Health Canada Santé Canada

Helping the people of Canada maintain and improve their health

Aider les Canadiens et les Canadiennes à maintenir et à améliorer leur état de santé

Consumer Health Products Framework

Natural and Non-Prescription Health Products Directorate

CAPRA Education Day 2015

Canada

Purpose

To provide an overview and update on the Consumer Health Products (CHP) Framework.

Scope

- Consumer health products (CHPs) are those self-selected by consumers.

- Health Canada regulates these products under various regulations of the ***Food and Drugs Act*** (FDA):
  - natural health products (NHPs) under the ***Natural Health Products Regulations*** (NHPR)
  - non-prescription drugs (NPDs), including disinfectants, under the ***Food and Drug Regulations***
  - cosmetics under the ***Cosmetics Regulations***

Scope


Toothpastes
Disinfectants
Sunscreens
Antiperspirants
Consumer Health Products
Vitamins and Minerals
Cold Remedies
Contact Lens Solution
Pain Relievers

Overview

- CHP Framework objectives:
  - to protect the health and safety of Canadians
  - to apply to CHPs an aligned approach that is proportional to product benefit, harm and uncertainty
  - to apply a range of tools (operational improvements, policy and guidance change, regulatory change) to achieve alignment and proportionality

- Guiding principles:
  - science based approach
  - due consideration of the benefit, harm, and uncertainty profile of products
  - flexibility and foresight to achieve efficiency
  - international alignment, where appropriate

- Other key considerations:
  - oversight that is flexible and responsive to innovation and the evolving marketplace
  - factor into decision-making how Canadians use products and how health professionals interact and communicate with consumers on CHPs

Outcomes

The CHP Framework is expected to:

- Provide a consistent approach to products of similar risk whereby requirements are proportional to the benefit, harm, uncertainty profile - alignment of policies and regulatory oversight
- Improve the ability to focus more resources on higher risk, low certainty products
- Allow for greater openness and transparency of important product and manufacturing information
- Provide more access to information enabling Canadians to make safe, informed choices about products and self-care options
- Improve operational efficiency
- Reduce barriers to trade

Non-Prescription Drug Regulations: Scope

The proposed Non-Prescription Drug Regulations **apply to**:

- Non-prescription drugs for human use

- This category includes:
  - Over-the-counter drugs (including ‘behind-the-counter’)
  - Cosmetics that contain a medicinal ingredient (i.e., make health claims)
  - Disinfectant drugs for hard surfaces, other than those regulated under the *Pest Control Products Act*

Non-Prescription Drug Regulations: Scope

The proposed Non-Prescription Drug Regulations **will not apply to**:

- Natural Health Products:
  - Continue to be regulated under the *Natural Health Products Regulations*
- Cosmetics:
  - Continue to be regulated under the *Cosmetics Regulations*
- Veterinary drugs, ethical drugs, medical devices, medical gases, radiopharmaceuticals, biologics, drugs on the Prescription Drug List and drugs administered by puncturing the dermis

Non-Prescription Drug Regulations: Proposal

Market Authorization

- Proportional application pathways based on amount of corporate knowledge (e.g., monographs)
- Information incorporated by reference as monographs maintained by the Minister

Good Manufacturing Practices/Establishment Licensing

- Two-tiered licensing scheme which includes a Site Registration for certain lower-risk activities and products; satisfies international agreements, while providing flexibility to unique domestic manufacturers
- Modernized language and simplified format
- Reduced regulatory burden

