Health Canada Santé Canada

Canada

Update on the Self-Care Framework

Cosmetic Alliance Canada (CAC)

Fall Regulatory Workshop

October 10th, 2018

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Current Regulatory Approach – Case Study: Toothpaste

Similar products…			
	Cosmetic…	**Natural Health Product…**	**Non-prescription Drug…**
These three toothpastes are sold side by side on store shelves			
	…does not have a therapeutic claim	**…has a therapeutic claim <u>and</u> natural ingredient**	**…has a therapeutic claim <u>and</u> 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

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

Elements of the Self-Care Framework

Oversight proportional to risk

Similar evidence for similar claims

- Product Categorization
- Product Claims and Evidence

Informed consumer choice

- Improved product labelling

Risk-based post-market oversight

- Compliance Monitoring & Verification
- Site Licensing
- Quality Standard
- Vigilance

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.

September - October 2016: Online consultation conducted, with over 3,500 responses. *What We Heard* report released in March 2017.

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.

June 2018: Technical session with industry, academic experts and consumer support groups.

July 2018: Discussion groups with consumers held across the country. *What We Heard* report will be published online in the fall.

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

WHAT IS PHASE I?

Goal of Improved Labelling

- Plain Language Labelling Regulatory was passed for Non-Prescription Drugs in 2013
  - The goal was to assure that the regulations contain not only the labelling requirements, but also how those requirements are to be labelled
- This proposal builds on that precedence, while adopting changes to account for the differences in labelling for NHPs
- The objectives of this proposal are to improve the safe and effective use of NHPs, to help informed consumer choice by providing a comparative experience and clear and legible regulatory information and reduce the number of medication errors resulting from labels and packages
- More specifically, the proposed regulatory amendments are intended to:
  - introduce general requirements for plain language labelling to explicitly link readability of the label to certain elements such as colour contrast, minimum font size, and layout of text;
  - standardize the format for NHP labels in a table to help users locate important information

Changes to the Labelling Provisions in the NHPRs

- The phased approach will include changes within the existing *Natural Health Product Regulations*, and is NOT an amalgamation of regulatory frameworks.

- Changes apply to sections 86 through 94 (Part 5) of the NHPRs.

- These changes will not have an impact on product license applications as no label mock-ups will be required.
  - Mock-ups could conceivably be requested now, but on a risk-basis

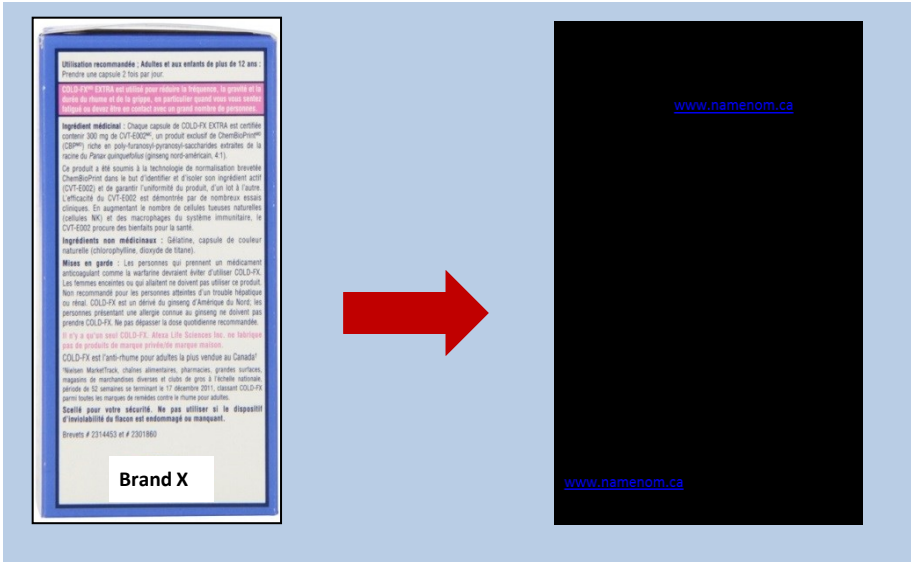
- The intent of the changes are to introduce standardization of labelling while providing flexibilities for packages that could not comply with the totality of requirements.

