Health Canada Santé Canada

Canada

The Regulation of Self-Care Products

Safety – Efficacy – Quality

Canadian Association of Professionals in Regulatory Affairs (CAPRA) Annual Education Day

June 1, 2017

YOUR HEALTH AND SAFETY... OUR PRIORITY.

What are self-care products?

Cosmetics
Used for cleaning, improving or altering the complexion, skin, hair or teeth (e.g., moisturizing creams, deodorants, shampoos)

Natural health products
Various uses including general health maintenance (e.g., mineral supplements, probiotics, traditional medicines)

Non-prescription drugs
Commonly referred to as "over-the-counter drugs" (e.g., pain relief, cold & flu symptoms, allergy relief)

- Canadians use self-care products every day to maintain health, treat minor ailments and improve appearance.
- Self-care products are generally lower risk than other health products regulated by Health Canada, such as prescription drugs.
- However, they are not completely without risk as they can cause negative effects if combined with other medications or if not used as directed.

Why do we need change?

- The regulations have not kept pace with consumer expectations and with how self-care products are marketed by industry.
  - Under the current approach, products making similar claims (e.g., “relieves pain”) sit side by side on store shelves, even though they may be subject to different rules.
  - This makes it difficult for consumers to make informed choices.
- Health Canada does not have consistent powers (e.g., fines, recall authorities) to address safety concerns and non-compliance.
- The current framework results in an uneven regulatory environment for importers and manufacturers.

Building on Success

- The present system has been built through a lot of collaboration with Canadians
- There are issues that, if addressed, could create a stronger foundation for the future
- Does this mean starting from scratch? No!
- Health Canada wants to build on our collective past successes:
  - Use of a notification system for cosmetics
  - Transparency and consistency on evidence requirements as found in the Pathway for Licensing Natural Health Products (NHPs) Making Modern or Traditional Health Claims
  - Cost-recovery requirements for non-prescription drugs (NPDs) to create a system that will be sustainable for decades to come.

What is Health Canada proposing?

Self-care products would be **regulated according to risk to consumers**.

Self-care products making similar claims would **require similar evidence**.

Health Canada would have **appropriate powers** to address safety concerns and non-compliance.

Benefits for Consumers

- ✓ **Continued access** to a wide range of safe and effective self-care products.
- ✓ **Better information** to support informed decision-making.

Benefits for Industry

- ✓ More **predictable and consistent** rules for bringing products to market.
- ✓ **Risk-based rules** that do not impose an unnecessary regulatory burden.

How have we sought feedback to date?

Fall 2014: A consultation was launched on a Framework for Consumer Health Products, proposing to modernize the oversight of health products intended for consumer use.

Spring 2016: Public opinion research was conducted with 2,500 Canadians to provide some baseline information on how Canadian consumers perceive and use self-care products.

Fall 2016: From September 7, 2016 to October 24, 2016, we sought input on the document **Consulting Canadians on the Regulation of Self-Care Products in Canada** and received over 3,500 responses from consumers, manufacturers, retailers, distributors, health professionals, researchers, and other regulators.

- Participants saw **benefits** in increased consistency and reliability of the information provided to consumers; they also welcomed increased predictability and consistency for manufacturers.
- Participants were **worried** that the proposed approach may reduce the range of natural health products available to consumers, either by explicitly prohibiting certain products or by discouraging manufacturers from bringing new products to the marketplace.

How did we adjust the proposal?

- **Not enough detail:** Health Canada responded by providing in-person sessions and webinars to provide updates on the development of the proposal.
- **Risk-based classification:** Health Canada believes that the classification system for the entire breadth of self-care products can be improved, including for NHPs.
- **Claims versus health claims:** Health Canada has adjusted the proposal to refer to claims as a concept with no such differentiation.
- **The disclaimer:** Health Canada responded with a refined proposal that incorporates feedback on the disclaimer. The framework could include a proclaimer, a symbol or a qualifying statement. We want to know what information consumers want to have to make informed choices.
- **Risk equals health claim:** Risk has been more clearly defined in the refined proposal.
- **Build on the present:** The proposal is to build on the successes, and anticipating the future needs of the program, offer a more consistent and efficient regulatory approach for self-care products and has been reflected in the refined proposal.
- **Traditional products:** Health Canada has clarified the inclusion of traditional products within the refined proposal.

Refined Elements of the Framework Proposal

During recent consultations, we delivered a presentation on both the context of the sessions and the policy proposal, including:

- product classifications based on a two-class categorization system of risk level including safety and failed product efficacy
- acceptable claims within each of the two classes
- unique label identifiers and statements on labels to help consumers easily identify products
- compliance and enforcement measures to address safety concerns

CLASSIFICATION

Risk = Product safety + Harm from failed efficacy

Risk **CAN** be managed through **REGISTRATION** with established requirements	Risk **NEEDS** to be managed through **LICENSING** with higher level of oversight
CLASS I	**CLASS II**
Products intended • To cleanse, protect, alter the complexion/ skin/ hair/ teeth, beautify • For general wellness, to maintain, support, manage, provide a source of, mechanism of action having physiological effect • To treat, prevent, mitigate certain conditions, including symptoms	Products intended • To treat, prevent, mitigate, diagnose certain conditions or diseases, including symptoms
Supported by **traditional use** or **modern evidence** available upon request by Health Canada	Supported by **modern evidence** to be reviewed by Health Canada

Consumers have access to a wide range of safe and effective products, and to information they need to make an informed choice

Statement on the label?

