JOINT INDUSTRY PROPOSAL FOR THE REGULATION OF NATURAL AND TRADITIONAL HEALTH PRODUCTS, MANUFACTURERS, IMPORTERS, EXPORTERS & DISTRIBUTORS

EXECUTIVE SUMMARY

Introduction

The proposal is based upon the following broad concepts:

(a) That Natural and Traditional Health Products (NaTHPs) have a long history of safe use; they are inherently safe,

(b) That there should be two categories of therapeutic products for the purpose of regulation: New or novel pharmaceutical chemicals that have no history of safe use in humans (therefore have no risk/safety profile and require testing before entering the market) and NaTHPs that have a long history of relatively safe use demonstrating very low risk profiles,

(c) That history has shown that the two categories cannot be properly regulated under the same legislative framework or under the control of the same regulatory body.

The regulatory requirements and philosophies for the two categories are fundamentally different to the point that administration of the existing Medicines Act 1981 and the Dietary Supplement Regulations 1985, under the Food Act 1981, has failed to provide both effective regulation of NaTHPs and market certainty resulting in a regulatory environment of increasing distrust and frustration between regulators and industry.

This industry model is based on removing safe NaTHPs from both food and medicines legislation and controlling such products under a purpose built framework that properly protects consumers whilst still supporting business and providing for innovation.

Intent

The intention of the proposal is to put in place in New Zealand a risk responsive and risk proportionate, robust and sustainable regulatory environment for NaTHPs whilst acknowledging that this class of products have a demonstrated extremely low risk profile.

This regulatory environment will provide a degree of certainty for industry, enable consumers freedom of choice, satisfy regulators of a robust process ensuring safety to consumers, minimize the potential for unnecessary technical barriers to trade, and reduce ongoing compliance and regulatory costs to levels as low as reasonably practicable to not limit innovation.

The intention of this legislation is to create a sensible, cost effective approach to regulation of the NaTHP industry. Because New Zealand is a small, diverse economy compared to most others and because NZ industry is comprised mainly of small to medium enterprises, adopting and recognizing other selected countries and jurisdictions' (1) manufacturing standards, (2) health claims and (3) ingredients lists takes advantage of all the work already undertaken by those countries and jurisdictions. This provides an extremely good base to start from and consequently keeps costs low and overcomes any safety concerns.

The intention of this legislation is to keep regulator discretion to an absolute minimum and keep industry uncertainty to an absolute minimum.

Principles Based Regulation

The essence of a principles-based regulatory system is that the principles take precedence over the rules. Under such a system the regulator, industry, and the officials are required to use their reason and judgment in support of the principles in the interpretation and application of the rules.

The principles are as follows:

- The regulations are intended to encourage the dissemination of evidence based knowledge regarding natural treatments for all known diseases, ailments, disorders and conditions.
- The regulator is ultimately employed by and accountable to the consumer.
- The regulation of NaTHPs embraces the principle that all consumers are different, that all consumers have different physiological requirements and may respond differently (i.e. there is no one size fits all). As such the regulator will not seek to reduce ingredients to the lowest common denominator.
- The regulator will at all times maintain a neutral stance in respect of the wide range of modalities that fall under the category of NaTHPs, focusing only on outcomes for the individual consumer.
- The regulator will actively seek, collate and present to the consumer and other interested parties information regarding the results obtained during the use of the NaTHPs it regulates.
- The regulations respect and ensure a consumer's right to choose.
- If any harm is reversible and use is voluntary, then the case for regulatory intervention is minimal and restricted to labelling and education. If the harm is irreversible and use is involuntary, then there is a high case for regulatory intervention.
- The seriousness of an illness has no bearing upon any risks associated with NaTHP use. Therefore, the seriousness of illness cannot be used as an excuse to restrict NaTHP use.
- Enforcement action must be applied evenly and transparently.
- The protection of life and well being must always be uppermost in the mind of the regulator when applying the regulations.
- The regulators will respond in a timely and meaningful manner to communications from consumers and industry.
- It is the role of the regulator to facilitate a regulatory environment where innovative NaTHP therapies can compete freely and openly with any medical establishment therapies.
- Regulatory charges must be kept low to prevent them from acting as a tariff barrier.

