Doing Business in Canada: Natural Health Products Legislation

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For international clients seeking to do business in Canada's natural health product ("**NHP**") sector, understanding Canada's regulatory landscape is a critical first step. Canada maintains a robust and detailed framework governing the classification, sale, manufacturing, labelling, importation and oversight of NHPs. While this framework is designed to promote product safety, quality and consumer confidence, it can be complex for companies doing business in the Canadian marketplace.

This overview has been prepared to address the questions most frequently asked by our international clients. It outlines the core requirements under the Natural Health Products Regulations ("**NHPR**") and highlights key considerations relating to product licensing, site licensing, good manufacturing practices ("**GMPs**"), labelling obligations and ongoing regulatory modernization.

We are pleased to support your business activities in Canada. If you have questions with respect to any portion of the below, or require further information on a topic not addressed here, please do not hesitate to contact us.

Category	Question	Answer
1. Core framework	What are the primary laws governing NHPs?	NHPs are regulated under the *Food and Drugs Act* and the NHPR.
2. Product scope	What business activities are regulated under the NHPR?	The NHPR applies to the sale, manufacturing, packaging, labelling and importation for sale of NHPs, as well as the distribution and related storage of NHPs.
3. Regulatory authority	What is the regulatory authority for NHPs?	The Natural and Non-prescription Health Products Directorate (formerly the Natural Health Products Directorate) regulates NHPs and non-prescription drugs in Canada.
4. Classification	What counts as NHPs?	Generally, NHPs are naturally occurring substances used to maintain or restore good health. NHPs may be derived from plant, animal, microorganism or marine sources. NHPs appear in many forms, including tablets, capsules, tinctures,

		creams, ointments and drops. Common examples include vitamins and minerals, herbal remedies, homeopathic and traditional medicines.
5. Prescription drugs	Are NHPs regulated differently from prescription drugs and medications in Canada?	**Yes** – NHPs are regulated differently from prescription drugs and medications. Products such as herbal remedies, certain sunscreens, vitamins and minerals are generally lower-risk and are regulated through requirements tailored to their specific risk profile.
6. Product licensing	Can we sell NHPs in Canada without a product licence?	**No** – A product-specific licence is required to sell NHPs in Canada. Licensed products are identified by a Natural Product Number or a Homeopathic Medicine Number on the label.
7. Licensing application	Is there required content that must be included in a product licence application?	**Yes** – A detailed product licence application must be submitted to the regulator. The application must provide information for each medicinal ingredient, a qualitative list of non-medicinal ingredients with their purposes, all proposed brand names, recommended conditions of use, supporting safety and efficacy evidence, proposed label text and product specifications with which the NHPs will comply. The application must include an attestation to compliance with the manufacturing, packaging, labelling, distribution and storage requirements under the regulations. If the applicant is located outside Canada, the application must include the contact information of a representative in Canada to whom notices may be sent.
8. Amendments	Do you need to amend a product licence before selling NHPs if certain changes are made to the product?	**Yes** – A licence amendment is required before selling any lot or batch affected by the change to the NHP. Amendments include changes to the recommended dose or duration of use; changes to the recommended use or purpose; deleting or modifying risk information on the label; changes to the source material or synthetic nature of medicinal ingredients; changes to potency; certain

		changes affecting safety or efficacy; or specific changes to the product's specifications or test methods.
9. Notification	Do you need to notify the regulator if certain "non-fundamental" changes are made to NHPs after they have been licensed?	**Yes** – If "non-fundamental" changes are made, the licensee must notify the regulator within 60 days after the change has been made. These changes could include updates to applicant information, adding or substituting a non-medicinal ingredient that does not affect safety or efficacy, selling NHPs under a new brand name, changing the common or proper name of a medicinal ingredient or adding risk information to the label.
10. Site licensing/ manufacturing & importing	Do we need a site licence to manufacture, package, label or import NHPs for sale?	**Yes** – Under the NHPR, a site licence is required to manufacture, package, label or import NHPs for sale in Canada.
11. Quality	Must NHPs be manufactured, packaged, labelled, imported, distributed or stored in accordance with GMPs in order to be sold?	**Yes –** NHPs must be manufactured, packaged, labelled, imported, distributed or stored in accordance with GMPs in order to be sold in Canada. When the product is imported, it may be sold if its manufacturing requirements are equivalent to those set out in the GMPs section of the NHPR.
12. Labelling	Do the new "improved labelling" rules apply, and is there a compliance deadline?	**Yes** – All NHPs have until June 22, 2028, to comply with the new labelling requirements. However, Health Canada encourages implementation of the improved labelling requirements as early as possible.
13. Recalls	If we start a recall, do we have to report it to the Minister within a fixed timeline?	**Yes** – Recalls must be reported within three days after the day the recall is commenced.
14. Regulatory modernization	Is the NHPR being modernized to support innovation, reduce business barriers and protect Canadians?	**Yes** – The NHPR is being modernized as part of the federal government's "Red Tape Review" launched in July 2025. Health Canada's September 2025 report outlines planned regulatory changes for NHPs, including introducing a simple registration pathway for certain products, reducing pre-market requirements where post-market oversight is more suitable, establishing flexible risk-based vigilance for all NHPs

