Comparing NHP Regulations from Canada and the United States of America

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, their regulation is not, with most countries having different regulatory frameworks for these types of products. Given the complexity of the sector and differences between the regulatory approaches, comparing national approaches does not make for easy reading. Instead, this article will provide a high-level understanding of how the regulatory approaches for Canada and the United States of America compare with one another by looking 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 more resources that provide more details about each regulatory approach can be found at the end of the article.

Terminology and Classification

Both Canada and the USA take a similar approach in grouping different types of products under an umbrella term – Natural Health Products in Canada and Dietary Supplements in the USA. These terms capture the same types of products in each country notably vitamins, minerals, nutritional substances, probiotics, traditional medicines and herbal medicines. The one exception is homeopathic medicines which are NHPs in Canada but are not considered dietary supplements in the USA. Also, by definition, dietary supplements only include products that are taken by mouth and so exclude products used topically such as creams and ointments, as well as sublingual products.

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, NHP are considered to be a subset of drugs. In the United States (US), dietary supplements are also covered by a specific set of implementing regulations created in response to revision of the law called the *Federal Food, Drug, and Cosmetic Act.* The revision is the *Dietary Supplements Health Education Act (DSHEA).* Note that there is a misconception that dietary supplements are not regulated. This is not the case.

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 the primary centre

of excellence therein is the Natural and Non-Prescription Health Products Directorate (NNHPD). The NNHPD is responsible for issuing product, and site licenses, conducting post market health hazard evaluations and providing policy support to post market operations. The organizations responsible for the post market operations are the Marketed Health Products Directorate (MHPD), 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 the United States the regulation of dietary supplements is primarily the responsibility of the federal government through the U.S. Food and Drug Administration (FDA). Though many different parts of the FDA as well as other agencies and departments of the federal government have responsibilities for the regulation of dietary supplements, the primary centre of excellence is the Office of Dietary Supplements Programs within FDA's Center for Food Safety and Applied Nutrition. Responsibility for enforcement of various FDA regulations is FDA's Office of Regulatory Affairs.

How are the regulations applied?

In both Canada and the US criteria are used to determine whether a product is or is not in compliance with the law. However, in Canada, a pre-market application and licensing process is used to determine if a product meets standards prior to it being sold in the market. Sites where products are made must also be licensed under Canadian regulations. In the US, products that do not meet regulatory requirements for finished dietary supplements are subject to regulatory action. This is similar to how the majority of all food products are regulated in both Canada and the US and reflects the difference in how the products are legislated. In order for either the Canadian or US system to be effective post-market validation must occur.

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.

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 use of monographs to facilitate this process. This approach to evidence means that there are no disclaimers on the labels of Canadian products related to the product's safety, efficacy or quality.

In the United States as dietary supplements are considered to be foods, they are far more limited in the claims that they can make and in fact do not need to make a claim at all. Dietary supplements can only make claims related to structure and function, and are prohibited from making disease cure, treatment, or prevention claims. In addition, if a claim is made, the label must contain a disclaimer that it has not been reviewed by the FDA. An additional disclaimer that "This product is not intended to cure, treat, mitigate, or prevent a disease" is mandated on finished dietary supplement products in the US.

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 facility registration in the USA. 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 an unvalidated review approach as there is no systematic government led/managed on-site/physical inspection required. In the US, the FDA do conduct onsite/physical inspections as part of GMP enforcement.

In a world where product quality is one of, if not the largest risk to health, many in the industry question whether either approach is adequate. To ensure quality, this has led many manufacturers to obtain inspections from valued third parties such as the United States Pharmacopeia (USP), NSF or ISURA.

What must be on the product labels?

While requirements for what needs to be on a label exist for both countries, the requirements for Canada are far more detailed and rigorous than in the United States. In the United States, under DSHEA, labels for dietary supplements are required to contain:

- the statement of identity (name of the dietary supplement)
- the net quantity of contents
- the nutrition labelling
- all other ingredients
- the name and place of the business of the manufacturer, packer or distributor.

In addition, there are additional requirements under food regulation to ensure safe use. Dietary supplements also need to have a supplements fact table on the product label, based on the

Nutrition Facts panel required for conventional food, but this is only required to contain very limited information. The label must contain a disclaimer that any claim has not been reviewed by the FDA and that the product is not intended to cure, treat, etc.

The requirements for labels of NHPs in Canada are comprehensive including 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.

In addition, the label must contain lot numbers, an 8-digit Natural Products Number (NPN) or DIN-HM for homeopathic medicines issued by HC together with information on the manufacturer/distributor/supplier. As with all products sold in Canada, this information must be presented in both official languages, English and French.

There are major changes on the way with the recent publication of new regulations aimed at improving NHP labels. Amongst the changes are improved cautionary labeling around allergens; gluten and aspartame, use of electronic contact information; and in most cases mandatory use of detailed Product Facts Tables. These changes will come into effect in the next 3 years for new products with an additional 3 years for products that were on the market when the new regulations were published.

Final thoughts

The question everyone asks is which one is the better approach? In truth, both have advantages and disadvantages and were developed to reflect each country's needs and priorities at the time. The original Canadian *NHPR* are almost 20 years old, and the US DSHEA came into force in the 1994. Both sets of regulations could be improved to better reflect a very changed world and market. In Canada, there are current discussions about what improvements need to be made, and in the USA, there is on-going debate as to whether DSHEA is still the best approach or whether a "DSHEA 2.0" is needed.

The information in this article provides a general comparison between the regulatory approaches of Canada and the USA. If you would like more information about any 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 US approach at https://www.fda.gov/food/dietary-supplements

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.