
# LABELS, ENDORSEMENTS, AND SCIENTIFIC PROOF: A NEW APPROACH TO SELF-CARE PRODUCTS IN CANADA

*Posted on September 28, 2016*

**Categories:** Insights, Publications

As part of its mandate to improve regulatory transparency, earlier this month Health Canada initiated public consultation on the regulation of self-care products (SCPs). This consultation seeks feedback on Health Canada's proposed SCP regulatory amendments, which are aimed at creating more knowledgeable consumers. These changes could require companies selling SCPs in Canada to reconsider how these products are packaged and labelled, and could even result in companies needing to meet additional requirements before bringing SCPs to market. The SCP designation includes three product types: (1) natural health products (NHPs), such as vitamins and probiotics; (2) cosmetics, such as deodorants, moisturizers, and makeup; and (3) over-the-counter (OTC) drugs, such as cold and flu medications.

## I. Current Regime

Right now, NHPs, cosmetics, and OTCs are each governed by their own specific regulations[1] (the Regulations) detailing: product evaluation and approval procedure; labeling, manufacturing, and packaging requirements; permissible product claims; ongoing safety and compliance monitoring; and potential consequences for non-compliant companies. Although the Regulations generally address the same themes, the rules and standards are inconsistent across SCP categories, a fact which Health Canada believes leads to consumer uncertainty. For example, the level of proof required to support a claim for an OTC is typically more onerous than that required of a NHP, which can be licensed for sale on the basis of non-scientific evidence. Thus, when it comes to choosing among products making similar claims, consumers may have difficulty determining which product is most effective or has undergone the testing required to substantiate the claim.

## II. Health Canada's Proposals

To resolve these issues and enable consumers to make more informed choices, Health Canada suggests establishing a new SCP framework based on three main proposals.

### *Proposal 1: Risk-Based Approach*

While many SCPs have a long history of safe use, SCPs containing new or higher risk ingredients, or which

claim to treat serious medical conditions, require more scrutiny. Thus, Health Canada proposes a three tier risk classification system so that SCPs of similar risk profiles would be treated similarly, ensuring that the rules for bringing SCPs to market are more consistent and easier to understand:

- **Lower Risk SCPs** would be neither reviewed nor licensed by Health Canada. Instead, Health Canada would set requirements for companies to meet prior to selling these products. Any such SCP could not make claims about the diagnosis, treatment, prevention, or mitigation of a disease or a condition (i.e. health claims), and any non-health claims made would need to be truthful and accompanied by a disclaimer indicating that Health Canada had not reviewed the product for effectiveness. Examples of low risk SCPs include cosmetics, many vitamin and mineral supplements, and homeopathic products.
- **Moderate Risk SCPs** would be reviewed and licensed by Health Canada based on safety and effectiveness, as well as meeting specified quality standards. SCPs in this category could make health claims when supported by scientific evidence and approved by Health Canada. Examples of moderate risk SCPs include topical pain relievers, cough and cold products, and allergy relief products.
- **High Risk SCPs** would be subject to full review by Health Canada, with companies needing to provide scientific evidence to support the SCP's safety, quality, effectiveness, and any health claims made. Examples of high risk SCPs include those products switching from prescription to non-prescription status, those with new medicinal ingredients, and those for use in at-risk groups such as pregnant women and children.

***Proposal 2: Requiring Scientific Proof for Health Claims***

Health Canada proposes to limit the definition of "health claims" to those claims relating to diagnosis, treatment, mitigation, prevention, or cure of a disease, disorder, or abnormal physical state or its symptoms. Companies making such claims would need to furnish scientific proof substantiating them for Health Canada's review. Examples of health claims include "prevents cavities", "treats symptoms of cough, cold, and flu", and "relieves pain". Examples of non-health claims include "moisturizes the skin", "source of omega-3", and other marketing statements.

***Proposal 3: Compliance and Safety Monitoring***

Health Canada already monitors products on the market and proposes to continue to do so proportionately with a given SCP's risk profile. In other words, the more potential risk associated with a product, the greater the level of compliance oversight by Health Canada. This approach would still include actions such as facility inspection, complaint response, and product testing.

**III. Impact of the Proposals on Regulated Parties**

Health Canada anticipates that the new changes would affect manufacturers, suppliers, advertisers, and distributors of SCPs in the following ways.

***Notification for Products Not Making Health Claims***

A product that does not make health claims would be able to go to market immediately, but shortly thereafter the company would have to inform Health Canada of its availability through a simple electronic notification process (similar to the system currently used for cosmetics). The notification would require the company to provide basic information, such as what the product contains and a confirmation of compliance with all applicable requirements in making and selling it. All claims on such products would need to be truthful and Health Canada could ask the company to provide evidence at any time.

***Product Labels***

Product labels for SCPs making health claims would be marked with an authorization number indicating that Health Canada reviewed and approved of the product, and that the claim is supported by scientific evidence. Disclaimers on labels of SCPs making non-health related claims would indicate that Health Canada did not review or approve such claims.

Health Canada could also require companies to submit copies of final SCP labels to assist in determining whether a safety issue not already identified on the label might arise, as well as to try to proactively address potential advertising complaints.

***Unique Product Identifiers***

Health Canada is also considering assigning unique tracking numbers to products it has neither reviewed nor approved. The tracking number would not be used to indicate product approval, nor would it necessarily be included on the SCP's main display panel. The objective of having such numbers would instead be to help Health Canada quickly identify and trace products in case a safety issue were to arise.

**IV. Next Steps and Consultation Information**

The proposed amendments represent a significant change to the current regime, undoubtedly raising questions from consumers and businesses alike. As such, Health Canada is inviting Canadians, including affected companies, to participate in a consultation process open until October 24, 2016 via an online consultation form. The public may also submit any opinions to nnhpd_consultation_dpsnso@hc-sc.gc.ca.

by Sandra M. Knowler, Rebecca Rock and Bill Olaguera (Articled Student)

[1] NHPs must meet the Natural Health Products Regulations, Cosmetics must meet the Cosmetic Regulations,

and OTCs must meet the Food and Drug Regulations.

**A Cautionary Note**

The foregoing provides only an overview and does not constitute legal advice. Readers are cautioned against making any decisions based on this material alone. Rather, specific legal advice should be obtained.