

Regulation of Natural Health Products in Canada

Presentation at Dietary Supplement Public Meeting

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Outline

1. Regulatory Context

- *Natural Health Products Regulations* (NHPR)
- What can be included in Natural Health Products (NHPs)?
 - Approach to Synthetic Duplicates
 - Approach to Probiotics

2. Pre-Market Review

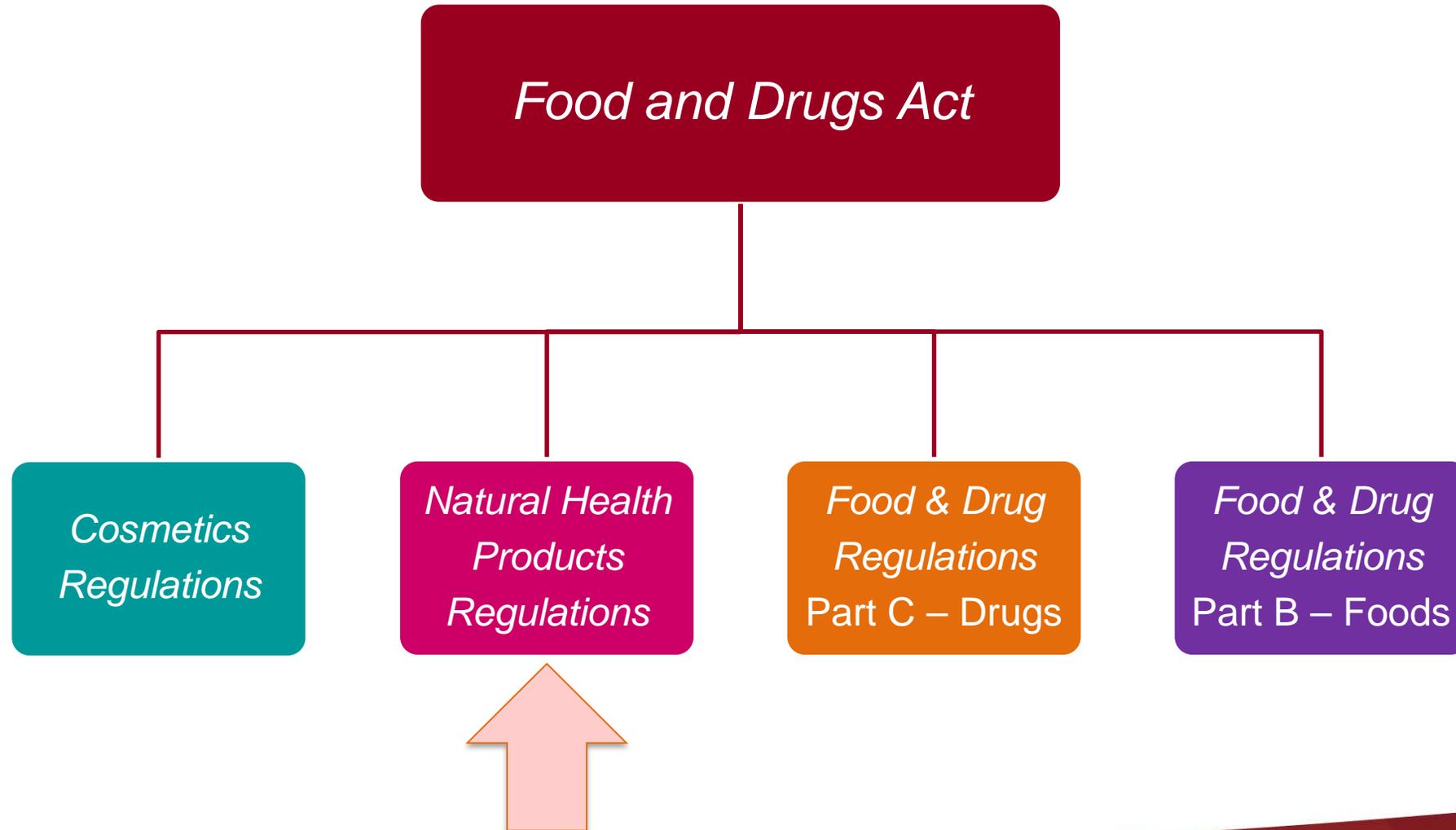
- Product pathways
- Approach to Safety and Efficacy and Experience to Date
- Approach to Quality and Experience to Date
- Processing Overview

3. Post-Market Activities

- Reactive Approach
- Proactive Approach

4. Current Regulatory Modernization Efforts

Regulatory Context



Natural Health Products Regulations (NHPR)

- All NHPs sold in Canada are subject to the NHPR, which came into effect in 2004
- Result from extensive consultation with broad range of stakeholders.
- Take into account concerns about NHP availability and safety, as well as the House of Commons Standing Committee on Health's 53 recommendations on the regulation of NHPs in Canada
- Purpose is to balance access to NHPs with the need to ensure appropriate standards are in place for:
 - Safety;
 - Efficacy; and
 - Quality

Scope of NHPs

In Canada, “natural health product” refers to a range of health products including:

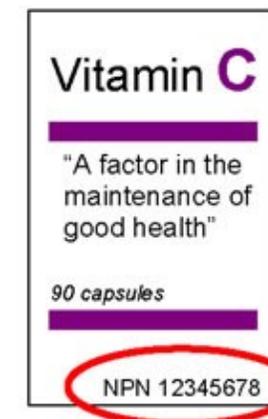
- Vitamin and mineral supplements
- Homeopathic medicines
- Plant and herbal remedies
- Traditional medicines
- Probiotics
- Certain personal care products

A 2010 survey showed that 73% of Canadians regularly take NHPs.

