Incoming changes to the Natural Health Products Regulations in Canada

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Health Canada has introduced important amendments to the *Natural Health Products Regulations*, S.O.R./2003-196. The amendments create new labelling requirements for natural health products, which include probiotics, herbal remedies, certain vitamins, minerals, homeopathic medicines, traditional medicines such as traditional Chinese medicines, and other products like amino acids and essential fatty acids. The new labelling requirements include a Product Facts table for most natural health products; uniform font and formatting requirements; and labelling of food allergens, gluten, added sulphites, and aspartame. The amendments also remove security packaging requirements for topical natural health products and clarify existing provisions in the *Natural Health Products Regulations*.

Product Facts tables

Labels for most natural health products will soon need to display a Product Facts table. The Product Facts table provides a standardized way to convey information already required under the *Natural Health Products Regulations*, in addition to the new requirement to list information specific to natural health products containing a food allergen, gluten, added sulphites, or aspartame. The regulations will require the following headings and information in one bilingual or two unilingual tables (one in French and one in English) titled “Product Facts/Info-produit,” or alternatively, “Drug Facts/Info-médicament”:

- **Medicinal ingredients/Ingrédients médicinaux**: a list of the medicinal ingredients of the natural health product that sets out the proper name of each ingredient or, if the proper name is the chemical name, the common name, the quantity of each ingredient per dosage unit, and if applicable, the authorized potency of each ingredient; and a description of the source material of each medicinal ingredient of the natural health product;
- **Uses/Usages**: at least one recommended use or purpose of the natural health product (unless the information is shown elsewhere on the same label);
- **Warnings/Mises en garde**: the risk information, including any cautions, warnings, contra-indications or known adverse reactions associated with the use of the natural health product. Also, under this heading, natural health product labels will need to include a warning if a food allergen source or gluten is present

in the product of if the presence in the product of added sulphites is 10 p.p.m. or more. There will also need to be a warning if the product contains aspartame.
- **Directions/Mode d'emploi**: the recommended dose and recommended duration of use;
- **Other information/Autres renseignements**: the recommended storage conditions (unless shown elsewhere on the same label);
- **Non-medicinal ingredients/Ingrédients non médicinaux**: a qualitative list, by common name, of the non-medicinal ingredients of the natural health product; and if the natural health product contains mercury or any salts or derivatives of mercury as a non-medicinal ingredient, a statement that sets out the quantities of those ingredients; and
- **Questions**: the telephone number, email address, or website address of a contact person who represents the product licence holder of the natural health product.

Alternatives and exceptions to the Product Facts table requirement

The amendments to the *Natural Health Product Regulations* allow some flexibility for product labels with insufficient surface area for a Product Facts table. In addition, certain natural health products will be exempt from the Product Facts table, generally including products in small packages, certain low-risk products, products that are to be used within one day or less (as per the directions on the label), and products with package(s) that contain, at most, three dosage units. However, these products will still need to follow labelling requirements under the *Natural Health Product Regulations*.

New formatting requirements

The amendments to the *Natural Health Products Regulations* include provisions to promote clear and prominently displayed label text. These provisions include minimum font sizes for required statements, information, or declarations under the regulations. The required text will need to be in a single colour, visually equivalent to 100 per cent solid black (as in, dark blue, green, brown, or purple) and be contrasted with a white or uniform neutral background with maximum five per cent tint of colour. These legibility requirements will not apply to specific information such as lot numbers, product numbers, brand names and advertising information.

Security packaging requirements

Currently, all natural health products, with the exception of throat lozenges, are required by the *Natural Health Products Regulations* to have security packaging. The new amendments will remove security packaging requirements for certain products, such as sunscreens and other topical products. The types of natural health products subject to security packaging requirements will be mouthwashes; natural health products that are to be inhaled, ingested (other than lozenges), or inserted into the body; and natural health products for ophthalmic use.

Transitional provisions

The amendments to the *Natural Health Products Regulations* to clarify existing rules and to include new security packaging requirements will come into force upon registration of the regulations. The provisions regarding product labelling, including the Product Facts table and formatting requirements, will come into force three years following registration. After year three, all new natural health products will have to meet the new labelling requirements.

Natural health products licenced and labelled in Canada prior to the day that the amendments come into force will have an additional transition period of three years to meet the new labelling requirements. This provides natural health products with existing licences a total period of six years to comply with the new requirements.

Key takeaways

Businesses should start implementing the new labelling requirements for natural health products as soon as possible. Manufacturers and importers of natural health products will need to consider how to redesign their packaging, labelling configurations, and product leaflets or inserts to comply with the new regulations. Manufacturers and importers will need to continue monitoring their natural health products for the presence of food allergens, gluten, and aspartame. They will also need to measure the added sulphites in their products and provide a warning if the amount is 10 p.p.m. or more.

Our Product Liability Group can help your business navigate this complex area of regulation. If you would like to learn more about the natural health product regulatory amendments, please contact any of the authors or a member of our Product Liability team.

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