Non-Prescription Drug Regulations: Proposal

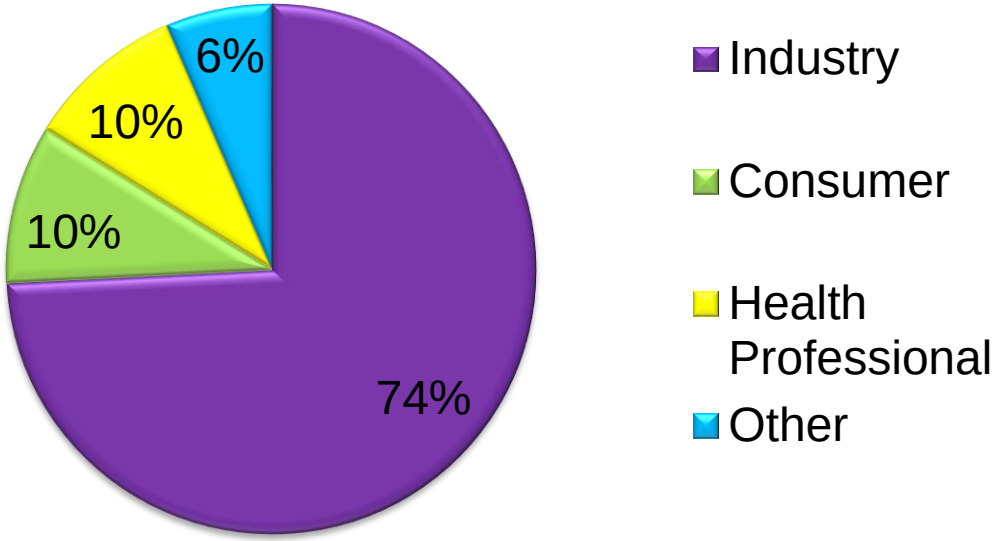
Post-Market

- Recall (Vanessa's Law) and other post-market powers
- For pre-clearance pathways, Minister could order action based on non-compliance with compendia
  - For other pathways, action will be determined by risk to health
- Appropriate vigilance requirements

CHP Framework: Consultation

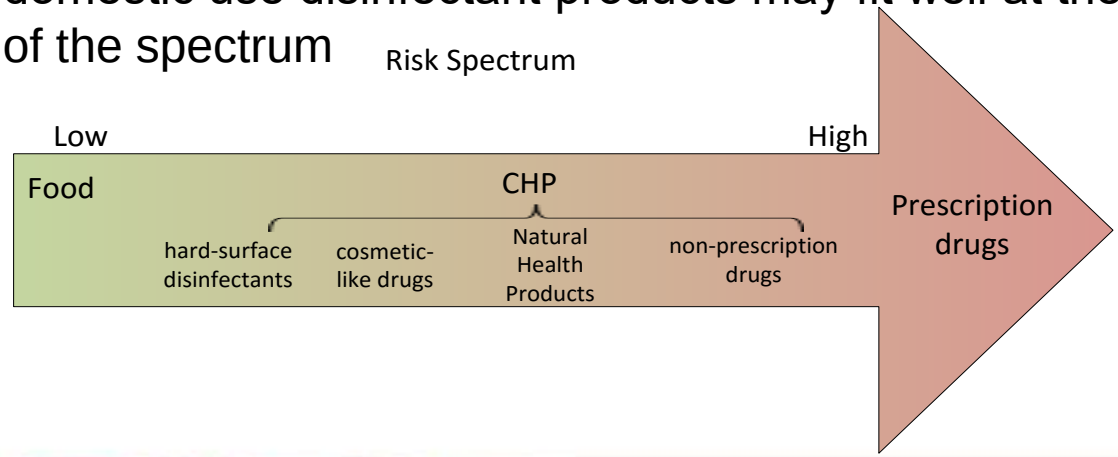
- CHP Framework discussion document was published for public consultation from Nov 2014 – Feb 2015.

- Health Canada received over 300 pages of comments in 31 individual submissions from industry, health professional groups, consumers and others.



Consultation: Low-Risk

- During the consultation on the CHP Framework, stakeholders concurred that not all CHPs are “low- risk”; they constitute rather a spectrum of risk which factors in type of product (e.g., lipstick with SPF vs. emergency contraception) and type of regulated activity (e.g., manufacturing vs. distribution) involved.
- This means we need to provide flexible and customized options that allow for proportional oversight
  - Preliminary consultation analysis shows that personal care products and domestic use disinfectant products may fit well at the “low risk” end of the spectrum



Consultation: What We Heard

- Support for the CHP Framework and its principles
- Protecting health and safety of Canadians remains a primary focus in the development of the Framework.
- Continue to use a risk-based approach.
- Ensure flexibility to address varying benefit, harm, uncertainty profiles to accommodate different product commodities.

Consultation: What We Heard

- Allow for innovation.
- Align internationally where possible.
- Minimize export challenges (e.g., Canada's Mutual Recognition Agreement partners and the participating authorities of the Pharmaceutical Inspection Co-operation Scheme).
- Ensure responsive post-market tools to manage safety issues and product uncertainties.