- These flexibilities will be presented both in a risk-based and graduated approach.
  - Unlike the present approach in the NHPRs, labelling flexibilities can only be accessed after moving through the graduated flexibilities.

Phase I – Improved labelling of NHPs

From: Inconsistent labelling

To: Consistent, plain language labelling



This includes:

- Format requirements for 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

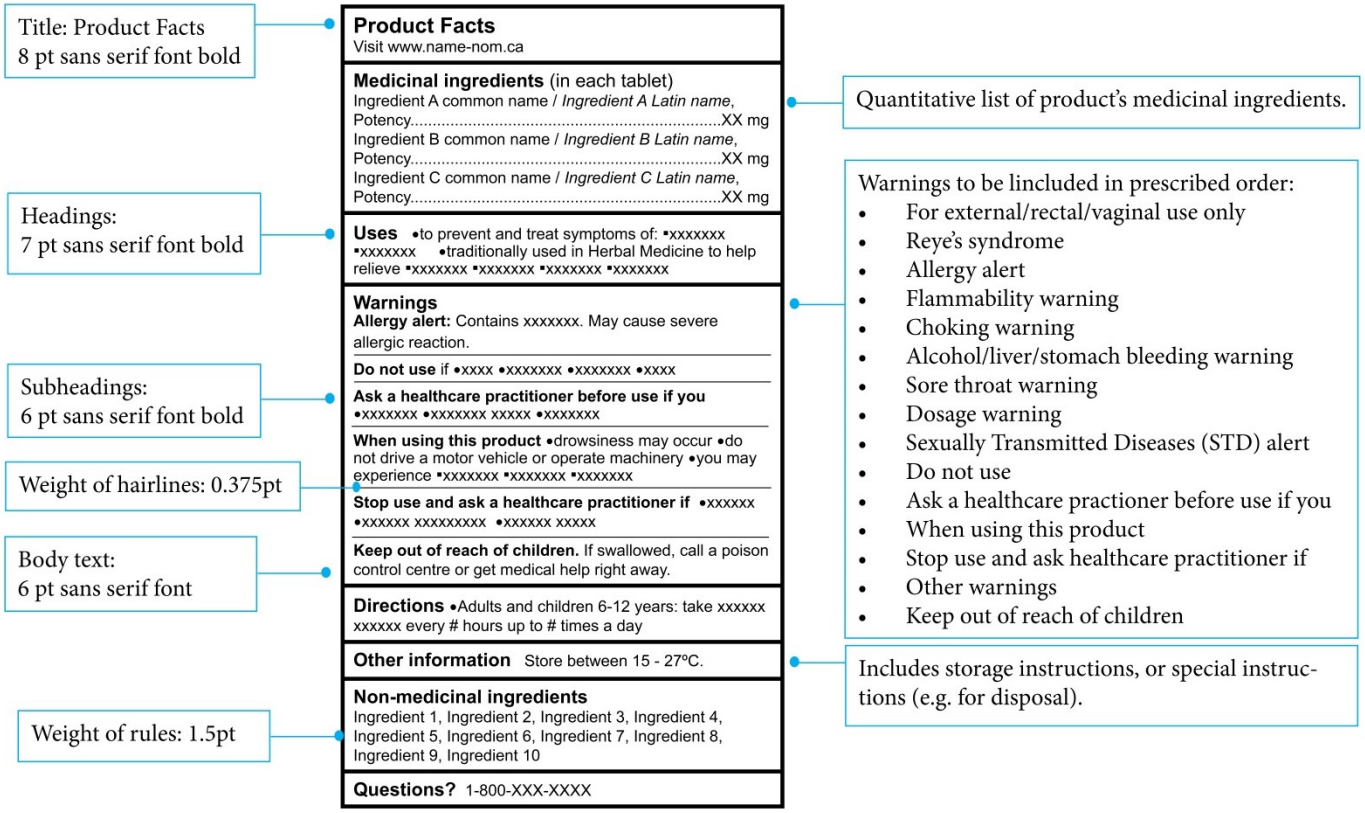
Requirements:

- Minimum font size
- Contrast in the presentation of regulatory information
- The use of a table for all but the lowest risk, cosmetic like, NHPs
- Standardized headings for the table
- Flexibilities to allow for the information to fit on as many packages as possible
  - Common name/proper name
  - Storage information
  - Use(s)
  - Use of condensed font
  - Removing non-medicinal ingredients
  - Removing risk-statements that are “point-of-use”

Improved labelling of NHPs – Category I products

- For the purposes of an exemption from the requirement to have a Products Facts Table, as per the SCF proposal, it was necessary to define Category I
  - This has been the least commented of Categories over the last two years of consultation
- Category I is defined as:
  - Topical products, localized effect for things that self-resolve or are unlikely to worsen requiring health care practitioner intervention
  - Products that have well – established history of safe use containing ingredients that are not high risk
  - Cannot be applied to broken skin
  - Cosmetic purpose or a therapeutic purposed considered acceptable for Category I (e.g. risk reduction, will self-resolve, treatment of gingivitis)
- Category I products must present information in a clear and discernible way
  - Simple sentences using bullets, short lists
  - Legible font styles and sizes with sufficient contrast

Improved labelling of NHPs – Product Facts Table



Labelling guidance document outlining available formatting flexibilities to be published for consultation at the same time as the proposed regulatory change

Testing the Concept: Consumer discussion groups

Consumer discussion groups were held in July 2018 across Canada to:

- Inform the consumer-focused approach to NHP labelling
- Consult and better understand how consumers use labels to inform decisions when selecting and using a self-care product
- To obtain feedback on:
  - the usability and the legibility of current product labels
  - the various font types and sizes used on product labels
  - the comparability of proposed NHP labelling to OTC labelling
  - the importance of listing medicinal or non-medicinal ingredients and allergens
  - the information that is needed to select and use a self-care product

What We Heard report will be published online in the fall

Cost-Benefit Analysis Survey

- A Cost-Benefit Analysis (CBA) survey was sent to industries that could be affected by 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 were accepted until **May 30, 2018.**
- CBA analysis and report are under way.