Key Considerations of the Proposed Model

With the notable exceptions of recommendations (b) and (e) the proposal is primarily modeled on the recommendations of the Health Select Committee's first inquiry report into the Joint Trans-Tasman Therapeutic Goods Agency (later renamed the Australia New Zealand Therapeutic Products Agency (ANZTPA)), which recommended that a regulatory model for NaTHPs should:

(a) be risk-based;

(b) establish a separate category for low-risk complementary healthcare products that do not make therapeutic claims distinct from categories for food and medicine;

(c) require all products and their ingredients to be notified by the supplier on a central register;

(d) include a simple electronic lodgment and notification system;

(e) be based on a negative list that records which ingredients are not permitted to be used because a safety issue has been identified;

(f) take full account of the voluntary nature of risks accepted by consumers in this area and places an appropriate emphasis on disclosure of adequate and accurate relevant information to consumers;

(g) have labeling requirements that govern the adequate and accurate disclosure of information;

(h) require compliance with good manufacturing principles;

(i) include monitoring, enforcement, and review of quality assurance, with ongoing random sampling and auditing to ensure maximum compliance;

(j) allow for innovation in products and processes and new product entry;

(k) take into account the impact of the cost of complying with any regulatory regime on the New Zealand complementary healthcare products industry.

As mentioned above the proposed Act contains two variations that relate to Health Select Committee recommendations (b) and (e).

> b) The proposal provides for evidence-based health claims utilizing a schedule of sources of acceptable claims such as pharmacopoeia, certain overseas or international regulatory agencies (e.g. Australia, Canada, EU, Codex, WHO), scientific papers/reports, monographs and history of traditional purpose of use (evidence of traditional use may be oral in certain cultures). Other sources of evidence can be utilized but must be held by the claimant.
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> e) The proposal includes a hybrid notification system embracing elements of both positive and negative listing systems and enabling additions of 'new' ingredients via a notification system that enables the regulator to disallow the ingredient if it does not meet the definition of a NaTHP or poses intolerable safety concerns.

Therapeutic claims will be allowed when supported by valid evidence and will be subject to the Fair Trading Act.

A hybrid listing system is proposed which requires all new ingredients to be notified to the regulator via the online ingredient notification system prior to marketing and the regulator will have a predetermined time frame in which to challenge (disallow) the ingredient.

All decisions of the regulator are subject to a defined dispute resolution mechanism.

Like the unanimous recommendations of the Health Select Committee report, the proposal does not support the Australia New Zealand Therapeutic Products Agency as set out in the treaty between the Governments of New Zealand and Australia signed in December 2003.

The proposal has been the subject of extensive industry and Maori consultation. Where possible, the proposal has also been empathetic to the concerns of various stakeholders as expressed in submissions to the Health Select Committee inquiries/hearings.

The proposal establishes an industry specific regulatory agency, separate and distinct from agencies responsible for the regulating of foods and pharmaceutical medicines, but acknowledges that there will be interface issues that need to be appropriately and fairly managed.

The proposal provides for a co-regulatory model suitable for a low risk industry. Agency costs will be shared by the government and industry. A levy is proposed as the most efficient means of collecting industry contributions. It is also seen as a means of controlling or limiting the expansion of the regulatory agency via regulatory creep.

The proposal is consistent with the recent European Court of Justice ruling that presenting a herbal extract in capsule form does not make a product a medicine.[1] The ECJ ruled that a capsule is simply a small container. In this case, garlic extract in a capsule is no more or less a food than whole garlic.

The proposal also includes provision for a risk proportionate dispute resolution mechanism.

