Update on the Self-Care Framework
## 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>
Overall Objectives of the Self-Care Framework

- 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
Research and Consultations to Date

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


April - July 2017: Online and in-person consultation sessions held across the country

Fall 2017: Reviewed input received throughout consultations to inform approach forward

February 2018: Announcement of phased approach to implementing self-care framework
Phased Approach

In February, Health Canada announced a phased approach to updating self-care product regulations

Phase I – Fall 2018: Introduce, for consultation, targeted amendments to the *Natural Health Products Regulations* to **improve labelling** of natural health products

Phase II – Early 2019: Introduce, for consultation, targeted amendments to the *Food and Drug Regulations* to introduce a **risk-based approach to regulatory oversight** for non-prescription drugs

Phase III – Starting in 2020: Introduce, for consultation, regulatory amendments to address **evidence standards** for similar health claims, extending **risk-based regulatory oversight**, and seeking **additional powers** for Health Canada for all self-care products
Phase I – Amendments to the NHPR

From: Inconsistent labelling
To: Consistent, plain language labelling

This includes:

- comprehensible and readable language (use of plain language attributes) on all NHP labels
- a facts table to
  - standardize the format for important information
  - make it easier for consumers to locate important information on the product;
- modernized contact information for problem reporting and questions:
  - e-mail address, toll-free phone number

Better support consumers in selecting and safely using a product
Cost-Benefit Analysis Survey

• A Cost-Benefit Analysis (CBA) survey was sent to industries that could be affected, should the government proceed with the proposed requirements for improved labelling for NHPs.

• Health Canada wishes to be made aware of any potential costs that you could incur as a result of these potential changes.
  – Survey questions
  – Other costing considerations specific to your industry

• The CBA survey was sent out February 23, 2018.
• Webinar for clarification on April 4 and April 6, 2018.
• Comments will be accepted until May 30, 2018.
Phase I - Timeline

**Stakeholder Engagement**
- **Technical Sessions**
  - Feb 2018: Discussion of proposed approach to labelling in Vancouver
  - Mar 2018: Discussion of proposed approach to labelling in Toronto
  - Apr 2018: NPD PLL Lessons Learned
  - Apr 2018: Discussion of proposed approach to labelling in Montreal
  - Jun 2018: Discussion of regulatory elements with early look at guidance
  - Oct 2018: Discussion of proposed guidance

**Health Canada**

**Regulations and Guidance** for labelling of Natural Health Products
- Feb 2018: Announcement of phased approach
- Mar – Apr 2018: Analysis of feedback from technical discussions, including PLL Lessons Learned
- May 2018: Analysis of survey results
- Jun 2018: Analysis of focus group feedback
- Jul – Oct 2018: Completion of proposed regulations

**Survey** to determine potential costs of changes to label requirements for NHPs.
- Mar 2018: Launch of survey
- Apr 2018: Q&A sessions on the cost survey
- May 2018: Completion of survey

**Focus Groups** with consumers on NHP labelling
- May – June 2018: Focus group sessions

**November 2018**

Public Consultation (CG I) on:
- Proposed changes to *Natural Health Products Regulations*
- Proposed guidance related to labelling of natural health products
Phase II – Amendments to the *FDR*

<table>
<thead>
<tr>
<th>FROM</th>
<th>TO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification:</strong> Prescription and non-prescription treated the same- despite differences in risk</td>
<td><strong>Classification:</strong> Based on risk to the consumer</td>
</tr>
<tr>
<td><strong>Review:</strong> All products</td>
<td><strong>Review:</strong> Focus on higher-risk products</td>
</tr>
<tr>
<td><strong>Efficiency:</strong> Duplicative reviews</td>
<td><strong>Efficiency:</strong> Leverage previous and foreign reviews</td>
</tr>
<tr>
<td><strong>Site license:</strong> Required for all (up to $35,000)</td>
<td><strong>Site license:</strong> Risk-based (not required for lower-risk products)</td>
</tr>
<tr>
<td><strong>Service Standard:</strong> 230 days</td>
<td><strong>Service Standard:</strong> 1, 60 or 180 days</td>
</tr>
<tr>
<td><strong>Fees:</strong> $$$$$</td>
<td><strong>Fees:</strong> $ - $$$</td>
</tr>
</tbody>
</table>

This includes:

- Reduce undue burden by expediting pathways for lower-risk products
- Common, risk-based quality standard
- Risk-based licensing requirements

Align the oversight for non-prescription drugs with level of risk to the consumer
Phase II - Timeline