Cost Benefit Analysis – Filling in the gaps

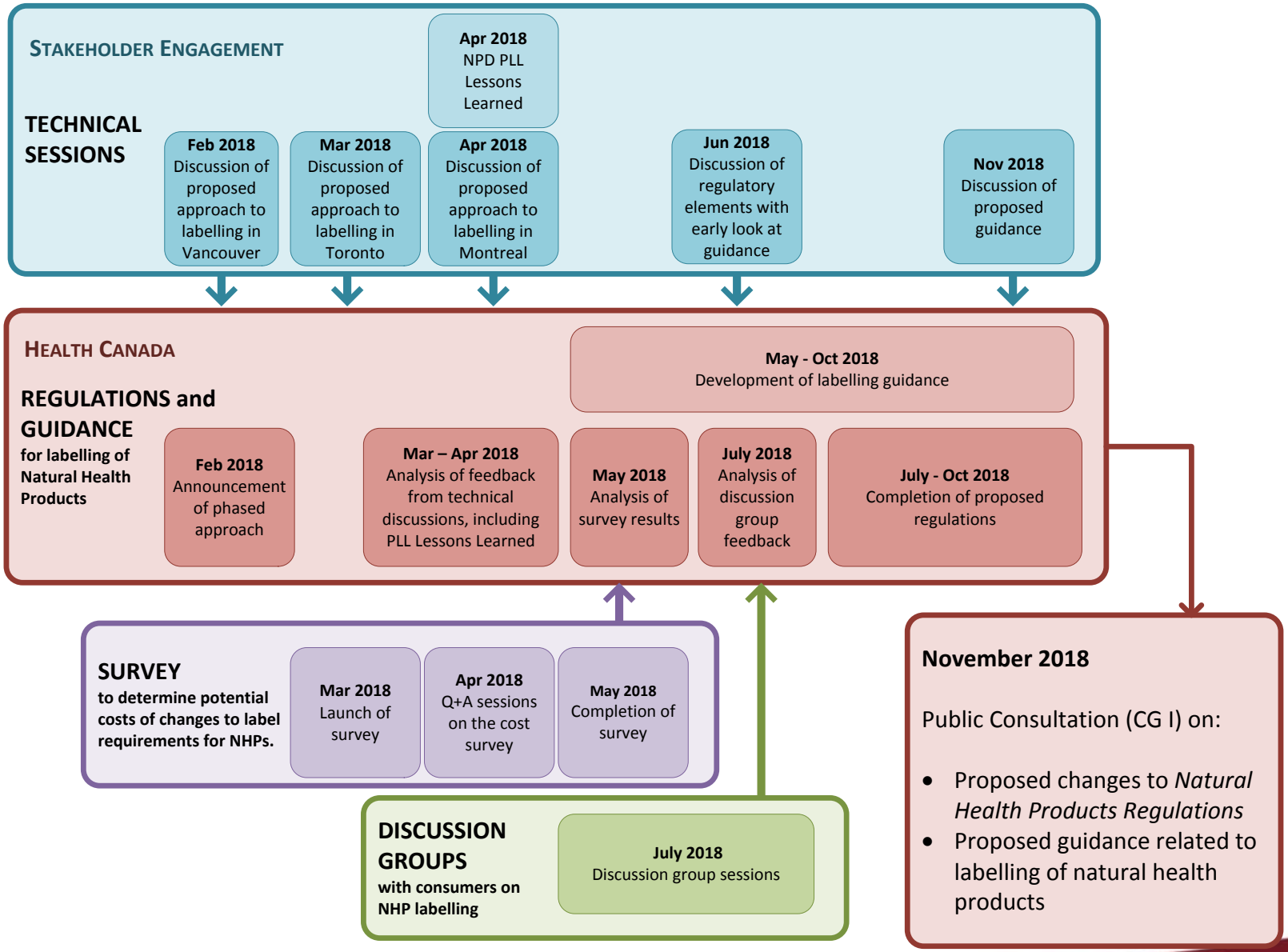
1. We would like any data on the expansion of the market since 2011; how much has it grown since 2011 in terms of market size/revenue?
2. What is the best approximation of the percentage of category I products, vs. category II/III products; what would this equate to in terms of total market share/revenue for category I and category II/III?
3. What is the percentage breakdown of: manufacturers, importers, manufacturers and importers, and exporters?
4. In addition, the following information would be helpful, stratified by business size, if possible:

- Information by company size (S/M/L) Sector-wide (All) Small Medium Large
- Estimated annual % of SKUs discontinued
- Percentage of licensed products that are marketed
- Total percentage of active product licenses marketed
- Average SKU(s) per product license

Categories of NHPs

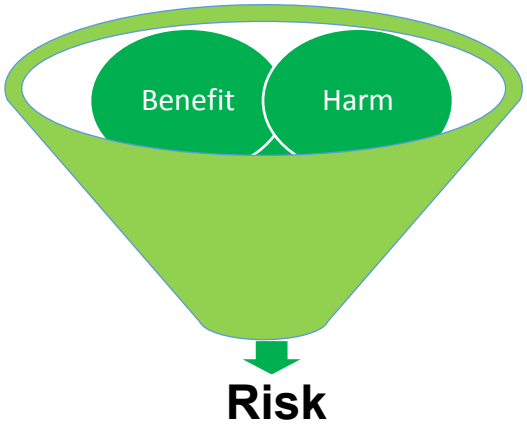
- Categorisation exercise : definition, list, exemptions
- Creation of three categories for NHPs based on risk
- Revision of monographs
- It is important to note, this only relates to category I
  - Category II and III will be Established as a part of Phas II (through public consultation

Phase I- Timeline



Phase II – Amendments to the *FDR*

FROM	TO
Classification: Prescription and non-prescription treated the same	**Classification:** Based on risk to the consumer
Review: All products	**Review:** Focus on higher-risk products
Efficiency: Duplicative reviews	**Efficiency:** Leverage previous and foreign reviews
Site license: Required for all (up to $35,000)	**Site license:** Risk-based (not required for lower-risk products)
Service Standard: 230 days	**Service Standard:** 1, 60 or 180 days
Fees: $$$$	**Fees:** $ - $$$



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

What Does This Mean?

