

Technical Alert

Industry Consultation Regulation of Self-Care Products in Canada

Dear member,

Health Canada is examining new approaches to the regulation of natural health products (self-care products), including refocusing the approval of health claims to those based on scientific evidence.

Public opinion research conducted in April 2016 revealed that the Canadians surveyed did not consider themselves well-informed when purchasing self-care products. Health Canada also identified several key concerns relating to the current system for regulating self-care products, including issues identified in its regulation of the products as well as concerns that have been raised by Canadians, companies, health professionals, and researchers.

The Government of Canada website states "A new approach will continue to allow for a wide range of products to be available domestically, while, at the same time, taking a more consistent approach to the oversight of self-care products that will ultimately better support consumers' ability to make an informed decision".

Consultation: Click here for the <u>online</u> consultation for the Regulation of Self-Care Products in Canada. Health Canada is committed to reviewing and considering all comments to the consultation paper received by **24 October, 2016**.

Proposal: Risk-based Approach to Self-Care Products

The Department is proposing a new framework for self-care products. The approach will include the following 3 main proposals (see figure 1, next page for further details):

- 1. Products of similar risk profiles would be treated in a similar manner.
 - This ensures rules for bringing products to market are:
 - more consistent
 - easier to understand
- 2. The Department would review health claims based on a new definition.
 - o Companies would require scientific proof to support these health claims.
- 3. A risk-based approach to compliance and safety monitoring will continue.
 - This allows Health Canada to take quick action to protect consumers.

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Figure 1: Proposed Risk Classification System

Lower Risk Self-Care Products

No Health Canada review or licensing of these products

Health Canada sets requirements that companies would meet to sell these products, including quality Health Canada sets exclusions as to which ingredients/products would

not be in this group

Health Canada would not review claims

No claims could be made about the diagnosis, treatment, prevention, mitigation of a disease or condition

Claims other than diagnosis, treatment, prevention, cure or mitigation of a disease, would be accompanied by a disclaimer indicating that Health Canada has not reviewed the product for effectiveness

*Claims must be truthful and accurate and companies are required to have this supporting information

> Product examples: cosmetics, many vitamin and mineral products, toothpaste, mouthwash, homeopathic products, diaper rash products

Moderate Risk Self-Care Products

Some review by Health Canada and licensing of products based on evidence of safety and effectiveness published in a monograph (a licensing standard)

Companies would be required to meet quality standards

(Full review would not be required because there are standards already in place for the products in this group)

Heath Canada would approve claims

Claims relate to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition; or the claims specified in the monograph

*Claims would be based on science

Product examples: topical and oral pain relievers (such as acetaminophen and ibuprofen), cough and cold products, laxatives, allergy relief products

Higher Risk Self-Care Products

Full review by Health Canada Companies must provide evidence to support the safety, quality, and effectiveness of products

Health Canada would approve claims related to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition

*Claims must be based on

Product examples: products that are switching from prescription to nonprescription status, products that contain new medicinal ingredients, products related to cardiovascular health

<u>Description of Figure 1</u>: The above graphic describes the oversight that could be provided, including potential examples, in the proposed risk-based classification system.

Source: http://healthycanadians.gc.ca/health-system-systeme-sante/consultations/selfcare-autosoins/document-eng.php

Resources: Summary Report: Consultation on a Framework for Consumer Health Products

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