Comparing NHP Regulations from Canada and Australia

As with other health products, the manufacture, sale, and distribution of natural health products (NHP) is now truly international. Though the market may be global, the regulation of NHPs is not, with most countries having different regulatory frameworks for these types of products. Given the complexity of the sector and differences between the various regulatory approaches, comparing national approaches does not make for easy reading. As with a previous article comparing the approaches taken between Canada and the United States [isura.ca/2022/04/12/comparing-nhp-regulations-from-canada-and-the-usa/] this article will provide a high-level comparison of the regulatory approaches for Canada and Australia. It will explore some common features:

- Terminology and classification
- Who manages the regulations?
- How are the regulations applied?
- What claims/use can products make?
- How they must be made and inspected?
- What must be on the product labels?

Links to resources that provide more details about each regulatory approach can be found at the end of the article.

Terminology and Classification

Both Canada and Australia take a similar approach in grouping different types of products under an umbrella term – Natural Health Products in Canada and Complementary Medicines in Australia. These terms essentially capture the same types of products in each country notably vitamins, minerals, nutritional substances, probiotics, traditional medicines, and herbal medicines. Though the regulations are not the same, internationally both countries are considered leaders in the field and in many ways take similar approaches.

In Canada, a specific set of regulations - the *Natural Health Products Regulations* (*NHPR*) implement the law called the *Food and Drugs Act*. Under the law, NHPs are considered to be a subset of drugs. In Australia, complementary medicines are captured by a specific set of regulations and guidelines under the auspices of the *Australian Therapeutic Goods Act (ATGA).* Unlike the USA which considers most of these products as a type of food, both Australia and Canada regulate the NHP/Complementary Medicines category as a type of drug or therapeutic good.

Who manages the regulations?

In Canada, as with most other types of health products, NHPs are primarily regulated by the federal government. The responsible department is Health Canada (HC), and its primary centre of excellence, the Natural and Non-Prescription Health Products Directorate (NNHPD). The NNHPD is responsible for issuing product licenses, site licenses, as well as conducting post-market health hazard evaluations and providing policy support to post-market operations. The organizations responsible for post-market operations are the Marketed Health Products Directorate (MHPD), which is responsible for adverse drug reaction monitoring, and the Regulatory Operations and

Enforcement Branch, which is responsible for compliance and enforcement actions (a role it also plays for the majority of other therapeutic products).

As with Canada, in Australia the regulation of complementary medicines is primarily the responsibility of the national government through the Therapeutic Goods Administration (TGA). Many different parts of the TGA as well as other agencies and departments of the commonwealth government have responsibilities for the regulation of complementary. The primary responsibility lays with the Complementary Medicines and Over the Counter Medicines Branch Office, with the Manufacturing and Quality Branch overseeing certification of manufacturing sites and processes.

How are the regulations applied?

In both Canada and Australia, criteria are used to determine whether a product is, or is not, in compliance with the law. Though different approaches are taken, in each country, a pre-market application and licensing process is used to determine if a product meets standards prior to it being sold in the market.

In Canada, all product applications need to be evaluated by Health Canada before being approved with the process dependent on the type of application e.g., attestation to a monograph, requiring full review, etc. In Australia, there is no single regulatory "class" of product, with complementary medicines either being categorised as a listed medicine, an assessed listed medicine or a registered medicine – the categories are determined largely by the product claim that can be made and its safety profile. The review process reflects this with:

- listed medicine approved online through a system called the electronic listing facility (ELF),
- assessed listed medicines approved online but with assessment of evidence for efficacy made by the TGA premarket, and
- registered medicines undergoing a full evaluation of all aspects by the TGA premarket.

The vast majority of approved complementary medicines (approximately 11,000) are categorised as listed medicine with registered medicines numbering under 100 with many of those grandfathered before the *ATGA* came into force. The category of assessed listed is still new with very few being approved and, on the market,

In both countries, a risk-based approach is taken with required monitoring for products on the market. Each country has specific requirements for reporting adverse events and side effects. Again, this is a very high-level overview, and both sets of regulations are far more detailed.

A major operational difference between Canada and Australia is that the Australian regulations are completely cost recovered with sponsors required to pay a fee for implementation of the regulatory framework. This includes product listing, assessed listed, registration and site audits discussed in the next section. Though cost recovery was identified as an important step when the Canadian *NHPR* were being developed, this currently does not occur in Canada for NHPs with funding coming from government budget. Health Canada has identified developing and implementing a cost recovery regime in the coming years as a priority.

What claims can products make?

In Canada, NHPs are the same as any other non-prescription health product in terms of the claims they may make. They *must* make a claim, that is, an NHP cannot be sold as a medicine without any supporting proof of what it does or investigation into its safety. The use may come from the full gamut of treatment, altering function, risk reduction and health promotion. NHPs can also make claims based on traditional forms of health and healing such as western herbalism or traditional Chinese medicines. The type of claims must be reflected in the type, quantity, and quality of supporting evidence submitted for review by Health Canada. For example, the traditional evidence that is accepted by Health Canada is that which reflects scientific principles of reproduceable results, integrity in the dosage form and consistency in the patient population over decades of recorded study. For any use, additional data must be produced and considered to support more specific clinical claims. Health Canada has developed specific review pathways including the use of monographs to facilitate this process.