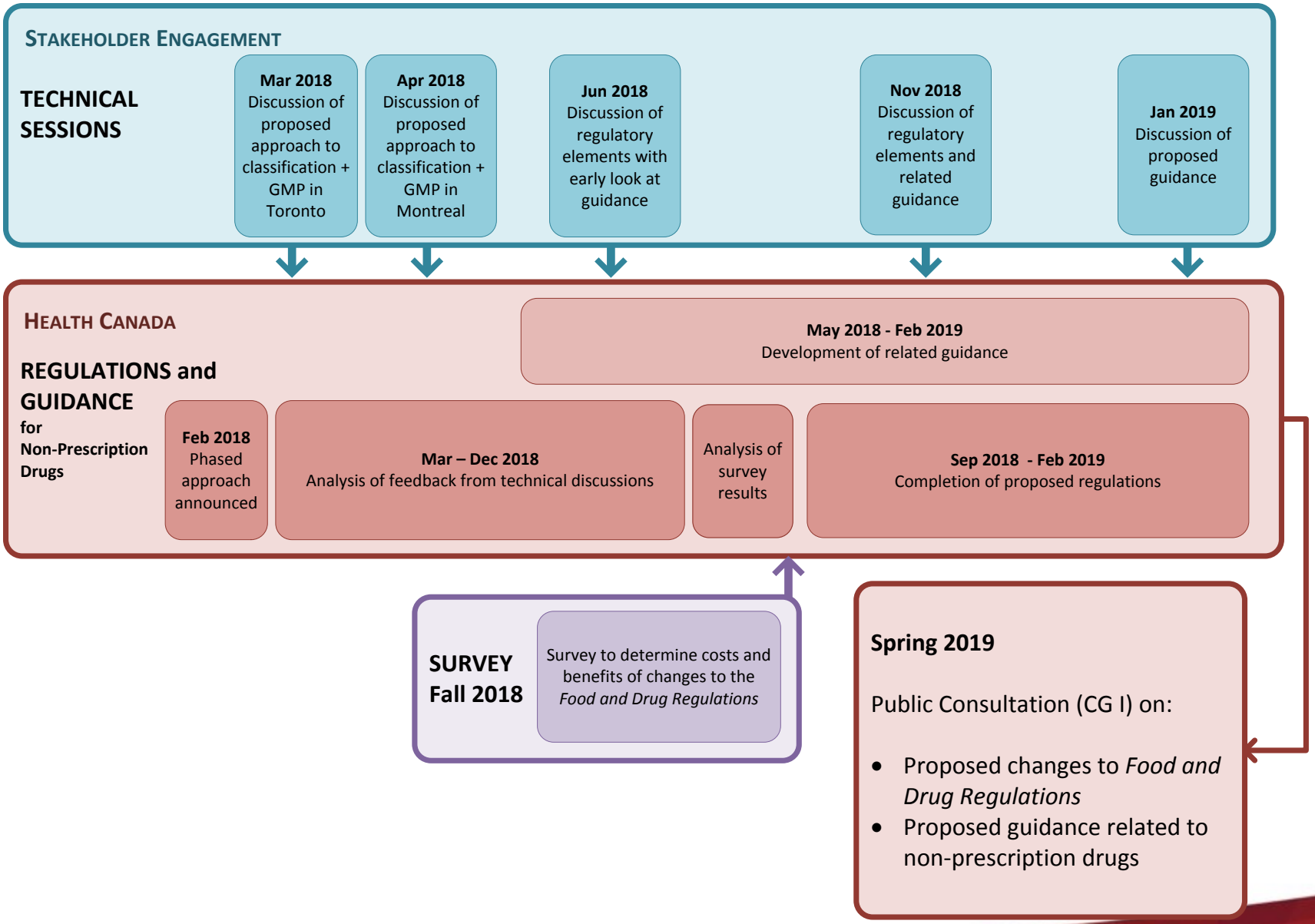
- Product Licensing
  - A clear evidentiary standard that differentiates by category
  - Pathways for all three categories, including registration or licensing (resulting in a DIN or NPN depending on the Phase)
  - Ability to require label samples
  - Establish new systems to support expedited processes

