Health Canada Santé Canada

Canada

The Canadian experience – reforms to the regulation of self-care products

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

What are self-care products?

Cosmetics	Natural health products	Non-prescription drugs
Used for cleaning, improving or altering the complexion, skin, hair or teeth (e.g., moisturizing creams, deodorants, shampoos)	Various uses including general health maintenance (e.g., mineral supplements, probiotics, traditional medicines)	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.

How are self-care products regulated now?

- Canada has rules in place that govern the safety, efficacy and quality of self-care products.
- All self-care products fall under one law in Canada – the *Food and Drugs Act* – but they are regulated under three different sets of regulations:
  - the *Cosmetic Regulations;*
  - the *Natural Health Products Regulations;* and
  - the *Food and Drug Regulations.*
- This means:
  - different rules for how to bring products to market;
  - different levels of evidence required for health claims made by manufacturers; and
  - different levels of post-market monitoring and compliance enforcement.

Current Regulatory Approach – Case Study: Toothpaste

Similar products…			
These three toothpastes are sold side by side on store shelves	**Cosmetic…**  **…does not have a therapeutic claim**	**Natural Health Product…**  **…has a therapeutic claim and natural ingredient**	**Non-prescription Drug…**  **…has a therapeutic claim and synthetic ingredients**
…different rules			
Different rules	· No product review · No site licence · No inspection · No cost to industry · No adverse reaction reporting	· Expedited product review based on claims · Site licence · No inspection · No cost to industry · Adverse reaction reporting	· In-depth product review based on scientific evidence · Establishment licence · Mandatory inspections · Cost to industry (up to $340,000) · Adverse reaction reporting
Inconsistent powers	· No recall authorities · Maximum fine is $5,000	· No recall authorities · Maximum fine is $5,000	· Recall authorities exist · Maximum fine is $5,000,000

Why do we need change?

- There are different evidence requirements for self-care products making similar claims
- There is different information provided to the consumer for similar products
- There is a proliferation of “too good to be true” advertising claims (e.g., weight loss)
- There is limited deterrence for non-compliance and no recall power for NHPs and cosmetics in Canada
- This all results in an uneven playing field for industry

What are we working toward?

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

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

Benefits for Industry

- ü More **predictable and consistent** rules for bringing products to market
- ü **Risk-based rules** that impose the appropriate level of regulatory oversight

Policy Objectives and Approach

Oversight proportional to risk

Similar evidence for similar claims

Informed consumer choice

Risk-based post-market oversight

Cost recovery for <u>all</u> products
Modern business systems

Approach to Policy Consultation

September to October 2016

Step 1
Online consultation

Purpose:
Seek feedback on high level principles

Stakeholders engaged:
- General public
- Industry associations
- Health professionals
- Academics
- NGOs

Output:
What we heard report

February to May 2017

Step 2
Expert sessions

Purpose:
Refine the policy proposal

Stakeholders engaged:
- Industry associations
- Health professionals
- NGOs

Output:
Revised policy proposal

April to July 2017

Step 3
Public consultations

Purpose:
Seek broad views on the refined policy proposal

Stakeholders engaged:
- General public
- Industry associations
- Health professionals
- Academics
- NGOs

Output:
Consultation Summary

May to October 2017

Step 4
Who have we not heard from?

Purpose:
Consult with stakeholders who have not had a voice so far during the consultation

Stakeholders engaged:
- General public
- Health professionals
- Academics

Output:
Revisions to policy proposal

MARKET ENTRY: What is Health Canada proposing?

- Classification would be based on risk, including product safety and harm of failed efficacy
- Lower-risk self-care products would be grouped into Category I and II, and would come to market through a registration process
- Higher-risk self-care products would be in Category III, and would come to market through an authorization process
- Given feedback during the first consultation, we are proposing a distinction between products making therapeutic claims and those that do not
- There would be similar levels of requirements for similar levels of claims
- Health Canada would have a more consistent application of user fees to recover costs of regulating self-care products
- There would be an appeals process (i.e., right to be heard) that is impartial and transparent

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

Non-therapeutic claims

Minor therapeutic claims

Stronger therapeutic claims

No scientific evidence required

Types of claims:
- Cleans
- Protects
- Improves/alters appearance

Topical products only

Established science
§ Peer-reviewed literature
§ Case studies from medical practice

Types of claims:
- General wellness
- Provides source of vitamin
- Relieves minor symptoms

Other permissible information – Limited to claims for minor ailments
§ History of use within a paradigm (e.g., traditional Chinese medicine)
§ Homeopathic references

Types of claims:
- Homeopathic claim for minor ailment
- Herbal claim for minor ailment

Cannot be contradictory to established science

CLINICAL EVIDENCE BAR

Clinical evidence required
§ Clinical trials
§ Observational studies
§ Foreign regulatory decisions