The framework of the proposal assumes that:

- intervention by Government should generally be used only when there is a problem or potential problem that is either unlikely to be solved in any other way or inefficient or ineffective to solve any other way;
- the amount of intervention should be the minimum required to solve the problem;
- the benefits of intervening must exceed the costs.

Safe Harbour

In essence the proposal provides enabling legislation that operates to provide a safe harbour for qualifying products. If the answer to all four of the following questions is 'yes' then the product would be regulated by this proposed Act and then be exempt from compliance with both medicines and food law unless the supplier of the NaTHP chooses otherwise.

[1] C-319/05, http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=C-319/05

(1) Does the product comply with the definition of a natural and traditional health product?

(2) Does the product manufacturer and distributor have an accepted Risk Management Programme or Good Manufacturing Practice system in place?

(3) Does the manufacturer and distributor have available the required evidence for any health claims made?

(4) Have the ingredients and product been lodged on the central register?

- The database on the central register does not determine whether the ingredient can be used; the definition of NaTHP in the proposed Act does.

This proposal adopts and where necessary adapts appropriate best practice from around the world**.**

Impact on Existing Industry

Following enactment;

- No products currently on the market will be removed from the market unless intolerable safety issues emerge.
- Compliance will be phased in progressively over five years.
- Manufacturers, importers, exporters and distributors will have the choice of implementing Risk Management Programmes (RMP) which will be submitted to the regulator for acceptance.
- A RMP will be required to meet certain safety/integrity standards and may be customised or be an acceptable Good Manufacturing Practice (GMP) scheduled by the Act and chosen by the manufacturer.
- Simple Risk Management Programmes will embrace well defined and sensible HACCP principles and have requirements not unlike those required under the current Animal Product, Wine and Food Acts.
- Health claims will be permitted subject to acceptable evidence being held by the manufacturer, importer, exporter or distributor or the health claims must be contained in the schedule of sources of acceptable claims

Board of Guardians

The proposed model provides for a Board of Guardians to consist of an independent chair appointed by the Auditor General's Office who is skilled in good regulatory practice, a person skilled in alternative dispute resolution nominated by the Chairperson of the New Zealand Chapter of Lawyers Engaged in Alternative Dispute Resolution and 8-10 members also appointed by the Auditor General's Office including members nominated by and representing the following sectors: exporters, importers, local manufacturers, distributors, Maori, natural and traditional healthcare practitioners, retailers and raw products distributors.

The Board would act as a fast and cost effective avenue of complaint for any stakeholder concerned with a decision made by regulators and would also act as the advisory body to the regulators as required. Stakeholders would however retain full rights to apply to the Court system at any time to review any decision of either regulators or the Board. In view of the Board's role it is imperative that the Board retains its independence from the regulatory body, and the right of industry and stakeholder groups to appoint the members of the Board will be enshrined in the legislation.

Funding

The proposed co-regulatory model is intended to be funded 50/50 by government and industry.

Government funding is cognizant of the fact that there is a considerable degree of public good created by consumers choosing to self-care in order to maintain wellness and to self treat their own disorders.

Industry funding is proposed to be via a parliament approved levy of 0.5 [to 1%] wholesale or 0.25 [to 0.5%] export value based on self declared turnover similar to the way IRD operates. Exports would pay only 50 percent of the actual costs with no cross subsidizing either direction.

Funding should include provision for public education and contested research.

Summary

This proposal provides for a regulatory system that:

(1) Is enabling;

(2) Establishes NaTHPs as an important class of goods in their own right via the proposed Natural and Traditional Health Products Act;

(3) Recognises that there will be interface issues relating to the Food Act and the Medicines Act that need to be pro-actively and fairly managed;

(4) Recognises and provides for Treaty of Waitangi related matters;

(5) Provides political assurance and certainty;

(6) Provides clear guidelines as to the regulator's discretionary powers;

(7) Provides industry assurance and certainty;

(8) Provides for consumer choice, innovation and maintenance of product safety;