- Site Licensing
  - Requiring a license for testers
  - Annual licensing

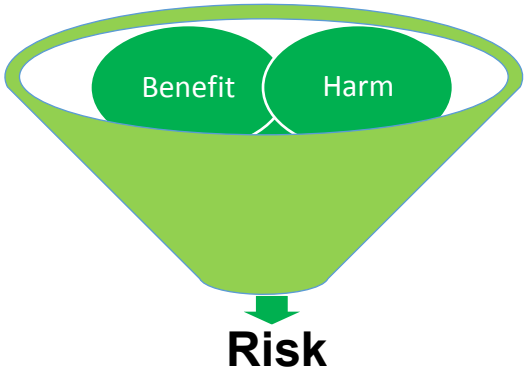
- GMP
  - Changes to a few provisions that have been irritants, including package, raw material and finished product testing, qualified person and stability

- Cost Recovery
  - Fees for product, site and annual licensing

Phase II - Timeline



Phase III: Other regulatory amendments



Starting in 2020 – Consulting in Early 2019

For consultation: regulatory amendments to address

- extending **risk-based regulatory oversight to NHPs and cosmetics**
- similar **evidence standards** for similar health claims
- 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

Align the oversight for self-care products with level of risk to the consumer

Risk-based categorization criteria

Category I

Uncertainty:

- Well-established **safe use** (i.e., on the register/ assessed previously)

AND

Harm:

- Intended to have a **topical** and **localized** effect
- **non-systemic** (i.e. excluding broken skin application)
- Non-ingestible (teeth, gums, mouth)
- Excluding products (see Category III)

AND

Benefit:

- **Cosmetic**
- **Lowest risk drugs for cosmetic purpose** (note: excluding therapeutic purpose)
- **Deemed acceptable low risk therapeutic purposes** (i.e. prevents gingivitis)

Category II

Uncertainty:

- **Known** (i.e., on the register/ assessed previously)
- High certainty for low impact on population health concern

AND

Harm:

- Intended for a **systemic effect**, including topical and non-topical (e.g. ingestible)
- Other drugs intended for use on the skin, mouth, teeth or gums
- Excluding products (see Category III)

AND

Benefit:

- **Lowest-risk drugs** with -
  - Therapeutic purpose

-E.g. General wellness, health maintenance, symptomatic relief of conditions that self-resolve

Category III

Uncertainty:

- **Low/unknown certainty** (product/ingredient/claim has not previously been assessed under the product's proposed recommended conditions of use) ; OR
- Certainty for impact on population health concern

OR

Harm:

- Ingredients of **higher risk/concern**,
  - including NSAIDs, corticosteroid, antiviral, antibiotic, sterile, erectile dysfunction, PPIs, weight loss

OR

Benefit:

- Drugs that confer a **higher benefit**
  - Therapeutic purpose

-E.g. claims for diseases and conditions not established in the register

Classification

- NNHPD is undergoing a review of the principles to create regulatory definitions that can be consulted on

- This will include further defining what these terms mean

- Classification Exercise:
  - Internal review of product licenses/monographs
  - Determination of class
  - Consultation principles (as defined) and categorization

- Category II will NOT establish a precedence that is just borrowed for Category III

- The two phases will be consulted on concurrently to support a finalization of the categorization to support any regulatory proposal

Risk-based oversight

<table>
<tr><th>Category I</th><th>Category II</th><th>Category III</th></tr>
<tr><td colspan="3">Labelling:
• General principles of plain language
• Modernized contact info
• Allergens to be disclosed
• Facts table (optional)
• Compel label</td></tr>
<tr><td>• No label review</td><td colspan="2">• No label review</td></tr>
<tr><td colspan="3">Labelling:
• General principles of plain language
• Modernized contact info
• Allergens to be disclosed
• Facts table (required)
• Compel label</td></tr>
<tr><td>• Label review</td><td colspan="2"></td></tr>
<tr><td>Compliance & Enforcement:
• Compliance Monitoring/ Verification – lower priority in absence of extenuating factors, such as contamination, could move issues up</td><td colspan="2">Compliance & Enforcement:
• Compliance Monitoring/Verification – the inspection program would focus on higher risk activities and those with a history of non-compliance.
• Medium priority in absence of extenuating factors, such as contamination, could move issues up</td></tr>
<tr><td>• Site Licence not required</td><td colspan="2">• Site Licence required for: manufacture, package, label, import, and test</td></tr>
<tr><td>• Quality Standard recommended – sanitary conditions</td><td colspan="2">• Quality Standard required</td></tr>
<tr><td colspan="3">Vigilance:
• Report serious domestic adverse reactions and serious unexpected foreign adverse reactions
• Monitor and assess safety information (reports submitted based on risk)
• Summary reports developed and provided upon request</td></tr>
</table>