Australia takes a similar approach to Canada for complementary medicines with products able to make the full gamut of self-care claims based on the quantity and quality of evidence provided by the sponsor. Again, like Canada, traditional as well as modern clinical evidence are accepted with details outlined in the *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM). The "claim permitted" reflects the extent of review with

- listed medicines limited to lower-level indications such as traditional use and health promotion,
- assessed listed medicines include more treatment related indications, and
- registered complementary medicines allowed to have full treatment indications.

Both of these approaches to "evidence required to support claims" means that there are no disclaimers on the labels of either Canadian or Australian products related to the product's safety, efficacy, or quality.

How must these products be made and inspected?

Both countries have specific requirements for Good Manufacturing Practices (GMPs) which manufacturers, importers and distributors must ensure are being followed in order to maintain required site licences in Canada or site audit in Australia. However, each country takes a very different approach to how the regulations are applied.

In Canada, with its pre-market approach, a site licence must be issued for the manufacturing facility before a NHP is allowed to come to market. This is typically an unvalidated review approach as there is no requirement for a systematic on-site inspection required. In Australia, as with all other therapeutic goods, all manufacturing sites must have passed an onsite audit by the TGA or other recognised regulatory agency. These inspections are based on the principles of the Pharmaceutical Inspection Cooperation Scheme (PICs). Irrespective of whether the product is considered listed, assessed listed or registered, a successful site audit is required before any product approval process can even begin. This Australian approach is widely considered to be the international gold standard.

What must be on the product labels?

Given that both Australia and Canada have established, drug/therapeutic good-based regulations, it is not surprising that they have very well-defined requirements for product labeling.

These comprehensive labeling requirements for labels include information such as:

- all ingredients (medicinal and non-medicinal),
- quantities,
- dosage form,
- recommended dose and duration of use,
- indications/purpose of use, and
- risk information such as potential drug interactions, side effects contraindications, allergens

In addition, the regulations in both countries require that a label contains a number identifying that they have been approved by the regulator. In Canada, this is an 8-digit Natural Products Number (NPN) or DIN-HM for homeopathic medicines. For Australia, this is shown by an Aust L or Aust R number. Both countries require details of the manufacturer, supplier, and distributor to be on the label.

Guidelines also deal with how information must be presented on the label. As you can imagine, there are a great deal of similarities between each country's approach. While Canada currently does not require a product fact table, this will become mandatory under the new regulations coming into force in the coming years[1].

As with all products sold in Canada, this information must be presented in both official languages, English and French. Health Canada is currently exploring how labeling for NHPs can be improved – learn more in this ISURA article: *Improved Labelling for Natural Health Products – Health Canada Initiative* in the Articles & Info section of the ISURA website: isura.org.

Australia takes a different approach by only recommending the use of tabulated Critical Health Information for listed medicines rather than making such information mandatory on product labels.[2] Since listed medicines make up the vast majority of approved complementary medicines in Australia, this means that the majority of products in this category currently do not require the equivalent of a product facts table.

Final thoughts

Australia and Canada have long been considered global leaders in the regulation of complementary medicines/natural health products. Both countries consider them as a specific category of medicines rather than foods. Many other regulators look to these countries' successes and failures in developing national regulatory frameworks. Though similar in many ways the two countries do differ in some aspects of their approach to regulating these types of products. Australia has focused on quality and manufacturing establishing the gold standard in Good Manufacturing Practices and

[1] https://canadagazette.gc.ca/rp-pr/p2/2022/2022-07-06/html/sor-dors146-eng.html
[2] https://www.legislation.gov.au/Details/F2017C00744

utilizing required site audits as an essential part of the regulations. Canada has focussed on product evaluation and the evaluation of evidence supporting claims made for a product including establishing an extensive set of NHP monographs exclusively developed as regulatory tools. The question now is what next?

Though both countries' regulations are still considered at the vanguard of the regulations for this category, it has been more than 20 years since both approaches were established. In the past couple of decades much has changed with the emergence of a truly international market; the increase in global manufacturing; online sales; changes in how these products are used; advances in research and innovation; and the role that natural health products/complementary medicines now have in the larger health care system. In response, the regulations in both countries have evolved to better reflect the current reality and specific domestic priorities. It will be interesting see how things develop over the coming years.

The information in this article provides a general comparison between the regulatory approaches of Canada and Australia. If you would like more information about specific areas mentioned above or specific topics such as advertising/marketing regulations, you can find more details about the Canadian approach at https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation.html
and the Australian approach at How we regulate | Therapeutic Goods Administration (TGA).

About the author:
Michael Smith trained as a pharmacist and as a naturopathic doctor. He is recognized internationally as an expert in natural health products and complementary & alternative medicine. For more than 10 years, he worked in senior regulatory positions at the then Natural Health Products Directorate, Health Canada, and the Therapeutic Goods Administration in Australia. In addition to his international work as a consultant, he is an Adjunct Professor at the National Center for Natural Products Research at the University of Mississippi, USA and an Adjunct Associate Professor at the National Centre for Naturopathic Medicine at Southern Cross University, Australia. Michael is a member of ISURA's Scientific Advisory Committee.