(9) Maintains quality assurance through approved Risk Management Programmes (RMPs);

(10) Enables the regulator to know who is in the market and what is on the market so that they can responsibly monitor the industry and enforce the legislation effectively and efficiently;

(11) Ensures that the principles of the government's Good Regulatory Practice (GRP) are complied with especially the principle of equity (i.e. proportionality);

(12) Requires the regulator to be certified as GRP compliant;

(13) Prohibits the adulteration of NaTHPs with pharmaceutical or other similar ingredients;

(14) Ingredients found in products are permitted only if they meet the definition of NaTHPs;

(15) Provides a mechanism to ensure that compliance and regulatory costs are kept to as low as reasonably practicable levels commensurate with GRP;

(16) Enables the entry of defined NaTHP ingredients onto the market whilst at the same time preventing the use of this legislation to introduce novel, non-natural or non-traditional ingredients;

(17) Recognises that whilst NaTHPs have a long history of safe use safety issues do emerge from time to time that need to be managed in a risk proportionate manner;

(18) Minimizes compliance costs and reduces technical barriers to trade;

(19) Requires 'True to Label' manufacture and packaging;

a. Recognises verifiable QBI (Quantify By Input);

b. Requires certain post manufacture testing where appropriate such as microbiological, heavy metals, rancidity of oils;

c. If it is shown that ingredient levels need to be tested then testing will be limited to one easily, accurately and economically identifiable ingredient.

i. If a problem is indicated then manufacturing input records are examined to determine the problem (e.g. mixing).

(20) Provides a Proprietary Knowledge Labeling Exemption;

(21) Provides for evidence based health claims, but health claims are not mandatory;

(22) Provides marketing and quality certainty for New Zealand's burgeoning NaTHP industry;

(23) Provides a regulatory environment that maintains a healthy 'tension' or 'balance' between the operational needs of small cottage industry and large industry players;

(24) Enables the regulator to undertake Post Market Monitoring and Auditing to maintain the integrity of the regulatory system;

a. Sensible ongoing monitoring is essential to ensure compliance with this legislation.

b. Post Market Monitoring of known and emerging issues related to the NaTHP industry is be undertaken with priorities & resources being established utilizing HACCP type principles;

c. Post Market Auditing is to be risk responsive and involve some degree of testing of targeted ingredients and/or products as issues emerge. For example,

- Recently it emerged overseas that certain toothpastes contained diethylene glycol,
- Cooperation between international regulators identified a limited number of countries as being the likely source of these products,
- The regulators risk management response was to initiate recalls where specific products were identified, and to test a range of high risk products for adulteration and withdraw any unacceptable products,
- Similar regulatory responses occurred with regards to certain soya sauces,
- These regulatory responses were risk proportionate and appropriate for NaTHP regulation.

(25) Prevents the heavy-handed approach such as the recall and mandated destruction of Pan Laboratory's products in 2003;

(26) Prevents the regulator from abusing their power, though it would enable it to responsibly initiate the withdrawal of unsafe products or ingredients from the market place where the risk posed cannot be managed otherwise;

(27) Prevent the regulator from choosing consultants/advisors philosophically opposed to the use of NaTHPs when considering risk management options or other regulatory matters;

(28) Provides for a robust dispute resolution system to prevent regulatory creep, prevent the excessive use of regulatory power, to ensure compliance, and to ensure that any safety issues are managed in compliance with Good Regulatory Practice including in a risk proportionate manner.

Major advantages of the proposal are that in accepting and applying equivalency it minimizes compliance costs and reduces technical barriers to trade.

In addition, major cost savings are accrued by recognizing other selected countries' and jurisdictions' ingredients, health claims and manufacturing standards because of reduced regulatory costs. This proposal would have the following additional advantages as well:

a. encouraging controlled innovation,

b. enabling exporters and importers to rationalize inventory and not having to maintain slightly different formulae simply to satisfy a plethora of red tape.