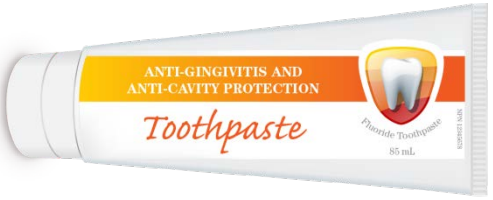
Health Canada Santé Canada

Canada

Update on the Self-Care Framework

YOUR HEALTH AND SAFETY... OUR PRIORITY.

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 <u>and</u> natural ingredient**	**Non-prescription Drug…**  **…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

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

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

Product Facts / Information sur le produit For the full table, visit / Pour le tableau complet, visitez : www.namenom.ca
Medicinal ingredients / Ingrédients médicinaux
Ingredient1/Ingrédient1 (xxx mg), Ingredient2/Ingrédient2 (xxx mg), Ingredient3/Ingrédient3 (xxx mg)
Warnings / Mises en garde •Warning_a / MiseEnGarde_a •Warning_b / MiseEnGarde_b
Directions / Mode d'emploi •First direction / Premier mode d'emploi
Non-medicinal ingredients / Ingrédients non médicinaux For the list, visit / Pour la liste, visitez : www.namenom.ca
Questions? 1-888-123-4567

