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

October 2017
Matthew Bown
Health Canada
What are self-care products?

<table>
<thead>
<tr>
<th>Cosmetics</th>
<th>Natural health products</th>
<th>Non-prescription drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used for cleaning, improving or altering the complexion, skin, hair or teeth (e.g., moisturizing creams, deodorants, shampoos)</td>
<td>Various uses including general health maintenance (e.g., mineral supplements, probiotics, traditional medicines)</td>
<td>Commonly referred to as &quot;over-the-counter drugs&quot; (e.g., pain relief, cold &amp; flu symptoms, allergy relief)</td>
</tr>
</tbody>
</table>

• 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

<table>
<thead>
<tr>
<th>Similar products…</th>
<th>Cosmetic…</th>
<th>Natural Health Product…</th>
<th>Non-prescription Drug…</th>
</tr>
</thead>
<tbody>
<tr>
<td>These three toothpastes are sold side by side on store shelves</td>
<td>...does not have a therapeutic claim</td>
<td>...has a therapeutic claim and natural ingredient</td>
<td>...has a therapeutic claim and synthetic ingredients</td>
</tr>
</tbody>
</table>

### …different rules

<table>
<thead>
<tr>
<th>Different rules</th>
<th>Cosmetic…</th>
<th>Natural Health Product…</th>
<th>Non-prescription Drug…</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No product review</td>
<td>• Expedited product review based on claims</td>
<td>• In-depth product review based on scientific evidence</td>
<td></td>
</tr>
<tr>
<td>• No site licence</td>
<td>• Site licence</td>
<td>• Establishment licence</td>
<td></td>
</tr>
<tr>
<td>• No inspection</td>
<td>• No inspection</td>
<td>• Mandatory inspections</td>
<td></td>
</tr>
<tr>
<td>• No cost to industry</td>
<td>• No cost to industry</td>
<td>• Cost to industry (up to $340,000)</td>
<td></td>
</tr>
<tr>
<td>• No adverse reaction reporting</td>
<td>• Adverse reaction reporting</td>
<td>• Adverse reaction reporting</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inconsistent powers</th>
<th>Cosmetic…</th>
<th>Natural Health Product…</th>
<th>Non-prescription Drug…</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No recall authorities</td>
<td>• No recall authorities</td>
<td>• Recall authorities exist</td>
<td></td>
</tr>
<tr>
<td>• Maximum fine is $5,000</td>
<td>• Maximum fine is $5,000</td>
<td>• Maximum fine is $5,000,000</td>
<td></td>
</tr>
</tbody>
</table>
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

- **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 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 all 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

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

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

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

Types of claims:
- Treats
- Prevents
- Cures

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

Market entry via registration

 Authorized via licensing

No scientific evidence required

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

Topical products only

Clinical evidence required

Types of claims:
- Treats
- Prevents
- Cures

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
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.
Back of Package
• Information that is legible, easy to find and easy to understand for all products
• URL on the back of label to provide product information for all products (directions for use, warnings, ingredients)
• Mandatory facts table for products with stronger therapeutic claims
• Allergens disclosed for all products

Front of Package – Under Consideration
• Warning statements
• Proclaimer, such as “This product has been reviewed by Health Canada”

Market entry via registration
Authorized via licensing
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 consultations 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:
selfcareproducts-produitsautosoins@hc-sc.gc.ca