

## Regulatory consistency for consumer health products in a modernized *Food and Drugs Act*

**EXECUTIVE SUMMARY:** The *Food and Drugs Act* has not been overhauled since the mid-1950s. The Government of Canada has stated that it plans to amend the *Food and Drugs Act* to reflect modern food and health product science, commercial practices and regulatory principles. A key aspect of this modernization should be to move towards a relative risk framework for regulating all therapeutic products. The consumer health products industry supports the shift to relative risk based regulation.

Therapeutic products can be grouped according to the need for intervention by health care professionals. Higher risk products require the intervention of a licensed practitioner for their safe and effective use while lower risk products can be safely and effectively used by consumers without such interventions. Unfortunately, not all consumer health products are regulated according to their lower risk profile. Some consumer health products are regulated by the *Natural Health Products Regulations* while other consumer health products fall under the same regulatory framework as prescription drugs (i.e. Part C of the *Food and Drug Regulations*).

The consumer health products industry is urging the federal government to ensure that the amended *Food and Drugs Act* mandates the development of regulations for all consumer health products that are distinct from those for prescription drugs, thereby allowing the consistent regulation of all products intended for self-care.

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**OUR ASSOCIATION:** Consumer Health Products Canada is the national industry association representing manufacturers, marketers, and distributors of consumer health products. The Association's members, which range from small businesses to large corporations, account for the vast majority of sales in Canada's \$4.7 billion market for consumer health products. Our members' sales are equally proportioned between natural health products and other consumer health products. Consumer Health Products

Canada (formerly known as NDMAC) has been the leading advocate for the consumer health products industry for more than 110 years.

**THE ISSUE:** The intent behind modernizing the *Food and Drugs Act* is to move towards a relative risk framework for regulating therapeutic products. This approach ties the level of regulatory burden imposed on a product to the level of health risk posed by that product. Currently, some consumer health products are



regulated by the *Natural Health Products Regulations*, while other consumer health products fall under the same regulatory framework as prescription drugs (Part C of the *Food and Drug Regulations*). While both sets of products are assessed to be of lower risk, requiring one set of consumer health products to meet the regulatory requirements of prescription drugs is contrary to the intent of the new legislation and creates unnecessary and unfair regulatory hurdles for consumer health products.

Modernizing the *Food and Drugs Act* provides the opportunity to ensure that products of higher risk (e.g. prescription therapeutic products) are clearly distinguished from other health products in legislation so that distinct regulatory boundaries can also be established.

**BACKGROUND:** Consumer health products such as sunscreens, medicated shampoos, allergy products, and upset stomach remedies have been regulated under Part C of the *Food and Drug Regulations* for decades. Because these regulations are primarily associated with and applied to prescription drugs, many of the accompanying policies and guidelines that have been developed over the subsequent years have been developed with higher risk products in mind. Therefore, over the years, consumer health products have been subjected to more and more regulatory barriers that were never intended to apply to lower risk products. This

problem was further exasperated in the mid-1990s, when Health Canada folded the bureau responsible for these products into the prescription drug program.

The growing frustration of the consumer health products industry and its consumers as a result of this change contributed directly to the decision to re-examine the treatment of natural health products. The Standing Committee on Health produced a report recommending a relative risk approach to regulating these products. The resulting *Natural Health Products Regulations* are the most up-to-date regulatory framework under the *Food and Drugs Act* and are based on the relative risk model. Critically, these regulations are distinct from Part C of the *Food and Drug Regulations*, which regulate prescription drugs.

## ORPHANED CONSUMER HEALTH PRODUCTS

### In regulation:

When the *Natural Health Products Regulations* were passed into law in 2004, many consumer health products that had been regulated under Part C of the *Food and Drug Regulations* became subject to the new NHP regulations. However, many consumer health products were left behind (i.e., “orphaned”) to continue to be regulated in Part C of the *Food and Drug Regulations* and under the administration of the Therapeutic Products Directorate, which is



responsible for prescription drugs. These orphaned products include sunscreens, medicated shampoos, allergy products, upset stomach remedies, antiperspirants, hard surface disinfectants and other products that are of lower risk relative to prescription therapeutic products.

### **In legislation:**

After the first reading of Bill C-51 (An Act to amend the Food and Drugs Act), the former Minister of Health faced a concerted lobby effort by some of the health food community aimed at stopping the legislative process. The “stop sign” campaign set out to confuse and frighten consumers with false information about what the amended *Food and Drugs Act* would do. Most notably, the stop sign groups made statements that if the Bill were to pass, natural health products would become subject to the same provisions as prescription drugs or “pharmaceuticals.”

In June 2008, as lobbying pressure mounted to stop Bill C-51, the Minister announced that amendments would be introduced at the Committee stage, which would define NHPs in the Act to ensure they would persist as a separate category of therapeutic products. This amendment was announced in recognition of the need to ensure that these lower risk products would not fall under the prescription drug regulations.

Consumer Health Products Canada and its member companies agree with the Minister’s assessment regarding NHPs,

but notes that there needs to also be a direct legislative reference to ensure separate regulation for the other lower risk consumer health products that are currently regulated under Part C of the *Food and Drug Regulations*.

### **RECOMMENDATION**

Consumer Health Products Canada recommends that Parliament amend the *Food and Drugs Act* to mandate the development of regulations for consumer health products that are distinct from those for prescription products, thereby ensuring the consistent regulation of all health products intended for self-care.

Consumer Health Products Canada  
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