



# Health Canada Developing New Framework for Regulation of Self-Care Products

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In September 2016, Health Canada announced a proposed new framework for the regulation of cosmetics, natural health products and non-prescription drugs (referred to as “self-care” products). In its [Consultation Paper on the Regulation of Self-Care Products](#), Health Canada states that the current approach to regulation prevents consumers from making informed choices when purchasing self-care products, relying in part on an April 2016 survey of 2500 Canadians. According to Health Canada, the new framework is meant to increase consistency and transparency which will benefit both consumers and manufacturers/importers of self-care products.

Because the current approach to regulation is based on a product’s categorization type as a cosmetic, natural health product or non-prescription drug, products intended to treat similar conditions may be regulated in different ways but these differences are not apparent on their face to consumers. For example, two products could be intended to treat headaches, but if one is a natural health product and the other is a non-prescription drug, the products are subject to different licensing, approval, labelling, and compliance rules. To address this issue, the new framework proposes a risk-based approach to regulation. Products that pose similar levels of health risk to consumers will be regulated in a similar manner.

The new regulatory framework proposes changes to the following areas:

1. **Product Classification** Products will be regulated based on the level of risk they pose to consumers. Higher risk products will be subject to greater regulatory scrutiny.
2. **Regulation of Health Claims and Promotional Claims** Products that make health claims, for example, “prevents gingivitis” or “relieves joint and arthritis pain” must be approved by Health Canada and supported by scientific proof. Promotional claims such as “helps metabolize fat” and “improves the look of acne scars” must also be truthful and accurate and have supporting documentation.
3. **Remedial Powers** Health Canada is evaluating its authority to recall products in addition to non-prescription drugs in cases of non-compliance. Health Canada may increase the maximum fine for non-compliance for cosmetics and natural health products.

Health Canada is currently soliciting feedback from consumers, industry, health professionals and other stakeholders on the proposed framework until October 24, 2016.

## 1. Product Classification

The new framework re-classifies self-care products into three different categories: lower risk products, moderate risk products, and higher risk products. The level of risk dictates the amount and type of

information Health Canada needs to review for approval, the degree of scrutiny required before the product can be made available in Canada, and the level of monitoring for safety and compliance with the law once the product is available.

Health Canada states that it will tailor the intensity of its compliance activities to each of the three risk categories of self-care products. For lower risk products, there will be less oversight; for higher risk products, there will be more oversight.

## **2. Health Claims and Promotional Claims**

**The new framework redefines “health claim” to mean claims that “relate to the diagnosis, treatment, mitigation, prevention or cure of a disease, disorder, or abnormal physical state or its symptoms in humans and that are considered to have moderate or serious consequences for health”. For example, “prevents gingivitis” or “relieves joint and arthritis pain” would be considered health claims. Claims that are no longer considered health claims are statements made for the purpose of promoting or marketing a product or providing information about a product, including its potential benefit. For example, “helps metabolize fat” and “improves the look of acne scars” would not be health claims.**

**Claims that are “health claims” must be approved by Health Canada. To obtain approval, companies must provide scientific evidence to support the claim. Claims that are not health claims do not require approval but the claims must be truthful, accurate and substantiated.**

## **3. Remedial Powers**

**Health Canada is considering re-evaluating the scope of its authority to address non-compliant or unsafe products that are currently classified as natural health products or cosmetics. Under its current authority, Health Canada can only order a product recall if the product is classified as a non-prescription drug. Additionally, the maximum fine for non-compliance is significantly greater for non-prescription drugs. Health Canada has not proposed new powers based on its new product classification approach but its authority may be the subject of future proposals. As part of its consultation process, Health Canada is asking stakeholders whether they believe additional powers to change labels, require a recall and add new penalties would help address safety issues and discourage companies from breaking the law.**

**Self-Care Products – Summary of Proposed Regulatory Changes**

	Lower Risk	Medium Risk	Higher Risk
<b>Self-Care Product Examples</b>	<ul style="list-style-type: none"> <li>• Cosmetics,</li> <li>• Vitamins, minerals</li> <li>• Toothpaste</li> </ul>	<ul style="list-style-type: none"> <li>• Topical and oral pain relievers</li> <li>• Cough and cold products</li> <li>• Laxatives</li> </ul>	<ul style="list-style-type: none"> <li>• Contain new medicinal ingredients</li> <li>• Relate to cardiovascular health</li> <li>• Former prescription products</li> </ul>

	<ul style="list-style-type: none"> <li>• Mouthwash</li> </ul>		
	<ul style="list-style-type: none"> <li>• Homeopathic products</li> </ul>	<ul style="list-style-type: none"> <li>• Allergy relief products</li> </ul>	switching to non-prescription status
	<ul style="list-style-type: none"> <li>• Diaper rash products</li> </ul>		
		<ul style="list-style-type: none"> <li>• Some review</li> </ul>	
	<ul style="list-style-type: none"> <li>• None prior to sale</li> </ul>		<ul style="list-style-type: none"> <li>• Full review</li> </ul>
<b>Review and licensing</b>	<ul style="list-style-type: none"> <li>• <i>Set requirements for quality, ingredients, and labelling must be met.</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Evidence required to support safety and effectiveness based on licensing standards contained in monographs.</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Evidence required to support safety, quality and effectiveness.</i></li> </ul>
	<ul style="list-style-type: none"> <li>• No review</li> </ul>		
	<ul style="list-style-type: none"> <li>• <i>Health claims cannot be made about the diagnosis, treatment, prevention, mitigation of a disease or condition</i></li> </ul>	<ul style="list-style-type: none"> <li>• Approval required</li> </ul>	<ul style="list-style-type: none"> <li>• Approval required</li> </ul>
<b>Review of Health Claims</b>		<ul style="list-style-type: none"> <li>• <i>Must have scientific basis</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Must have scientific basis</i></li> </ul>
	<ul style="list-style-type: none"> <li>• <i>Must be truthful and accurate</i></li> </ul>		

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