**Stakeholder Engagement**

**Technical Sessions**
- **Mar 2018**: Discussion of proposed approach to classification + GMP in Toronto
- **Apr 2018**: Discussion of proposed approach to classification + GMP in Montreal
- **Jun 2018**: Discussion of regulatory elements with early look at guidance
- **Oct 2018**: Discussion of regulatory elements and related guidance
- **Jan 2019**: Discussion of proposed guidance

**Health Canada**

**Regulations and Guidance for Non-Prescription Drugs**
- **Feb 2018**: Phased approach announced
- **Mar – Jul 2018**: Analysis of feedback from technical discussions
- **Aug 2018**: Analysis of survey results
- **Sep 2018 - Jan 2019**: Completion of proposed regulations

**Survey (TBC)**
- **June - August 2018**: Survey to determine costs and benefits of changes to the Food and Drug Regulations

**Early 2019**

Public Consultation (CG I) on:
- Proposed changes to *Food and Drug Regulations*
- Proposed guidance related to non-prescription drugs
Phase III: Other regulatory amendments

For consultation: regulatory amendments to address
- evidence standards for similar health claims
- extending risk-based regulatory oversight to NHPs and cosmetics
- seeking additional powers for Health Canada, such as the ability to require a recall or label change for all self-care products

- This will include:
  - Classification
  - Informed consumer choice
  - Modernized site licensing
  - Modern quality standard for NHPs

- This is where we will have weightier discussions as it relates to the evidentiary standards for NHPs, as stakeholder feedback indicated that we needed more time for these discussions

Align the oversight for self-care products with level of risk to the consumer
What We Know Right Now – Resetting the Stage

• NPNs will be maintained

• Regulatory frameworks are not being collapsed
  – Changes would be in the NHPRs

• No disclaimers being proposed

• Maintaining pathway for licensing for evidentiary standard
Building from...

September 2016...

**Lower Risk Self-Care Products**
- No Health Canada review or licensing of these products
- Health Canada sets requirements that companies would meet to sell these products, including quality
- Health Canada sets exclusions as to which ingredients/products would not be in this group

**Moderate Risk Self-Care Products**
- Some review by Health Canada and licensing of products based on evidence of safety and effectiveness published in a monograph (a licensing standard)
- Companies would be required to meet quality standards
- (Full review would not be required because there are standards already in place for the products in this group)

**Higher Risk Self-Care Products**
- Full review by Health Canada
- Companies must provide evidence to support the safety, quality, and effectiveness of products

Health Canada would not review claims
- No claims could be made about the diagnosis, treatment, prevention, mitigation of a disease or condition
- Claims other than diagnosis, treatment, prevention, care or mitigation of a disease, would be accompanied by a disclaimer indicating that Health Canada has not reviewed the product for effectiveness
- *Claims must be truthful and accurate and companies are required to have this supporting information*

**Product examples:**
- Cosmetics, many vitamin and mineral products, toothpaste, mouthwash, homeopathic products, diaper rash products

...June 2017...

**Category I**
- Lower safety risk and lower risk of failed efficacy
- Limited concern with ingredients, combinations or conditions of use

**Category II**
- Higher safety risk or higher risk of failed efficacy
- Potential concern with ingredients, combinations or conditions of use

**Risk of Failed Efficacy (Claim)**
- Products intended:
  - To cleanse, protect, alter the complexion/kin/hairstyle, beauty
  - For general wellness, to maintain, support, manage, provide a source of, mechanism of action
  - To treat, prevent, mitigate, cure some minor (defined by factors) conditions or diseases, including symptoms

**Market Entry**
- Pre-market Registration
  - Legal for sale once registration requirements are met

**Evidence**
- Supported by historical use or baseline (or higher) clinical evidence for ingredients and claims
- Available upon request by Health Canada

**Category IA: Non-Therapeutics**
- A: Representation is not false or misleading

**Category IB: Therapeutics**
- B: Historical use
- C: Clinical evidence

**Category II: Therapeutics**
- D: Pre-cleared clinical evidence
  - International / Monographs
- E: Pre-cleared clinical evidence plus or partial review
  - e.g., expanded claims/dose
- F: Full review of clinical evidence
  - Need to establish safety and/or efficacy

