Background on the Natural Health Products Bill

Currently, natural health products are regulated by way of the Dietary Supplements Regulations 1985 or as medicines. The Dietary Supplements Regulations has some restrictions on amounts of certain substances allowed and also does not allow health benefit claims. It is widely accepted that the Regulations are outdated and various attempts to supersede these regulations have been undertaken. Due to these attempts, the regulations have not been kept up-to-date (with respect to the latest acceptable amounts of substances) or adequately enforced. With regard to Schedule 1 under the Medicines Regulations, many of the substances of interest were classified at the 7th meeting of the Medicines Classification Committee and have not been revisited.

The objective of the Natural Health Products Bill (or the Natural Health and Supplementary Bill) is that the resulting Act and regulations should provide consumers with natural health products (NHPs) that are safe, of low risk, have accurate and adequate information to provide for consumer choice, and have claims of health benefits that are backed by scientific or traditional evidence.

The Bill intends to regulate NHPs that are for unmediated retail sale; that is, consumers can self-select and their main information source is the label and the company's website. Products supplied to clients via consultation from a health practitioner (including a natural health practitioner) will not be regulated.

Regulation of NHPs is intended to be light-handed, with products notified to the Ministry of Health, rather than a pre-market assessment and approval of the product, as is the case with medicines. Notifiers provide information on their product, such as formulation, manufacturer, compliance with manufacturing standards, evidence to support health claims, into a database.

To ensure the products are of low risk, the Ministry will implement checks and balances. The most important and relevant to the Medicines Classification Committee is that notified products must contain only permitted substances.

Permitted substances

The Ministry has collated a large (>5,500) list of substances, the Permitted Substances List (PSL), that are considered to be low risk and allowable to be used in notified NHPs. This list has been collated over several years according to the following "rules" that the substance:

- is on the TGA or Health Canada list of permitted substances for their listed/natural medicines
- was on the draft list of substances allowed to be used in Class 1 medicines under the joint regulatory scheme with Australia (the ANZTPA project that was officially closed in 2014)
- has been requested by applicants where there is some robust information found regarding their safe use in a comparable product, e.g. allowed for sale in another reputable country, or a traditional setting, e.g. a plant used in Samoan traditional medicine

Substances not added to the list:

- **Scheduled medicines included in Schedule 1 of the Medicines Regulations 1984**
- Controlled drugs included in Schedule 1 of the Misuse of Drugs Act 1975
- Organisms in Schedule 1 of the Convention on the International Trade in Endangered Species (CITES)
- Substances that meet the definition of a psychoactive substance under the Psychoactive Substances Act 2013.

- Substances that the TGA has decided should not be allowed to be used in listable goods
- Substances which the previous Interim Joint Expert Advisory Committee on Complementary Medicines (IJEACCM) decided should not be allowed to be in Class 1 medicines
- Substances where the name is so unspecific as to provide any certainty in identification
- Substances that Health Canada advised were not used in a licensed natural health product in Canada

Many of the substances on the PSL have thresholds or conditions on their use in NHPs in order to maintain their low risk status. Frequently, this threshold or condition is the set by the Medicines Regulations for a particular substance or through the limits set for the Dietary Supplements Regulations.

Health Claims

Under the Dietary Supplements Regulations, no health claims can be made, and it is likely that some substances were restricted to prevent implied claims. The NHP regime will allow notifiers to make health benefit claims for their products when supported by scientific or traditional evidence. A health benefit is restricted to 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
- The relief of symptoms

The Bill allows for "named conditions", which means any disease, disorder, condition, ailment or defect listed in the ICD. A notifier cannot make a health benefit claim for a named condition unless that claim is an "allowable claim" that has been approved by the Authority. Again, the claim must be supported by evidence. It could be that now health benefit claims are allowed, there may be justification to raise the permitted levels.

Manufacturing Controls

Safe manufacturing is an important objective of the Bill. The Bill requires that the Authority must be satisfied that the product is manufactured in a facility that meets the Code of Manufacturing Practice. Compliance with the Code for New Zealand manufacturers will be monitored through regular site audits, either by the Authority or other recognised authorities, and for imported products the Authority would generally look for evidence that the facility is audited by a local trusted regulator. The Code of manufacturing Practice is based on the internationally recognised principles of good manufacturing practice, revised to incorporate the Bill's principle of proportionality – the regulation of NHPs should be proportionate to the risks of their use. The draft Code details minimum standards for personnel, premises and equipment, production, quality control, and complaints and recalls.

Oversight of the regime

The Bill provides for regulatory powers to ensure that the sale or export of NHPs meet the requirements outlined in the Bill. There are provisions providing for prohibited methods of administration (injection or parenteral infusion, and application to the eye), offences for endangerment of human health, certain advertising, and deception and false representation.

The Authority will, for the purpose of protecting the public, be able to publish statements, recall NHPs if there is a good reason to believe they are not fit for their intended purpose, is mislabelled, or incorrectly identified.

Work to be done

The PSL is still a draft list, and considerable work remains to be done to ensure that it is as comprehensive as possible when the regime commences.

Potential notifiers have been invited to advise the Ministry of any new substances or changes to the thresholds or conditions on a substance. There is a view in the natural products sector that having a PSL will reduce access to existing products, and they have provided examples where this could occur and voicing their opposition to the Bill. They also point out a number of products that are available in other jurisdictions that are not able to be sold on the New Zealand market.

The Ministry has convened a technical advisory subcommittee to look at the safety of many substances put forward by the natural products sector. The subcommittee consists of experts from a variety of disciplines, including naturopathy, nutrition, toxicology, consumer, medicine, rongoā Māori, Ayurveda, etc. It is important to the sector that decisions made on NHPs come from people with expertise in those products.

It is clear, however, that many of the sector's concerns regarding the PSL are not due to the Bill, but to the restrictions and thresholds placed on them by the Medicines Regulations Schedule 1. For example, Vitamin D, zinc, and iodine. It is also clear that many of the thresholds for some NHP substances that are in Schedule 1 have not been revisited for some time.

Therefore, the Ministry has taken the opportunity to have a special session of the Medicines Classification Committee to reconsider a selection of substances where restrictions are placed on them by the Medicines Regulations.

It is important to signal to the natural products industry that new safety information on substances currently restricted by the Medicines Regulations will be revisited, and looked at in the context of the acceptability of having such products available for unmediated sale.

The Medicines Classification Committee papers

The Ministry has complied papers for consideration by the Medicines Classification Committee on behalf of those in the NHP sector who have requested changes to the levels of substances that are restricted by the Medicines Regulations. The Ministry has undertaken this approach as many in the NHP sector are unfamiliar with the process and the information required. It is anticipated that this will help facilitate future submissions to the Committee, and allow for open and transparent debate on the requests.