Consultation: What We Heard

Proportionality

Cosmetics and other personal care products

- Subject to requirements intended for higher risk pharmaceutical products under current approach as regulated under the *Food and Drug Regulations.*

- Examples of requirements cited include:
  - quarantine and re-testing upon importation to Canada,
  - prohibition on sampling,
  - application of Active Pharmaceutical Ingredients requirements,
  - application of Plain Language Labelling requirements, and
  - registration with the Drug Shortages website.

Consultation: What We Heard

Transparency

- Access to information about consumer health products and manufacturing.
- General support for incorporation by reference

Sampling

- Proposal to introduce regulations that would allow the distribution of samples of any authorized non-prescription drugs to any person (i.e., exempt non-prescription drugs from the prohibitions in section 14 of the *Food and Drugs Act*).
- General support for the proposal.
- Further policy development work based on the outcome of the consultations.

Considerations: Plain Language Initiative

- **Good Label and Package Practices Guide**
  - Objective of guide is to provide direction to sponsors in designing safe and clear labels and packages, including guidance on the Product Facts table format.
  - Guide focuses on the inner and outer labels and packaging across the range of health products for human use: prescription and non-prescription pharmaceuticals, biologics, and NHPs.
  - While NHPs are not covered under the Plain Language Labelling (PLL) regulatory amendments, the guide offers guidance to NHP sponsors as best practices.
  - External consultation on the draft guide closed recently (May 2015); analysis of feedback received is currently underway.

- **Brand Name Assessment Framework for CHPs**
  - Will apply to non-prescription (OTC) drugs and NHPs
  - Will set out brand naming criteria, and will also provide direction on when a Look Alike-Sound Alike (LASA) assessment is necessary
  - Currently under development; external consultation to follow (summer 2015)

What's Next

- Regarding next steps on the CHP Framework, work is underway with our partners in the health portfolio to analyse what we heard from the consultation.
- The department will continue to engage stakeholders as work on the CHP Framework advances.

Timeline:

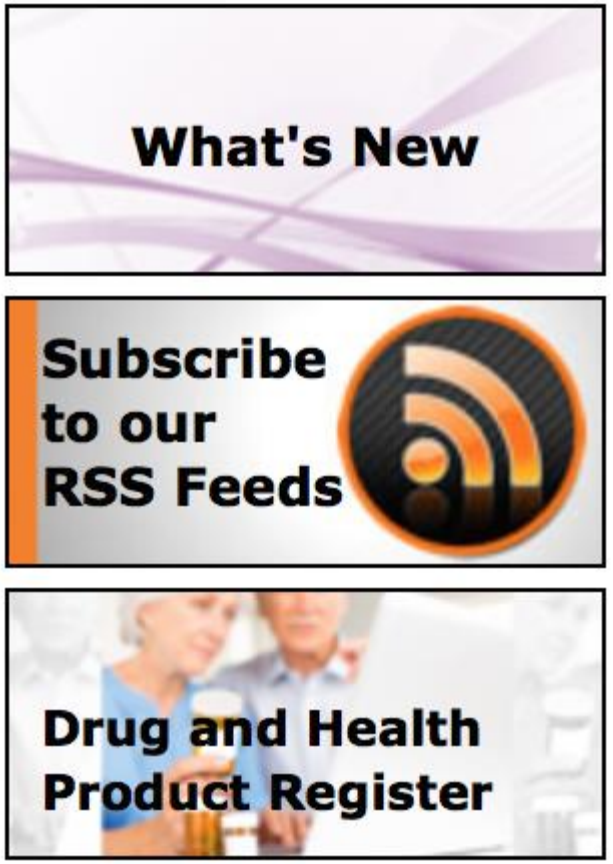
- Spring 2015: Completion of analysis of consultation comments
- August 2015: Publication of the CHP Framework document on what we heard from the consultation.
- Winter/Spring 2016: Develop non-prescription drug regulations

Further Information - NPDs

Website:

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index-eng.php

From this page you can access information about non-prescription drug products.



Further Information - NHPs

Website:

www.healthcanada.gc.ca/nhp

From this main page you can access most popular sections including What's New, Quarterly Reports, Licensed NHP Database, and Forms and Guidance.