**Market entry via registration**
**Authorized via licensing**
## Classification Criteria - April 2018

<table>
<thead>
<tr>
<th>Category I</th>
<th>Category II</th>
<th>Category III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Uncertainty:</strong></td>
<td><strong>Uncertainty:</strong></td>
<td><strong>Uncertainty:</strong></td>
</tr>
<tr>
<td>• Well-established <strong>safe use</strong> (i.e., on the register/assessed previously)</td>
<td>• <strong>Known</strong> (i.e., on the register/assessed previously)</td>
<td>• <strong>Low/unknown certainty</strong> (product/ingredient/claim has not previously been assessed under the product’s proposed recommended conditions of use); OR</td>
</tr>
<tr>
<td><strong>AND</strong></td>
<td>• High certainty for low impact on population health concern</td>
<td>• Certainty for impact on population health concern; OR</td>
</tr>
<tr>
<td><strong>Harm:</strong></td>
<td><strong>Harm:</strong></td>
<td><strong>Harm:</strong></td>
</tr>
<tr>
<td>• Intended to have a <strong>topical</strong> and <strong>localized</strong> effect</td>
<td>• Intended for a <strong>systemic effect</strong>, including topical and non-topical (e.g. ingestible)</td>
<td>• <strong>Ingredients of higher risk/concern</strong>, including NSAIDs, corticosteroid, antiviral, antibiotic, sterile, erectile dysfunction, PPIs, weight loss; OR</td>
</tr>
<tr>
<td>• Non-systemic (i.e. excluding broken skin application)</td>
<td>• Other drugs intended for use on the skin, mouth, teeth or gums</td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td>• Non-ingestible (teeth, gums, mouth)</td>
<td>• Excluding products (see Category III)</td>
<td><strong>Benefit:</strong></td>
</tr>
<tr>
<td>• Excluding products (see Category III)</td>
<td><strong>AND</strong></td>
<td>• <strong>Benefit:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
<td>• Drugs that confer a <strong>higher benefit</strong></td>
</tr>
<tr>
<td><strong>Benefit:</strong></td>
<td><strong>Benefit:</strong></td>
<td>• Therapeutic purpose</td>
</tr>
<tr>
<td>• Cosmetic</td>
<td>• <strong>Lowest-risk drugs</strong> with -</td>
<td>• Therapeutic purpose</td>
</tr>
<tr>
<td></td>
<td>• Therapeutic purpose</td>
<td>-E.g. claims for diseases and conditions not established in the register</td>
</tr>
<tr>
<td></td>
<td>-E.g. General wellness, health maintenance, symptomatic relief of conditions that self-resolve</td>
<td><strong>OR</strong></td>
</tr>
</tbody>
</table>
# Acceptable Purposes by Category

<table>
<thead>
<tr>
<th>Category I</th>
<th>Category II</th>
<th>Category III</th>
</tr>
</thead>
</table>
| *All current cosmetics*<br>*Secondary sunscreens*<br>*Toothpaste for prevention of gingivitis*<br>*Mouthwash*<br>*Diaper rash*<br>*Anti-septic cleansers*<br>*Anti-dandruff*<br>*Acne*<br>*Medicated skin care products* | *Primary sunscreens*<br>*Skin whiteners/lighteners*<br>*Traditional Chinese Medicine (TCM) - Traditional claims*<br>*Ayurvedic - Traditional claims*<br>*Probiotic - source of...*<br>*Traditionally used in Herbal Medicine as a nutritive tonic*<br>*Support/maintain status quo & healthy populations (e.g. adults)*<br>*Medicated skin products for oozing and weeping (i.e. systemic)*<br>*Source of antioxidant*<br>*For the removal of corns and calluses*<br>*Weight management*<br>*Helps in absorption of calcium*<br>*Relieves (itching, burning, cracking, etc.) of athlete's foot*<br>*Helps in development of teeth and gums*<br>*Seborrheic dermatitis shampoo*<br>*Psoriasis shampoo* | *NSAIDs, corticosteroid, antiviral, antibiotic, sterile, erectile dysfunction, PPIs, weight loss*<br>*Treatment/cure of a yeast infection*<br>*New stimulant laxative*<br>*Joint pain associated with osteoarthritis*<br>*For treatment of pink eye*<br>*Cognitive health products*<br>*Enhance claims, anxiety management*<br>*For vulnerable populations*<br>*Specific ingredients (e.g. hormones)*<br>*Probiotics*<br>*Claims for chronic conditions*<br>*For vulnerable populations*<br>*Cough, cold and flu*<br>*Relief from allergy symptoms*<br>*Relief from diarrhea*<br>*Temporary or chronic relief of pain*<br>

**Notes:**

- Excluding therapeutic purposes except if deemed acceptable (e.g. prevention of gingivitis)
- For local use on unbroken skin

*NOTE: Uncertainty and Harm components must be met in combination with benefit*
## Example of Category I and II Evidence

