Strategic Objective – CHC Shapes the Agenda and is the Voice of Industry

The Complementary Healthcare Council provides a summary paper on the New Zealand Natural Health Products Bill (Government Bill 324-1). This paper outlines the general policy and proposed reforms under the Bill and is intended to inform members in developing a position on appropriate regulatory models for Complementary Medicines.

Background

Natural Health Products (NHP) in New Zealand will not be regulated by ANZTPA. Instead, the government intends to introduce a NHP Regulatory Scheme. The regulator will be a unit within the Ministry of Health, separate from the medicines regulator Medsafe. The unit will be advised by a Technical Expert Advisory Committee. Currently NHP are regulated as dietary supplements under the *Dietary Supplements Regulations 1985* or supplemented foods under the New Zealand (Supplemented Food) Standard 2010. These dual standards are widely considered to be confusing for the industry and difficult to enforce.

The NZ Natural Health Product Bill

On 15 September 2011, the Natural Health Products Bill was read for the first time in the New Zealand Parliament. The proposed new legislation will cover most natural therapeutic-type products which are currently regulated as dietary supplements under the *Dietary Supplement Regulations 1985*. The current regime is generally considered to be out of date and unclear with products for ingestion being covered by the *Dietary Supplements Regulations 1985*, while other NHP are covered by the *Medicines Act 1981*.

The Natural Health Products Bill proposes a new category of products – 'Natural Health Products' (NHP). An NHP is a product that is intended by the Sponsor[1] of the product (i.e. those who import or manufacturer or arrange for the import or manufacture), to be administered to a person, to bring about a health benefit to that person. NHPs must contain only natural health product ingredients and no prohibited ingredients. Further, NHPs must be administered by the following means only:

- oral ingestion;
- application to the skin, scalp or nails;
- application to the teeth, throat, anal canal or vagina; or
- application to the mucosa of the mouth or nose.

The Bill proposes establishment of a Natural Health Products Regulatory Authority who will assess the safety, quality and efficacy of all natural health product ingredients. In addition the Bill gives power to the Regulatory Authority to impose penalties against those manufacturers or importers who contravene new Regulations. In this way, the proposed legislation aims to ensure that all natural products are safe and of high quality to give consumers and manufacturers confidence that natural health products are true to label. This is considered a positive move for both industry participants and consumers.

Before distributing the NHP, sponsors will be required to submit to the Authority information about the NHP, themselves, the manufacturer and health benefit claims of the NHP. The Authority will have the power to audit, suspend or cancel NHP notifications, as well as recall previously notified NHPs. Product notifications will not be required for any "export-only natural health products." However, if a sponsor requires an export certificate, it must do so meeting the requirements of the Authority which includes providing a product notification.

- All New Zealand manufacturers of NHPs will need to be GMP licensed, unless exempted by the Authority (for cases of export-only).

[1] A Sponsor of a NHP, within the context of the Bill, must be resident in New Zealand – s12 *Natural Health Products Bill*.

- Ingredients will need to fall within permitted ingredient classes, failing which ingredients cannot be used unless assessed and approved.
- All NHPs distributed in New Zealand will need to comply with labelling requirements.
- Heavy penalties for breaches: fines up to $500,000 for corporations and, in respect of individuals, fines up to $100,000 and imprisonment for up to 5 years.
- A staggered transition period of 3 years.
- The revocation of the Dietary Supplements Regulations 1985.

ANZTPA Impact

Concern has been voiced as to how this new legislation will impact the implementation of the joint scheme with Australia for the uniform trans-Tasman regulation of therapeutic goods. Despite these concerns, the New Zealand Ministry of Health has expressed its intention to continue moving ahead with the joint scheme, while continuing to regulate NHP under a New Zealand only scheme. This is similar to the manner of operation of the New Zealand Dietary Supplements Regulations, which the new Bill will replace, and will result in inconsistent regulations in New Zealand and Australia.

Additionally there are concerns with regard to the cost of establishing a new regulatory authority; developing an online, automatic product notification system that has integrity and is free from abuse and maintaining the NHP database and prohibited lists. Sponsors can also expect higher compliance costs, as they will be required to pay fees to notify the regulator of their products; if they currently do not have a GMP licence, they will need to obtain one for the manufacture of their products; and will be required to pay for audits of the manufacturing licence.

Some sponsors can also expect a greater regulatory burden as a result of the new labelling requirements. In addition, they will have to comply with the new manufacturing code of practice and provide the necessary evidence to support claims relating to the health benefits of their products. A particularly onerous regulatory obligation is that sponsors will be required to provide (and pay the cost of) a new product notification every time there is a change in the product's manufacturing arrangements, health benefit claims or ingredients – no matter how minor.

As the approval process in New Zealand will likely be more cost effective and time efficient, companies may continue to import New Zealand compliant products into Australia under the TransTasman Mutual Recognition Arrangement (subject to the risk inherent in relying on this Arrangement).[2]

Going Forward

Following the first reading of the Bill in September 2011, the Bill was referred to the Health Select Committee. The Committee is not due to deliver its report until **1 October 2012.**
The NZ Natural Health Products Bill 324-1 (2011) can be located here.

[2] When relying on the Trans-Tasman Mutual Recognition Arrangement there is always a risk that the Australian Quarantine and Inspection Service (**AQIS**) may seize the products if AQIS considers the products are a therapeutic good (for example in pill form) and thus should be listed with the Therapeutic Goods Administration.