BUDDLEFINDLAY

The Natural Products Bill: Will the remedy cure the problem?

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What is the problem?

The natural health products industry is a multi-million dollar enterprise encompassing a wide variety of products, from vitamin preparations through to potent herbal medicines and substances derived from animals. According to the Regulatory Impact Statement ("RIS") prepared by the Ministry of Health which accompanied the Bill on introduction, over 450 companies supply these products in New Zealand, marketing an estimated 6,600 products. Many companies are small businesses, with more than half having a turnover of less than $5m.

Regulation of these products is however piecemeal. The key existing requirements are contained in the Dietary Supplements Regulations 1985. They were designed to cover the range of products on the market at that time. They regulate maximum daily dosages, limit the content of some vitamins and minerals and restrict some other ingredients. They contain labelling requirements and, importantly, a prohibition on making therapeutic claims.

The Regulations do not however regulate products outside the dietary supplements definition, new ingredients, manufacturing, or claims made about the products (except for the prohibition on therapeutic claims).

The RIS identified various problems. The first is inadequate controls on safety and quality of products. Manufacturing of dietary supplements is subject to control under the Foods Act. However, the RIS states that products which have characteristics and usages more akin to medicines should be subject to greater control, in order to avoid risks such as adulteration.

There is inadequate information about risks and inaccurate information about benefits. The major identified risk is where consumers attempt to treat serious conditions by using the products, in the belief that the claimed benefits from the products are true, where there is no basis for such claims.

A Ministry of Health review of websites revealed widespread breach of the prohibition of therapeutic claims. In 2007, 78% of the 263 websites reviewed were in breach. A later review found that 107 out of 355 websites were in breach.

Enforcement difficulties were also identified. Breaches are widespread. The Ministry comments that attempts it made to increase awareness and enforcement of the legislation met with resistance from both suppliers and consumers. Further, there is no register of products so it is difficult to trace particular products which may present risks.

Other views about the problem

There is significant disagreement about the degree of risk presented by these products, and whether there is a need for regulation at all. This is a global phenomenon. The WHO has described the debate as "uncritical enthusiasm versus uninformed scepticism". However, the WHO recommends regulation, and States are moving in that direction.

New Zealand has been considering reform for over 20 years. Regulation of "complementary medicines" was proposed as part of the agreement to establish the Australia New Zealand Therapeutic Agency in 2003. However, the New Zealand Select Committee did not agree to the inclusion of "complementary medicine" within the scope of the new agency. As a result, the Natural Products Bill was introduced on 7 September 2011. It will provide for a standalone scheme for the regulation of natural health products. The Bill was reported back by the Health Select Committee on 31 October 2012.

What is the remedy?

A new Natural Health and Supplementary Products Act based on the following principles:

- Natural health and supplementary products ("NHSPs") should be fit for human use
- Regulation of NHSPs should proportionate to the risks associated with their use
- NHSPs should be accompanied by information that is accurate, and tells consumers about the risks, side effects and benefits of use

- The health benefit claims for NHSPs should be supported by scientific or traditional evidence.

The principle is that the products covered by the scheme will be low risk, with higher risk products requiring approval under the Medicines Act. In addition, within this scheme itself, there is also scope for varying degrees of control for NHSPs with varying degrees of risk.

What is an NHSP?

An NHSP is any product that:

- Is manufactured for human use and for the primary purpose of bringing about a health benefit; and
- Contains only permitted ingredients, or "new" ingredients approved by the Authority; and
- Is not a food, medicine, related product or medical device.

Health benefit is defined as any one or more of the following benefits:

- The maintenance or promotion of health or wellness
- Nutritional support
- Vitamin or mineral supplementation
- Affecting or maintaining the structure or function of the body
- Relief of symptoms.

A permitted ingredient is a substance listed in Schedule 1 of the Act, and declared by the Authority to be permitted.

Distinction with medicines

NHSPs can provide a health benefit, but they cannot treat named conditions, or be used wholly or principally for a therapeutic purpose.

The Bill will create an offence of publishing an advertisement that includes a health benefit claim that directly or by implication states or suggests that an NHSP is able to "treat or can assist in the treatment of a named condition". Interestingly, the Bill states there would be no offence if the "treatment" claim is approved by the Authority.

In addition, the Medicines Act regulates products used wholly or principally for a therapeutic purpose.

Accordingly, NHSPs provide health benefits, but do not treat conditions or have a therapeutic purpose.

The Bill also recognises that the distinction may not always be clear in practice. The Authority has the power to declare a product to be an NHSP if it is satisfied that the product meets the definition in the Bill, and that a declaration is necessary for clarity.

The regulatory scheme

An NHSP Authority is established, with significant powers. The Authority is the Director-General of Health.

For every NHSP, there must be a product notifier ("PN"), typically the manufacturer (in New Zealand) or the importer. The PN has significant obligations.

Product notification

The PN must make a product notification to the Authority, covering product, PN and manufacturer details, health benefit claims and any other information required by Regulations.

The PN must declare that the information is accurate and complete and that it is able to provide the Authority, on request, evidence to support the health benefit claims. In addition, the PN must publish, on the internet, a summary of the evidence relied on.

A product notification is not required for:

- An NHSP made by a practitioner for a specific person, on request of that person to use the practitioner's judgement as to the treatment required
- An NHSP used for export only, unless an export certification from the Authority is requested

- An NHSP exempted by the Authority, because compliance would be impracticable, unreasonable, and inconsistent with the principle that regulation should be proportionate to risk
- An NHSP with an active ingredient less than 20 parts per million.

The Authority can audit, suspend or cancel a product notification.