		and amending labelling rules to allow greater flexibility.

Successfully doing business in Canada's NHP market requires thoughtful planning and a clear understanding of the applicable laws. Our team regularly assists companies in navigating these obligations. We focus on delivering practical, business-focused advice tailored to your commercial goals.

Have more questions about doing business in Canada? Please click here or scan the QR code to access Aird & Berlis LLP's Market Expansion Dashboard, your one-stop-shop for market expansion resources.

Disclaimer: This article offers general comments on legal developments of concern to business organizations and individuals and is not intended to provide legal advice. Readers should seek professional legal advice on the issues that concern them.

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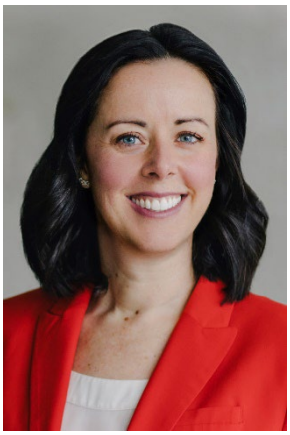
Fiona has extensive experience advising international businesses entering the Canadian market. To date, she has advised more than 100 companies expanding into Canada. Fiona advises clients in this space all day, every day. She has been practising for more than a decade and is a regular speaker and writer on market expansion matters. Fiona is proud to have been recognized by *The Best Lawyers in Canada, The Canadian Legal Lexpert Directory* and *Benchmark Canada.*

A proactive and comprehensive approach is required to succeed in a new market. Fiona manages teams of other lawyers and patent agents to provide her clients with a full range of legal services to help their businesses grow. She acts as project manager to ensure her clients receive seamless legal services in all relevant areas.

Fiona takes great care to understand her clients' businesses and deliver advice that is tailored to meeting their specific needs. Her responsiveness, dedication to clear communication and hands-on approach show that she is personally invested in the success of her clients.

Fiona is pleased to offer a multitude of resources answering often- asked questions about expanding into Canada, including this video and this one-page guide.



Kaitlin Soye, PhD

Partner

Kaitlin is an intellectual property lawyer who enjoys collaborating with clients to develop effective IP strategies. As a trained scientist with a PhD in experimental medicine, she is adept at fusing legal and scientific principles to devise creative solutions to complex problems.

Kaitlin is a member of the firm's Intellectual Property and Litigation & Dispute Resolution Groups. She represents a broad range of clients, including pharmaceutical, life sciences, technology and telecommunication companies, specifically with regulatory and IP litigation needs.

Kaitlin has extensive Federal Court experience and is efficient at managing the challenges that accompany complex litigation. She leverages her scientific background to represent life sciences and pharmaceutical industry clients in patent and regulatory disputes.

Alyssa Marchese

Articling Student

Alyssa summered at the firm in 2023 and 2024. She recently graduated from the JD program at Osgoode Hall Law School. During law school, Alyssa held a variety of leadership roles, including Co-President of the Canadian Italian Association of Osgoode, Communications Director of the Environmental Law Society, Marketing Director of the Osgoode Society for Corporate Governance, Events Coordinator of the Osgoode Emerging Technology Association and Osgoode Ambassador to the Ontario Bar Association. She also participated in the Osgoode Business Clinic and worked as a caseworker at the Investor Protection Clinic.

Prior to law school, Alyssa earned a Bachelor of Environmental Studies from York University, graduating *summa cum laude*, and was recognized with many awards for community leadership and academic achievement. She was active in student leadership, leading the Italian Student's Association, acting as a Peer Mentor Coordinator, and serving as a member of the Equity Committee, the Faculty Council and the Inclusion Group.