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

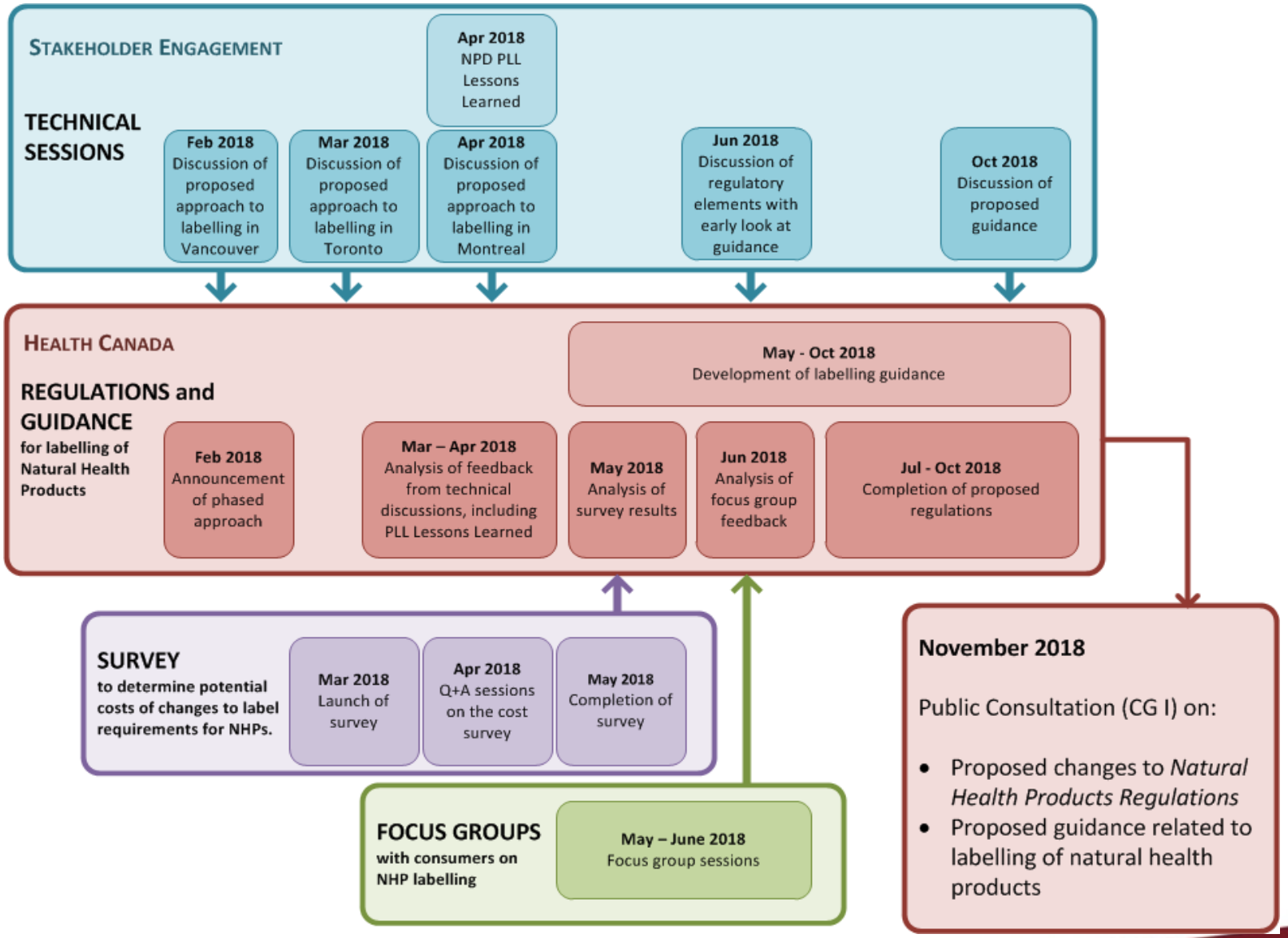
Cost-Benefit Analysis Survey

- 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

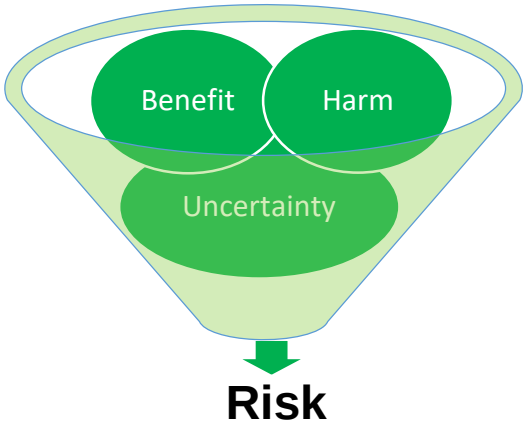
- The CBA survey was sent out February 23, 2018.
- Webinar for clarification on April 4 and April 6, 2018.
- Comments will be accepted until **May 30, 2018.**

Phase I- Timeline



Phase II – Amendments to the *FDR*

FROM	TO
Classification: Prescription and non-prescription treated the same- despite differences in risk	**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: $$$$	**Fees:** $ - $$$