Types of claims:
- Treats
- Prevents
- Cures

Market entry via registration

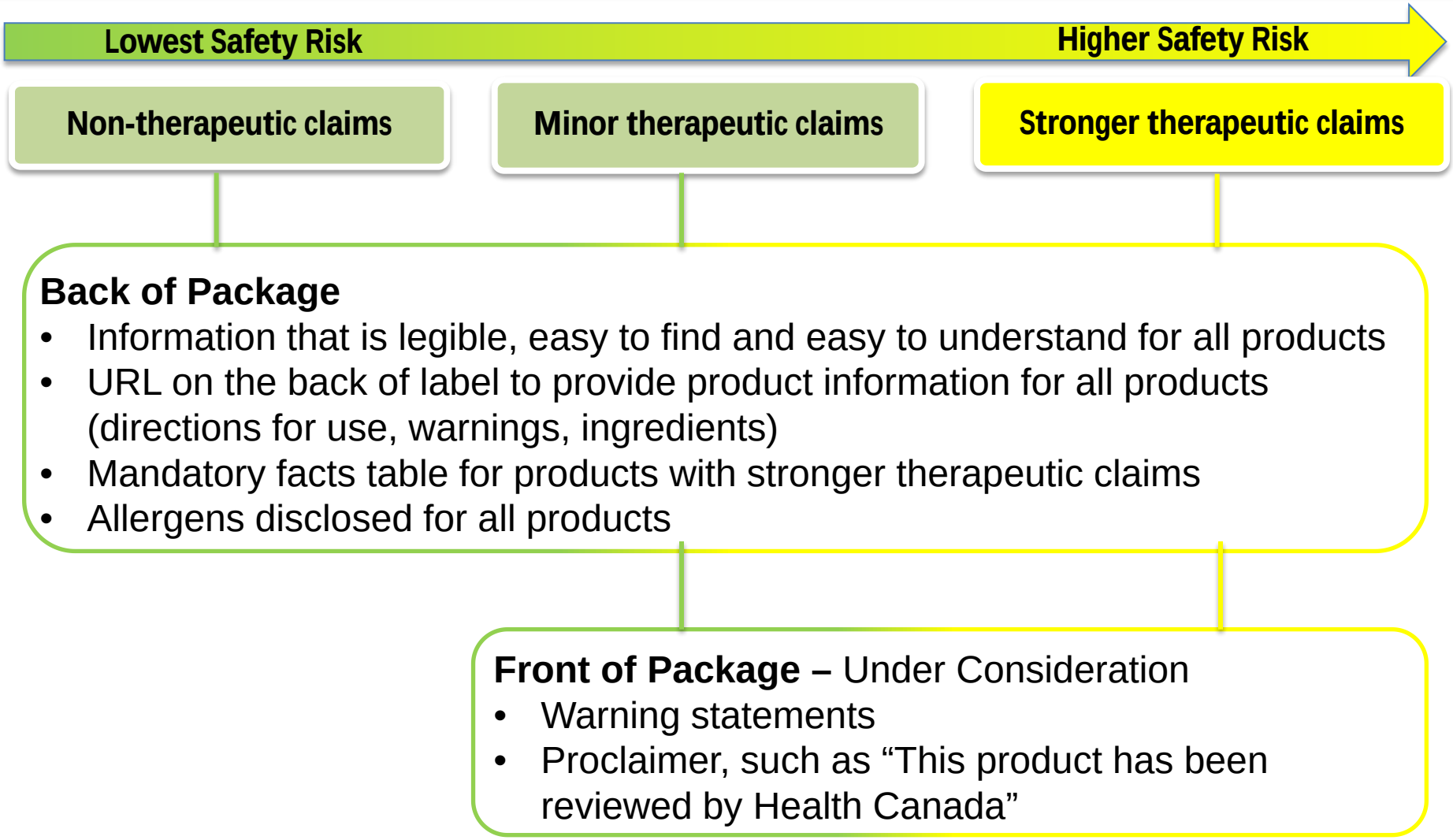
Authorized via licensing

INFORMATION FOR THE CONSUMER: What is Health Canada proposing?

- **Better labelling** to help consumers with product identification, selection and use, to support informed decision-making
- This would include **consistent content and format** that is easy to read and understand
- A **facts table** for self-care products making therapeutic claims
- Use of a **URL to provide additional information** for the consumer
- Stronger oversight and enforcement on **advertising**

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

Informed Consumer Choice – Essential Information at Point of Purchase



SITE LICENSING, COMPLIANCE & ENFORCEMENT, AND VIGILANCE: What is Health Canada proposing?

- Increase **proactive verification of compliance**, including inspections
- Require **site licences** for most categories of self-care products, including licensing for fabrication, packaging/labelling, importing, and testing
- Create a **baseline quality manufacturing standard** that is consistent across all product lines, with increased requirements as risk increases
- Continue to support the **issuance of trade certificates** for exportation purposes
- Establish a **risk-based approach to vigilance**
- Maintain a **risk-based response to health and safety issues**

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

NEXT STEPS

- Work to date has been focused on developing the policy framework and consulting extensively with a broad range of stakeholders and consumers

- Our focus is now on finalizing the policy proposal and determining how a new framework would be implemented (e.g., instrument choice)

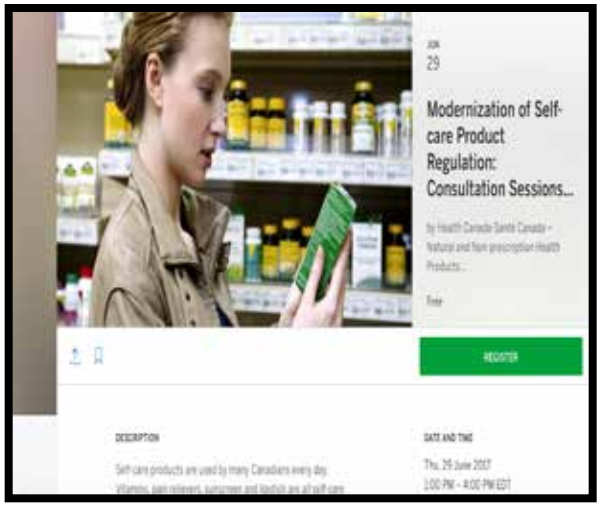
- Targeted consolations will continue to inform the approach, including consumer feedback on labelling changes

- We are very interested to continue international bilateral discussions to leverage best practices from other regulatory bodies and to mitigate any impact on trade or international collaboration.

Where can you find more information?

Health Canada self-care framework website:

www.canada.ca/selfcare-products



Contact the Health Canada self-care framework team:

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