT submitted that an additional paragraph should be added including “a substance normally found in a human body”. NZHT understands this submission was rejected on the basis that this may include poisonous substances. This makes no sense given that many of the listed substances may be poisonous depending on the concentration.

Schedule 2 Approved pharmacopeia

- This is a new schedule listing a number of approved pharmacopeia. The schedule can be added to by regulation (see comments on clause 47 above).
- If the Authority is considering whether a health benefit claim that relates to a named condition may be an “allowable claim”, it is obliged to accept relevant evidence in support of a claim derived from an “approved pharmacopeia”.

Further schedules

- NZHT submitted that an additional schedule be added to the Bill specifying a number of recognised authorities. This has not been done.