ACCEPTABLE PURPOSES BY CATEGORY* - DRAFT

CATEGORY I

- All current cosmetics
- Secondary sunscreens
- Toothpaste for prevention of gingivitis
- Mouthwash
- Diaper rash (not on broken skin)
- Anti-septic cleansers
- Anti-dandruff (not used for higher risk claims)
- Acne (lower-risk)
- Medicated skin care products (certain ones not on broken skin)
- Some skin whiteners/lighteners

Notes:

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

CATEGORY II

- Primary sunscreens
- Traditional Chinese Medicine (TCM) - Traditional claims
- Ayurvedic - Traditional claims
- Probiotic - source of…
- Traditionally used in Herbal Medicine as a nutritive tonic
- Support/maintain status quo & healthy populations (e.g. adults)
- Homeopathic products (single ingredient or combinations with a specific claim)
- Homeopathic products (non-specific claims)
- Medicated skin products for oozing and weeping (i.e. systemic)
- Source of antioxidant
- For the removal of corns and calluses
- Weight management
- Helps in absorption of calcium
- Relieves (itching, burning, cracking, etc.) of athlete's foot
- Helps in development of teeth and gums
- Seborrheic dermatitis shampoo
- Psoriasis shampoo
- Relief from diarrhea
- Temporary relief of pain
- Electrolytes
- General health claims
- Smoking cessation
- Joint health (not chronic)
- Throat lozenges
- Skin, hair, nails or teeth (oral)
- Aromatherapy
- Topical anaesthetic/analgesic (without NSAIDs)
- Mental alertness (rather than dealing with depression)
- Antiseptic
- Immunity claims
- Repertory health (unless Schedule A)
- Digestive health
- Laxative
- Detoxification
- Muscle building/amino acids
- Urinary health/diuretic
- Dental health
- Live microorganisms/enzymes

CATEGORY III

- NSAIDs, corticosteroid, antiviral, antibiotic, sterile, erectile dysfunction, PPIs, weight loss
- Cough, cold and flu
- OTCs for relief from allergy symptoms
- Chronic relief of pain
- Treatment/cure of a yeast infection
- New stimulant laxative
- Joint pain associated with osteoarthritis
- For treatment of pink eye
- Cognitive health products
- Enhance claims, anxiety management for vulnerable populations
- Specific ingredients (e.g. hormones)
- Probiotics for treatment in a hospital setting
- Claims for chronic conditions for vulnerable populations
- Certain women's and men's sexual health products (macca)
- Blood glucose
- Ear/eye health (when sterile)
- Directional heart health claims
- Directional liver health
- Improves the functions of the kidney
- Improving thyroid functions
- Enzyme (fibrino act.)

***NOTE: Uncertainty and Harm components must be met in combination with benefit**

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

Next Steps – Building Towards Phase III

- CHFA East - September 13th, 2018
- CBA Discussion – October
- Technical Session on Phase I guidance – November 2nd, 2018
- Canada Gazette I – Late Fall, 2019
  - 75 day consultation period
- Discussion on CBA for Phase II – Fall 2018
- Early 2019 – Technical discussions on Phase II, and its implications on Phase III
  - Classification
  - Pathways for Licensing
    - Registration, Licensing – Resulting in an NPN or DIN
  - Standards of Evidence
  - Changes to the application process
  - Site licensing requirements/changes
  - Good manufacturing practices changes
- In-person discussions – Winter 2019
- Canada Gazette I Phase II – Spring 2019

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, including for responses to the questions on the CBA:

selfcareproducts-produitsautosoins@hc-sc.gc.ca