New Canadian Regulations for Natural Health Products

by Charles Boulakia and Cynthia Tape

As of January 1, 2004, natural health products (NHPs) in Canada are subject to new sale, manufacturing, packaging, labeling, storage, importation, and distribution requirements.

Under the new Natural Health Products Regulations,[1] NHPs are materials, extracts, or isolates of plants, algae, bacteria, fungus, or animals; natural or synthetic amino acids, essential fatty acids, or certain vitamins; minerals; probiotics; homeopathic medicines; or traditional medicines that are manufactured, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state or its symptoms, or for restoring, modifying, or correcting organic functions in humans.

Some products are not classified as NHPs, including allergenic substances used for the treatment or diagnosis of allergic or immunological diseases; blood and blood derivatives; drugs obtained by recombinant DNA procedures; drugs other than antibiotics prepared from micro-organisms; immunizing agents; insulin; interferon; monoclonal antibodies; substances regulated under the Tobacco Act;[2] substances regulated by the Controlled Drugs and Substances Act;[3] substances that are administered by puncturing the dermis; antibiotics prepared from algae, bacterium, or fungi, or synthetic duplicates of such an antibiotic; and prescription drugs.

Product Licensing and Drug Identification

Effective January 1, 2004, no person is permitted to sell an NHP in Canada unless a product license is issued. A person seeking to market an NHP must first apply for, and obtain, an NHP license or, in the case of homeopathic medicines, a Drug Identification Number-Homeopathic Medicine (DIN-HM). The application must be submitted to the newly formed Natural Health Products Directorate, and must include information such as the following:

- the proper name and common name of each medicinal ingredient;
- the quantity of each medicinal ingredient per dosage unit;
- the potency of each medicinal ingredient if a representation relating to its potency is shown on the label;
- a description of the source material of each medicinal ingredient, and a statement indicating whether it is synthetically manufactured;
- a list of nonmedicinal ingredients and the purpose of each;
- the proposed brand name of the NHP;
- the recommended conditions of use for the NHP;

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- information supporting the safety and efficacy of the NHP when used in accordance with the recommended conditions of use;
- the text of each label proposed to be used in conjunction with the product;
- a copy of the specifications with which the product will comply; and
- an attestation that the product is manufactured, packaged, labeled, distributed, stored, and imported (if applicable) in accordance with good manufacturing practices contained in the NHP Regulations.

The NHP Directorate may request additional information or samples of the product if the information submitted is insufficient to enable it to determine whether the license should be issued.

The holder of the NHP license has a continuing obligation to document adverse reactions with respect to the NHP, reactions in an annual summary report, and to report to the Minister of Health all serious adverse reactions in Canada or serious unexpected adverse reactions anywhere in the world. The holder of the NHP license has an obligation to maintain records related to the ingredients contained in each lot or batch of the NHP and sufficient information to enable the recall of every lot or batch made available for sale.

Site License and Good Manufacturing Practices

Those who manufacture, package, label, or import an NHP must have a site license. Site licenses may be obtained by submitting an application to the NHP Directorate (forms are available on the Directorate's website at www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/forms_e.html). The licenses are valid for one year from the date of issue and can be renewed for periods of up to three years.

Those who manufacture, package, label, import, distribute, or store an NHP must do so in accordance with good manufacturing practices that are contained in the NHP Regulations. These practices include compliance with the specifications submitted in an application for an NHP license, as well as requirements related to recordkeeping, recall reporting, equipment use, personnel, premises, sanitation programs, quality assurance, stability, operations, sterile products, ophthalmic use products, and lot or batch samples.

Clinical Trials

The NHP Regulations set out detailed requirements for the performance of clinical trials on NHPs.

Labeling and Packaging

Under the NHP Regulations, the label of the NHP must—subject to small-package exemptions—include the following:

- the brand name for the NHP;
- the product's NHP license number, lot number, and expiry date;
- the recommended use or purpose of the NHP;
- the recommended route of administration, dose, dosage form, and duration of use of the NHP;
- the risk information relating to the NHP, including any cautions, warnings, contra-indications, or known adverse reactions associated with its use;
- the common name of each medicinal ingredient, and its proper name if the proper name is not the chemical name of the ingredient;
- the name and address of the product license holder and importer (where applicable);
- the quantity and authorized potency (if applicable) per dosage unit of the medicinal ingredients;
- the net amount of product in the container;
- storage conditions, if any are recommended;
- a description of the source material of each medicinal ingredient;
- the word "sterile" (if applicable);
- a list of all nonmedicinal ingredients; and
- the quantity of mercury contained within the product (if applicable).

Much of this information is required to be in both English and French, and on both the inner and outer labels of the NHP. In addition, NHPs will need to have security packaging.

Transition Period

The NHP Regulations came into force January 1, 2004. There is no transition period for new products that are NHPs, so these products must comply with the regulations as of that date.

There is a six-year transition period (i.e., until December 31, 2009) for products that currently have DINs.

There is a two-year transition period (i.e., until December 31, 2005) for the good manufacturing practices and site license requirements of the regulations (but not for the licensing requirements) for products that have been manufactured, packaged, labeled, or imported before January 1, 2004.

There are additional transition periods for products that were authorized for clinical trial before January 1, 2004.

Although the NHP Regulations indicate that all products already on the market will require an NHP license on January 1, 2004, the NHP Directorate has indicated that it will stagger enforcement over four years (i.e., through January 1, 2008), depending on the type of product. For example, a probiotic that is on the market before January 1, 2004; that is not deemed a health risk;[4] that is not on the Therapeutic Product NHP Directorate's New Drug List; and that contains no extracts, isolates, amino acids, or essential fatty acids will not be subject to a compliance action until June 2005. It remains to be seen, however, how this phased-in compliance and enforcement will be dealt with when consumer or trade complaints are made. The prudent course is to apply for and secure the necessary licenses now. △

Torys LLP (www.torys.com) is an international business law firm with more than 330 lawyers in New York and Toronto.

[1] Natural Health Products Regulations, S.O.R./2003-196.

[2] Tobacco Act, S.C. 1997, c. 1.

[3] Controlled Drugs and Substances Act, S.C. 96, c. 19.

[4] This includes that it is not a Schedule A or F drug; not a sterile product; not a prohibited substance; not used by children, pregnant, or breast-feeding women; and not a health hazard.

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