The product notification will be listed on a database maintained by the Authority.

Regulation of health benefit claims

Health benefit claims must be "allowable". A product notification may contain only allowable claims. The label and advertisements for any NHSP must only have allowable claims. This applies to NHSPs which do not need product notification.

The Authority decides what claims are allowable in respect of named conditions, and will publish a list of such claims. In deciding what claims are allowable, it must be guided by the principles of the Act, consider the nature and quality of the evidence provided, and be satisfied that the level of risk is low. If traditional evidence is provided and that evidence is reference to information in an approved pharmacopoeia, the Bill requires the Authority to accept that information.

A named condition is a condition listed in the WHO publication "*International Statistical Classification of Diseases and Related Health Problems*".

Evidence may be scientific or traditional. Scientific evidence is defined as evidence derived from empirical studies and repeatable experiments. Traditional evidence is evidence of traditional use of a substance based on knowledge, beliefs, or practices passed down from generation to generation.

Regulations may be made setting standards for scientific and traditional evidence and to prescribe restrictions or requirements on health benefit claims made for NHSPs which are exempted by the Authority from product notification or NHSPs with an active ingredient of less than 20ppm.

Other requirements

The PN of an NHSP must notify the Authority as soon as the PN "becomes aware of any serious adverse reaction to the product". This is a reaction which:

- Results in, or prolongs hospitalisation
- Is life-threatening or fatal
- Results in disability, incapacity or congenital abnormality, or
- Is an allergic reaction.

An NHSP cannot be sold for administration by injection or parenteral infusion, or by application to the eye.

Regulation of ingredients

Any ingredient used in an NHSP must be approved by the Authority. The ingredient must be or belong to a class of substances listed in Schedule 1 of the Bill which includes:

- A plant, an alga, a fungus, a mineral or a non-human animal material
- A substance obtained by extraction from the above
- Vitamins
- Amino acids
- A synthetic equivalent of any of the above
- A mineral compound
- A micro-organism
- An additive, or a formulation aid.

The Authority will prepare, and include on the database, a list of permitted ingredients. In deciding whether a substance is to be permitted, the Authority may conduct a safety assessment. It must have regard for and give weight to, as it considers appropriate, whether a recognised (overseas) authority permits these sort of substances in a similar product, and whether the substance is recognised in traditional medicine or pharmacopoeias.

The Authority may also declare a substance to be a prohibited ingredient.

If a PN intends to use a substance which is not permitted, it must apply to the Authority. If the Authority does not raise a concern within 90 days, the new ingredient may be used in the product. However, the PN may not complete a product notification (and therefore sell the product) until the Authority has given written approval that the new ingredient may be used.

Regulation of manufacturing

The Authority must establish a code of practice for manufacturing for NHSPs. In doing so the Authority must:

- Be guided by the principles of the Act
- Comply with any requirements specified in Regulations; and
- Consult with persons or organisations representative persons like to be affected.

A manufacturer must obtain a licence to manufacture NHSPs, except where the product will be exported and an export certification will not be sought, or where a practitioner makes an NHSP for administration to a particular person on request.

The Authority may grant a licence if it is satisfied that:

- The manufacturing facilities meet the requirements of the Code; and
- The licence holder is a fit and proper person.

The Authority can audit facilities and has the power of entry for that purpose.

Will it work?

A key objective of the regime is that regulation should be proportionate to the risks associated with NHSPs, and that it recognises that in general NHSPs are low risk.

The key features of NHSPs, under the new Bill, are that:

- Their primary purpose is health benefits, not treatment or a therapeutic purpose; and
- They use specified permitted ingredients.

The Bill therefore assumes that products with these features are low risk.

Such products can present significant risks if they are not manufactured safely. The regime does address this risk by requiring licensing of manufacturing facilities, establishing a code of practice for manufacturing, as well as requiring NHSPs to be made using ingredients authorised by the Authority.

The Bill also provides for flexibility to recognise differing degrees of risk within the NHSP category. For example; the Authority must have regard to the principle that regulation of NHSPs should be proportionate to the risks associated with their use when deciding on allowable health benefit claims, and whether a particular product should be exempted from the product notification requirement.

The Bill will regulate health benefits claims:

- Claims must be allowable, as determined by the Authority, based on its review of the scientific and traditional evidence
- They must be included in the product notification
- The PN must declare that it is able to provide evidence to support the health benefit claims to the Authority on request
- The PN must publish on the internet a summary of evidence that the PN relies on to support the claim.

The Bill will provide transparency:

- A database will established containing product notifications, and permitted and new ingredients
- The Authority must publish on the internet a list of allowable health benefit claims, and the code of practice for manufacturing of NHSPs.

The Authority has significant responsibility and powers. The workability and success of this system as a whole will, to a large extent, depend on the actions of the Authority, for example:

- Its decisions on allowable health benefit claims, and in particular the evidence base it will require

- Its decisions on the permitted and prohibited ingredients
- Its exercise of powers of audit, suspension and cancellation of product notifications
- Its regulation of manufacturing of NHSPs through the establishment of the code of practice for manufacturing, and its administration of the licensing and audit regime for manufacturers
- Using its power of product recall.

The success and workability of the scheme will also depend on Regulations made under the Bill. The Regulation making power is wide, and includes:

- Adding or removing substances (potential ingredients) from Schedule 1
- Adding or removing approved pharmacopoeia
- Standards for evidence
- Criteria for assessing new ingredients
- Labelling requirements.

In principle, the regime contains the elements needed for the system to achieve its stated objectives. The unknown is whether the new system will contribute to the reduction of the reported large number of therapeutic claims made for NHSPs, which are breaches of both the existing and new regime.

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