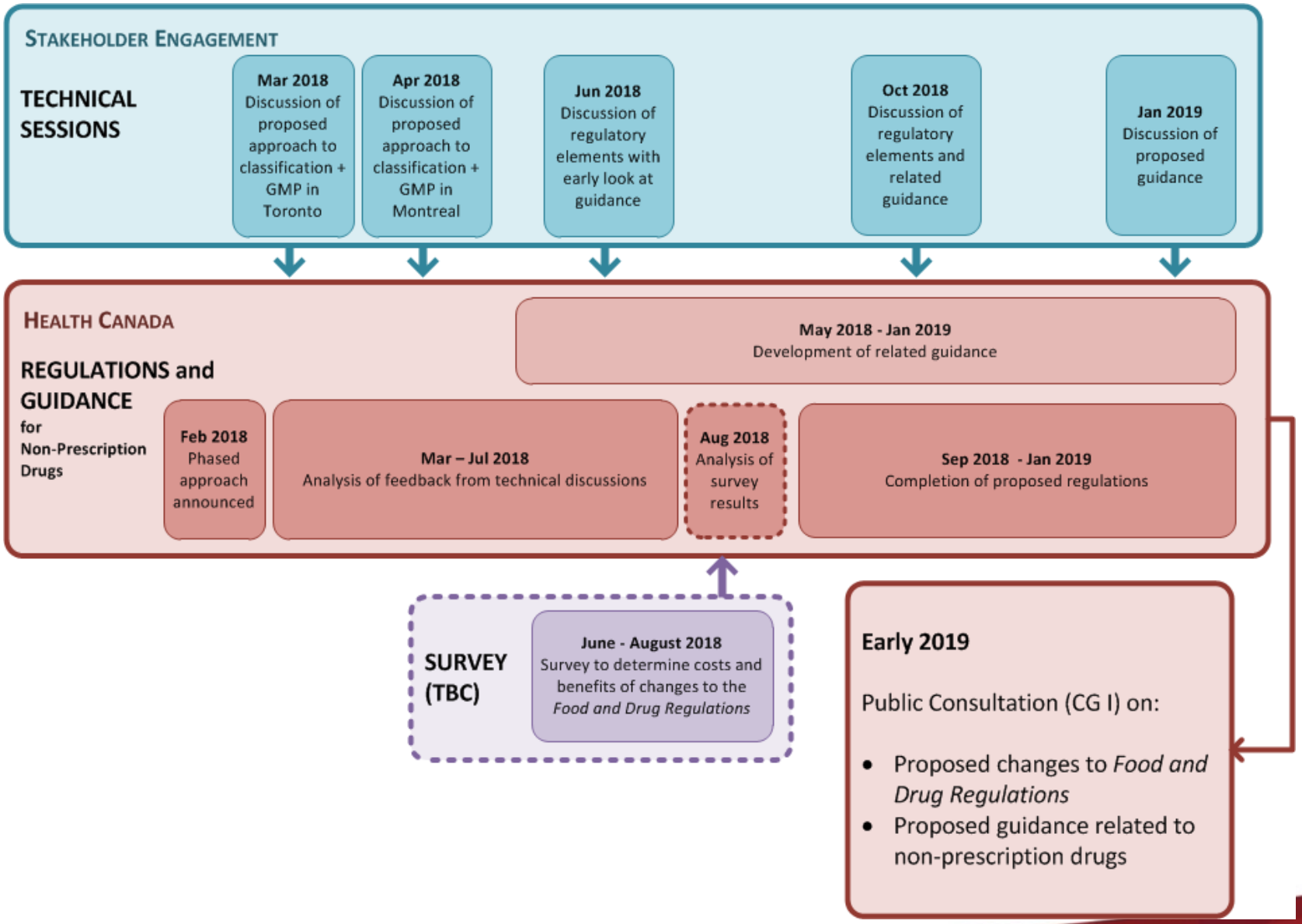


This includes:

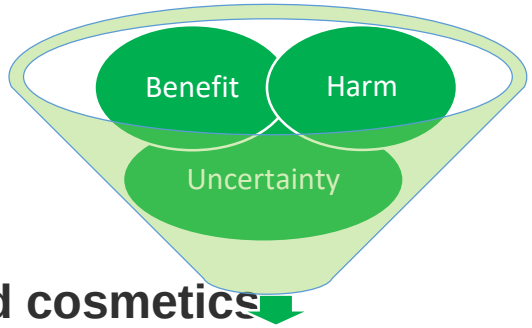
- Reduce undue burden by expediting pathways for lower-risk products
- Common, risk-based quality standard
- Risk-based licensing requirements

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

Phase II - Timeline



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

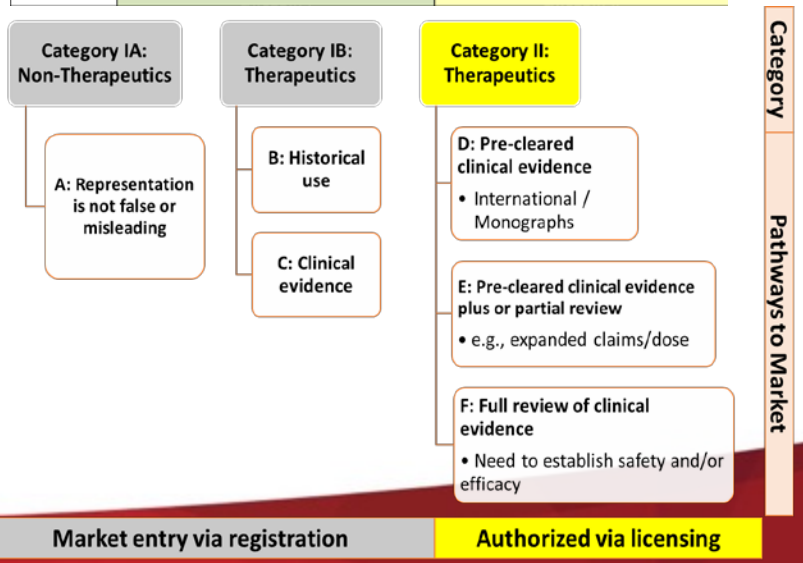
Building from….

