

Life Sciences: Coverage for the Nutraceuticals and Clinical Trials Industries

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Nutraceuticals:

The nutraceuticals market is rising in Canada, fueled by the increasing demand for personalized nutrition with medicinal benefits. North America's nutraceuticals market is already the largest in the world, followed by Asia Pacific and Europe. (1) The Canadian market is expected to grow at a compound annual growth rate (CAGR) of 5.62% from 2019 to 2024. (2)

Nutraceuticals are foods or food products that are fortified to both supplement the diet and provide medical benefits, especially for medical issues (e.g. gut-related conditions) where generic treatment is not effective. They include:

- Antioxidants
- Dietary supplements
- Fortified dairy products
- Citrus fruits
- Vitamins and minerals
- Herbals
- Milk
- Cereals

Nutraceuticals are not tested and regulated to the extent of pharmaceutical drugs; however, Canada's regulations are more stringent than in the U.S. Nutraceutical products are approved by local food and safety standard regulators, after the product's claims are examined. This means that the biggest issue facing nutraceutical companies in Canada is compliance to stringent health regulations - not just for their products but also for manufacturing processes.

Clinical Trials:

Four percent of the world's clinical trials are conducted in Canada, ranking the country fourth in number of clinical trial sites. In addition, Canada is globally recognized for the quality and expertise of its research clinicians, many of whom have made major medical discoveries and innovations, and its ability to conduct clinical research in complex therapeutic areas with diverse population bases. (3)

Canada is the number two or three location worldwide for clinical trials by leading pharmaceutical and biotechnology companies, making it highly sought after for

research and development in the research and testing of new nutraceutical products.
(3)

Rules, Regulations, and Liabilities:

Canadian rules and regulations can be difficult to navigate and are regularly updated. Penalties for non-compliance include fines, bans, notifications by The Food and Drugs Act (FDA), and possible criminal charges.

Rules and regulations from the FDR that govern the nutraceuticals industry include:

- **Labelling:** All natural health products distributed in Canada have registrations called Natural Product Numbers (NPNs) and must adhere to all of Health Canada's guidelines regarding formulation and labeling.
- **Packaging:** Health Canada may not allow products to be distributed if there are any errors on the packaging for natural health products, such as errors related to dosage miscalculations, incorrect ingredients, unproven claims, lack of visible warnings regarding side effects, drug interactions, or other critical health information. (4)
- **Manufacturing:** Nutritional content requirements vary depending on the supplement's Calories per serving. When a nutritional supplement contains less than 225 Calories per serving, for example, requirements include a minimum food energy content of 150 Calories per serving, a specified amount and quality of protein and a specified amount of various vitamins and mineral nutrients. (4)
- **Health Claims:** Criteria for making nutrient content claims and health claims on nutraceuticals is based on the stated serving of stated size for nutritional supplements when in their ready-to-consume form, or on the stated quantity of food when prepared according to directions for use, if the nutritional supplement requires preparation. (4)

Health Canada performs spot testing to guarantee that general natural health products are properly labelled and are not compromised by faulty ingredients or contamination. Many products are also monitored once they are available on the market to guarantee that they follow all natural health product regulations. More details about the regulations are available on the Health Canada website.

Regulatory changes not only influence whether or not a natural health product will be made available in Canada, but also how these products are assembled, packaged and transported within Canada. It is important that manufacturers of nutraceutical products work closely with underwriting specialists to make sure that all regulations are being met.

MedThree Life Sciences Insurance:

Life Science companies continually introduce new and exciting medical products and technologies that present unique risks. MedThree is able to assist with our local knowledge of the Canadian marketplace and our international capacity for the 'rest-of-world' needs.

Industries we underwrite:

- Pharmaceutical and Biotechnology companies (private and publicly traded)
- Medical device manufacturers and distributors
- Clinical Research Organizations
- Academic and Research Institutes

Our coverage spans:

- Product Liability (occurrence and claims-made policy forms)
- General liability including Product Liability (combined form or standalone)
- Property and Equipment Breakdown
- Cyber/Privacy Liability (first party expense reimbursement and third party liability)

Visit our website for [more coverage details](#).

Like any insurance policy, not all risks are covered, and it is important to review the policy.

Content is current as of the date of broadcast and is subject to change without notice.

Sources:

1. <https://www.naturalproductsinsider.com/regulatory/global-nutraceutical-market-case-study-canada>
2. <https://www.mordorintelligence.com/industry-reports/canada-nutraceuticals-market>
3. https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01774.html
4. <https://www.inspection.gc.ca/food-label-requirements/labelling/industry/foods-for-special-dietary-use/eng/1393627685223/1393637610720?chap=6>