Pathways to Market

Class I products products would follow a registration system with requirements established in advance.

- Pathway 1: Manufacturers and importers would register before sale (cosmetic)
- Pathway 2: Manufacturers would register before marketing to validate information (treatment of conditions)

Class II products would be reviewed by Health Canada.

- Examples of products that would require Health Canada review:
  - Pathway 1: Products that meet pre-cleared evidence in its entirety
  - Pathway 2: Products providing additional evidence to support deviations from pre-cleared evidence
  - Pathway 3: Products that meet the pre-cleared evidence for safety but require additional efficacy review (such as a slightly expanded claim, statements to the effect of)
  - Pathway 4: Products that are approved for safety and efficacy in an equivalent jurisdiction
  - Pathway 5: Products that require a fulsome review for safety and/or efficacy

CLAIMS

Class I Claims

- Claims that could cause harm from failed efficacy will not be permitted within Class I.
- Examples of claims would be permissible for Class I products:
  - “High” claims
  - “Treats, prevents or mitigates” a symptom of a condition
  - “Good Source of” claims
  - “Antioxidant” claims
  - Implied nutrient content claims
  - Structure/function claims
  - “Management” claims for conditions
  - “Healthy” claims
  - Beauty claims (e.g., “maintains youthful-looking skin”)
- Information to support that the product does what it claims must be available upon request.
- An administrative process would be established to add additional claims, provided they are appropriate for Class I.

Class II Claims

- Claims for Class II are:

  "any representation that a relationship exists between the use of a self-care product or an ingredient in the self-care product and the treatment, prevention, mitigation, cure or diagnosis of a certain disease or condition, including symptoms"

- Examples of claims would be appropriate for Class II products:
  - "Treats" allergies
  - "Prevents" cough, cold and flu
  - "Mitigate" pink eye
  - "Cure" any moderate disease
  - "Treats" a urinary tract infection
- Evidence to support these claims would be submitted by manufacturers and reviewed by Health Canada prior to market entry.
- This should not be read to say that all treat, prevent, mitigate or diagnosis claims would fall into Class II (conditions fall into Class I).

Traditional Claims

- Products with traditional use claims could be permitted in both classes.
- Products supported by a history of traditional use would be found in Class I.
- Claims are proposed to be permitted, as long as they fit within a traditional paradigm, such as the following:
  - Health maintenance, including for example claims relating to nutritional support
  - Relief of symptoms of a minor disease or condition (not referring to a disease or disorder)
  - Claims for traditional conditions and actions
  - Health enhancement
  - Reduction in frequency of a discrete event
  - Aids/assists in the management of a named symptom/disease/disorder
- These claims would need to be preceded by “for traditional use for…” or “supported by traditional or historic use”.

UNIQUE IDENTIFIER

Unique Identifier

- Health Canada is also proposing that all Class I products be assigned a unique identifier number when they are registered.
- Unique identifiers would help Health Canada identify products in the event of adverse reactions or complaints about product safety or quality.
- Currently some self-care products have a unique identifier on the label which also indicates Health Canada authorization, while others do not.
  - Cosmetics are assigned a unique number at the time of notification, but the number does not appear on the product label.
  - Licensed natural health products can be identified by the natural product number (NPN, or DIN-HM for homeopathic medicines) on the product label.
  - Non-prescription drugs can be identified by the drug identification number (DIN).
- Under the proposed approach, Class I products would be assigned a unique identifier number (somewhere on label) and Class II products would be assigned an authorization number (front of label).

STATEMENT ON THE LABEL

Statement on the Label

- Health Canada is exploring options other than a unique identifier number that could help differentiate products.
- The use of a disclaimer was divisively received during the fall 2016 consultation.
- A labelled statement would indicate what the Class I product is and the type of information used to support the product's sale in Canada.
- Examples of statements of the information used to the support that product could include:
  - "This product is marketed based on a history of safe use"
  - "This product is marketed based on traditional use"
  - "This product was reviewed by Health Canada"
- ALTERNATIVE: A statement on the label would not be required on Class II products, but other options such as a proclaimer could be used.
- A "proclaimer" would be a positive statement about Class II products, stating that the product claims have been reviewed by Health Canada.
- An example of a statement as a "proclaimer" could include:
  - "This product (or its claim) was reviewed by Health Canada"

COMPLIANCE AND ENFORCEMENT (C&E)