September 2016…

Lower Risk Self-Care Products	Moderate Risk Self-Care Products	Higher 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	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)	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, cure 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	Heath Canada would approve claims Claims relate to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition; or the claims specified in the monograph *Claims would be based on science	Health Canada would approve claims related to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition *Claims must be based on science
Product examples: cosmetics, many vitamin and mineral products, toothpaste, mouthwash, homeopathic products, diaper rash products	Product examples: topical and oral pain relievers (such as acetaminophen and ibuprofen), cough and cold products, laxatives, allergy relief products	Product examples: products that are switching from prescription to non-prescription status, products that contain new medicinal ingredients, products related to cardiovascular health

…June 2017…

	CATEGORY I	CATEGORY II
Classification	**Lower** safety risk and **lower** risk of failed efficacy	**Higher** safety risk or **higher** risk of failed efficacy
Product Safety	Limited concern with ingredients, combinations or conditions of use	Potential concern with ingredients, combinations or conditions of use
Risk of Failed Efficacy (Claim)	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 • To treat, prevent, mitigate, cure **some minor (defined by factors)** conditions or diseases, including symptoms	Products intended: • To treat, prevent, mitigate, diagnose, cure **most** conditions or diseases, including symptoms
Market Entry	**Pre-market Registration** • Legal for sale once registration requirements are met	**Pre-market Authorization** • Legal for sale once authorized by Health Canada
Evidence	• Supported by **historical use** or baseline (or higher) **clinical evidence for ingredients and claims** • Available **upon request** by Health Canada	• Supported by higher level **clinical evidence** • Evidence **reviewed** by Health Canada • Additional elements required (e.g., on the label)



Classification Criteria- April 2018

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

ACCEPTABLE PURPOSES BY CATEGORY*

CATEGORY I

- All current cosmetics
- Secondary sunscreens
- Toothpaste for prevention of gingivitis
- Mouthwash
- Diaper rash
- Anti-septic cleansers
- Anti-dandruff
- Acne
- Medicated skin care products

Notes:

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

CATEGORY II

- Primary sunscreens
- Skin whiteners/lighteners
- 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)
- 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

CATEGORY III

- NSAIDs, corticosteroid, antiviral, antibiotic, sterile, erectile dysfunction, PPIs, weight loss
- 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
  - Claims for chronic conditions
  - For vulnerable populations

- Cough, cold and flu
- Relief from allergy symptoms
- Relief from diarrhea
- Temporary or chronic relief of pain

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

Example of Category I and II Evidence

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

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)

Oversight Proportional to Risk- April 2018

<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 colspan="3">Labelling:
• General principles of plain language
• Modernized contact info
• Allergens to be disclosed
• Facts table (required)
• Compel label</td></tr>
<tr><td>• No label review</td><td>• No label review</td><td>• Label review</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>
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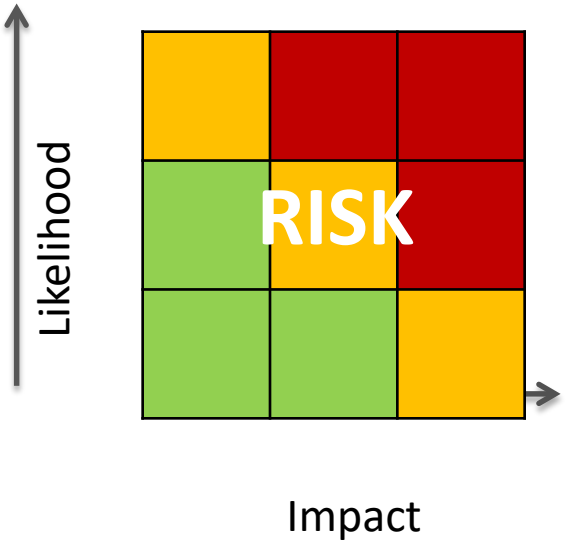
Risk-based licensing requirements

- **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