<table>
<thead>
<tr>
<th>CATEGORY I – NON-THERAPEUTIC</th>
<th>CATEGORY II THERAPEUTIC – HISTORICAL USE</th>
<th>CATEGORY II THERAPEUTIC – CLINICAL EVIDENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representation is not false or misleading or meets an acceptable test</td>
<td>Literature review</td>
<td>Any level of evidence used for Category II</td>
</tr>
<tr>
<td></td>
<td>Theories and concepts of systems of traditional medicine, including:</td>
<td>Epidemiological studies</td>
</tr>
<tr>
<td></td>
<td>- Traditional Chinese medicine</td>
<td>Pilot and open label studies</td>
</tr>
<tr>
<td></td>
<td>- Ayurvedic medicine</td>
<td>Reputable textbooks</td>
</tr>
<tr>
<td></td>
<td>- Herbal medicine</td>
<td>Demonstration of food use to support safety only</td>
</tr>
<tr>
<td></td>
<td>- Homeopathic medicine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phase II clinical trials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>History of use</td>
<td></td>
</tr>
</tbody>
</table>
# Example of Category III Evidence

## Pre-Cleared Clinical Evidence

- Health Canada pre-cleared evidence (e.g., published monographs)
- Foreign regulatory decision in an equivalent jurisdiction
  - Evidence of a positive decision from another regulatory agency

## Pre-Cleared Clinical Evidence Plus, Partial Review or Full Review

- Phase III or phase IV clinical trials (randomized, controlled, well-designed)
- Meta-analysis (controlled and well-designed)
- Prospective observational studies or combinations of one prospective study and one retrospective study
- Systematic review other than meta-analysis
- Published, peer-reviewed, detailed narrative reviews which cite detailed primary evidence
- Phase II clinical trials
- Epidemiological studies
- Published compilations referring to traditional use (for safety only)
<table>
<thead>
<tr>
<th>Category I</th>
<th>Category II</th>
<th>Category III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Labelling:</strong></td>
<td><strong>Labelling:</strong></td>
<td><strong>Labelling:</strong></td>
</tr>
<tr>
<td>• General principles of plain language</td>
<td>• General principles of plain language</td>
<td>• General principles of plain language</td>
</tr>
<tr>
<td>• Modernized contact info</td>
<td>• Modernized contact info</td>
<td>• Modernized contact info</td>
</tr>
<tr>
<td>• Allergens to be disclosed</td>
<td>• Allergens to be disclosed</td>
<td>• Allergens to be disclosed</td>
</tr>
<tr>
<td>• Facts table (optional)</td>
<td>• Facts table (required)</td>
<td>• Facts table (required)</td>
</tr>
<tr>
<td>• Compel label</td>
<td>• Compel label</td>
<td>• Compel label</td>
</tr>
<tr>
<td>• No label review</td>
<td>• No label review</td>
<td>• Label review</td>
</tr>
<tr>
<td><strong>Compliance &amp; Enforcement:</strong></td>
<td><strong>Compliance &amp; Enforcement:</strong></td>
<td><strong>Compliance &amp; Enforcement:</strong></td>
</tr>
<tr>
<td>• Compliance Monitoring/ Verification – lower priority in absence of extenuating factors, such as contamination, could move issues up</td>
<td>• Compliance Monitoring/Verification – the inspection program would focus on higher risk activities and those with a history of non-compliance.</td>
<td>• Compliance Monitoring/ Verification – lower priority in absence of extenuating factors, such as contamination, could move issues up</td>
</tr>
<tr>
<td>• Site Licence not required</td>
<td>• Site Licence required for: manufacture, package, label, import, and test</td>
<td></td>
</tr>
<tr>
<td>• Quality Standard recommended – sanitary conditions</td>
<td>• Quality Standard required</td>
<td></td>
</tr>
<tr>
<td><strong>Vigilance:</strong></td>
<td><strong>Vigilance:</strong></td>
<td><strong>Vigilance:</strong></td>
</tr>
<tr>
<td>• Report serious domestic adverse reactions and serious unexpected foreign adverse reactions</td>
<td>• Monitor and assess safety information (reports submitted based on risk)</td>
<td></td>
</tr>
<tr>
<td>• Summary reports developed and provided upon request</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Risk-based licensing requirements

- Applies to the activities of:
  - Manufacture
  - Importation
  - Packaging
  - Labelling
  - Testing

- Flexibility of a unique license against various quality standards:
  - New GMP standard
  - Part C, Division 2 of the FDR

- Annual license notification
- Risk-based site inspections
Common, risk-based quality standard - GMP

- **Premises, Equipment, Personnel, Sanitation**

- **QA**: independent QAP on site

- **Raw material** and **finished product** verification: within specifications, QA approved

- **Sample** retention

- **Packaging** material verification: within specifications

- **Stability** monitoring: within acceptable range

- **Recall** capacity: complete and rapid recall, notification to Health Canada

- **Record** keeping: distribution records, complaints, investigations, corrective actions

- **Self-inspection** program
Where can I find more information?

Health Canada self-care products website:
www.canada.ca/selfcare-products

Contact the Health Canada self-care products team:
selfcareproducts-produitsautosoins@hc-sc.gc.ca