	Class I self-care products	Class II self-care products
Manufacturing Standard*	• **Self-care products would be subject to manufacturing standards that will address safety and quality.** These standards could range from the NHP GMP to a higher standard. • The higher standard would be applicable if the activities of the regulated party involve Class II products. • Where a regulated party conducts activities related to both Class I and II products, the higher standard would apply. • Regulated parties dealing in Class I products would have the option of meeting the higher standard and obtain an Establishment Licence and be eligible to obtain export certificates, for example.	
Site Licensing*	**No licensing requirement** Registration - site and product components	**Licence required** Depending on risk, inspection may be required prior to issuance of license
Tools	In the context of a new self-care framework, Health Canada will look at the tools it requires to effectively enforce a new regulatory regime. Options may include administrative monetary penalties and mandatory recall.	

	Class I self-care products	Class II self-care products
Inspection*	**No regular inspections** A limited onsite visit component • targeted compliance monitoring projects • non-cyclical inspections.	**Regular inspection program** Depending on risk, inspection may be required prior a licence being issued. Frequency, depth and/or mode of inspection would change according to risk (e.g. paper-based, partial, full inspection).
Compliance Verification	**Risk-based compliance verification** Noncompliance will generally be considered a lower priority for C&E action when it concerns Class I products. However, assessment of other factors will influence the appropriate C&E action, including: • adulteration or contamination • vulnerable subpopulation (e.g., children, pregnant women) • compliance history • social sensitivities • actions of regulated party (premeditation, degree of cooperation) • the likelihood of the enforcement action being effective	**Risk-based compliance verification** Noncompliance will be considered a higher priority for C&E action when it concerns Class II products. Multiple risk factors will be assessed in determining the appropriate C&E action, including: • inherent product/site risk • adulteration or contamination • vulnerable subpopulation (e.g., children, pregnant women) • compliance history • social sensitivities • actions of regulated party (premeditation, degree of cooperation) • the likelihood of the enforcement action being effective

Consultation Continues

April/May: Round 1 discussions included:

- Classification
- Claims
- Statements on the Label
- Unique Identifier
- Compliance and Enforcement

June: Round 2 discussions will include:

- Classification, claims and evidence
- Product license and administration, including data protection and cost recovery
- Product information, including labelling and advertising
- Compliance and vigilance, including site licensing, quality standard, and inspections

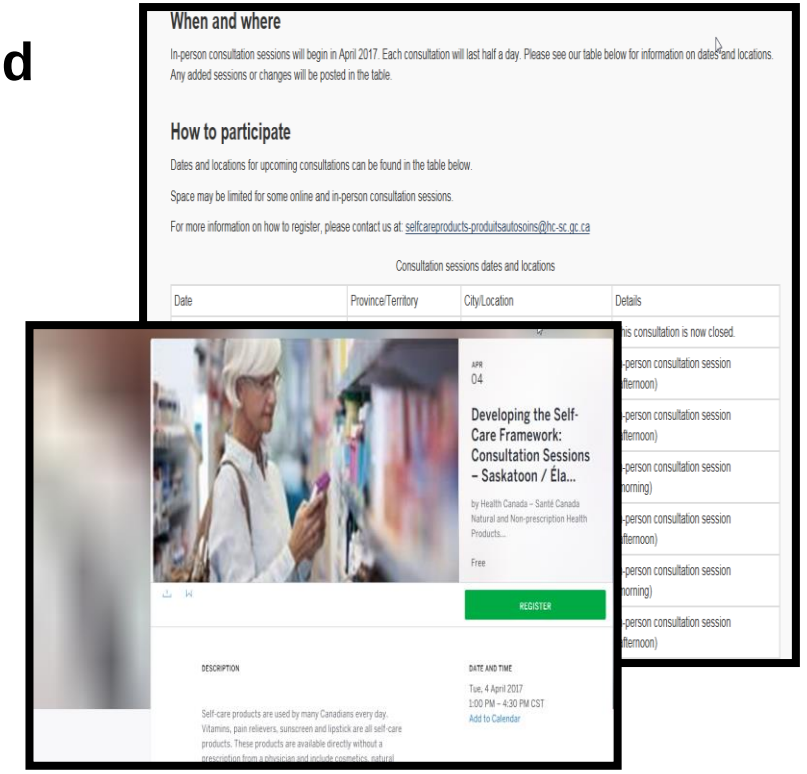
How can Canadians share their views?

From April until June 2017, in-person and online consultations will be held across Canada.

Round 1 of the self-care consultation is now complete.

Round 2 is now open for registration:

- Webinar (EN): June 29
- Edmonton: June 13
- Vancouver: June 14
- Toronto: June 21
- Montreal: June 27
- Webinars (EN and FR): June 29



Where can I find more information?

Health Canada self-care products website, including dates and registration information for upcoming consultations:

www.canada.ca/selfcare-products

Contact the Health Canada self-care products team:

selfcareproducts-produitsautosoins@hc-sc.gc.ca