Therapeutic Products Bill

Therapeutic Products Bill was introduced to Parliament on 30 November, and will, if passed provide greater regulation of natural health products and medicines made from biological components.

This article sets out the key provisions in the Bill relating to natural health products and potential implications for the rural and natural resources sector.

The Therapeutic Products Bill (Bill) will replace the Medicines Act 1981 and the Dietary Supplements Regulations 1985 with a new law for medicines, medical devices, natural health products (NHPs), and other biological products.

The Bill is intended, among other things, to ensure that there is an appropriate level of assurance that NHPs imported and supplied in New Zealand are safe or made to an appropriate standard of quality, and to regulate any health benefit claimed in relation to the products.

What are Natural Health Products?

NHPs are defined in the Bill as products that:

- are intended for use in, on, or in relation to humans for a therapeutic purpose, such as maintaining or promoting human health; and
- consist only of NHP ingredients (that do not exceed specified concentrations). These include:
    - plants, algae, fungi, non-human animal materials (or extracts);
    - vitamins and provitamins, including salts and other compounds;
    - minerals and mineral compounds;
    - amino acids; and
    - microorganisms.

Based on the proposed definition of NHPs it is anticipated that they will include herbal remedies (in the form of capsules, tonics, and skin creams), vitamin and mineral supplements, traditional Māori remedies, traditional Chinese medicine, homeopathic remedies, and some remedies based on animal products, such as deer velvet, bee jelly, and fish oil capsules. The Bill will not change the current regulatory arrangements relating to medicinal cannabis or drugs controlled under the Misuse of Drugs Act 1975, or psychoactive substances controlled under the Psychoactive Substances Act 2013.

This could have implications for farmers, veterinarians, horticulturists, apiarists, and producers of products used in the manufacturing, import, and export of NHPs. While the Bill is still in its early stages of development, it is important to be aware that the Bill could introduce regulatory requirements that could impact the day-to-day operation of people and businesses engaged in these industries.

How will Natural Health Products be Regulated?

The Bill establishes the role of Therapeutics Products Regulator (**Regulator**). The Regulator will administer a new risk-proportionate market authorisation process in respect of NHPs, make rules about quality and safety, manufacturing, labelling, packaging, product information and consumer information, and undertake enforcement under the Bill.

NHPs will be regulated as separate category from medicines and medical devices and will be subject to a less stringent regulatory regime (recognising that that

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NHPs are lower risk than medicine). However, it is important to note that, as the Bill is presently drafted:

1. Unless an exception in the Bill applies, all NHPs will have to have market authorisation before they can be imported into, supplied in, or exported from New Zealand.
2. The Bill will apply to both commercial and non-commercial NHPs.
3. Products made from only one or more of the ingredients on the NHP ingredient list (which would be developed as secondary legislation if the Bill is passed) may be regulated as NHPs under the Bill.
4. A licence or permit may be required to manufacture or export a NHP, or to import a low concentration NHP in the course of a business or undertaking.
5. Health benefit claims, for example that an NFP is beneficial for maintaining and promoting health, relieves symptoms, or is a good nutritional supplement, will need to be substantiated by scientific evidence, evidence of traditional use, or both.
    - In respect of health benefit claims, for commercially produced NHPs, producers would be required to either use a list of pre-approved health benefit claims or apply for approval if they want to make a health benefit claim that is not on the list.
    - For non-commercially produced NHPs, people who make them will only be able make health benefit claims that are on a pre-approved list.
6. While the Bill is primarily concerned with human health, Parliament recognises that some NHPs designed for human use may also be used in the treatment of animals. The Bill provides that veterinarians will still be able to access and use NHPs products at their clinical discretion.
7. The Regulator may issue fines or prosecute for non-compliance with the regime established under the Bill.

Summary

If you are involved in the production, manufacture, supply of products that may fall into the definition of a NHPs, it will be important to keep up-to-date with the development of the Bill and any regulations that have an impact on your business.

Want to know more?

If you would like to know more about the Bill and the likely affects these changes may have on your business, please contact Vanessa Robb or Rebekah Mapson.