A 2016 survey showed that Canadians have low perceived knowledge of safety and effectiveness of NHPs (19%) and generally feel uninformed when purchasing these products (33-58%)

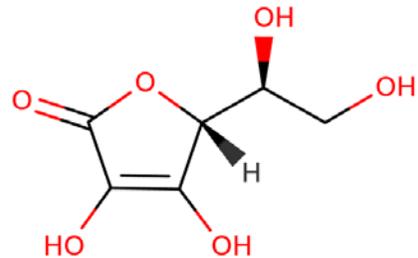
Authorized NHPs bear either a natural product number (NPN) or homeopathic medicine number (DIN-HM) on their labels

There are currently over 150,000 NHPs authorized for sale in Canada

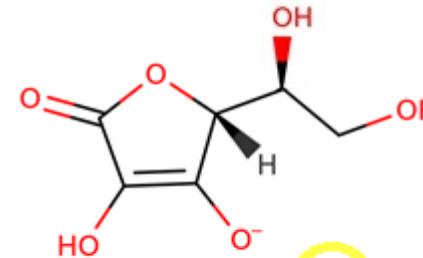


Approach to Synthetic Duplicates

- As an example, the NHPR allows for an extract or isolate of a plant, alga, a bacterium, fungus or a non-human animal material
- The activity of the synthetic substance should be identical to that of the naturally isolated substance



Vitamin C (as ascorbic acid)
commonly found in citrus fruits
and many vegetables



Sodium ascorbate (synthetic),
provides ascorbic acid

Approach to Probiotics

- Generally regarded as live microorganisms that provide a health benefit.
- Health Canada's monograph¹ for probiotics includes:
 - **General Health Claim** for all listed species:
 - Source of Probiotics
 - **General Health Claims** for **almost all** listed species:
 - Helps support intestinal/gastrointestinal health
 - Could promote a favorable gut flora
 - **Other strain specific claims:**
 - Acute infectious diarrhea (*Lactobacillus rhamnosus* GG)
 - Antibiotic associated diarrhea (L. rhamnosus GG, S. boulardii/cerevisiae (all))



¹<http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=probio&lang=eng>

Pre-Market Review: Product Pathways

- **Modern NHPs** (e.g., vitamins, fish oils) – evidence is stratified by risk and decision informed by a variety of sources including clinical trials, information from other regulatory agencies and scientific literature
- **Traditional Medicines** (e.g., Traditional Chinese Medicine) – based within a defined healing paradigm and supported by references to specified pharmacopoeia or other texts deemed acceptable by Health Canada. Safety considers the scientific literature as well
- **Homeopathic Products** (e.g., nosodes) – evidence must come from an accepted homeopathic reference (homeopathic pharmacopoeia), proving (homeopathic testing), or clinical trial data

Approach to Safety and Efficacy

Class I 60 calendar days	<ul style="list-style-type: none">• Products that comply with all parameters of an <u>individual monograph</u>• Risk-based review
Class II 90 calendar days	<ul style="list-style-type: none">• Products fully supported by a <u>combination of monographs</u>• Full review
Class III 210 calendar days	<ul style="list-style-type: none">• Other Products<ul style="list-style-type: none">• One or more non-monographed ingredients¹, and/or• Monographed ingredients but outside monograph parameters (e.g. higher dose, different source, unacceptable claim, etc.)• Full scientific review

- Issues with attestation model identified in early 2017 led to adjustment in pre-market review
- The Natural Health Products Ingredients Database (NHPID)¹ is an electronic repository of monographs, information on medicinal and non-medicinal ingredients in NHPs, and ingredients classification for selection in an electronic Product Licence Applications (e-PLA) submission

¹<http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/search-rechercheReq.do?lang=eng>

Approach to Quality

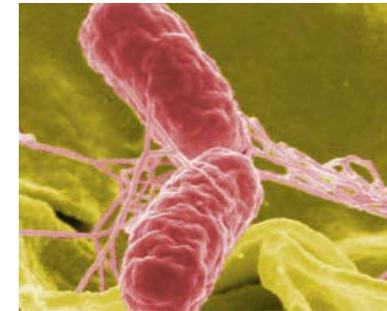
Identity:

- Physical description; and
- Chemical Identity for the respective medicinal ingredient(s)



Purity/Contamination:

- Microbial;
- Chemical; and
- Other (Pesticides, Solvent residues, etc.)



Quantity/Potency:

- Amount of each medicinal ingredient



Approach to Quality - Experience to Date

- Review of 1192 site licence (SL) applications identified issues with the current attestation model:
 - Specifications (52%)
 - Stability (35%)
 - Quality Assurance (13%)
- Proactive inspections at 46 NHP sites (~6%) conducted over past 3 years¹ identified issues ranging in severity found at all facilities, notably:
 - Specifications: unavailable or incomplete
 - Stability: no data, scientific rationale or program available to establish a product's shelf life
 - Quality Assurance: products not properly assessed against their specifications with partial or no testing
- Paper-based audits of 35 licensed sites (~4%) currently underway, focusing on key areas of concern
- Results will inform adjustments to pre-market quality review approach (Fall 2019)

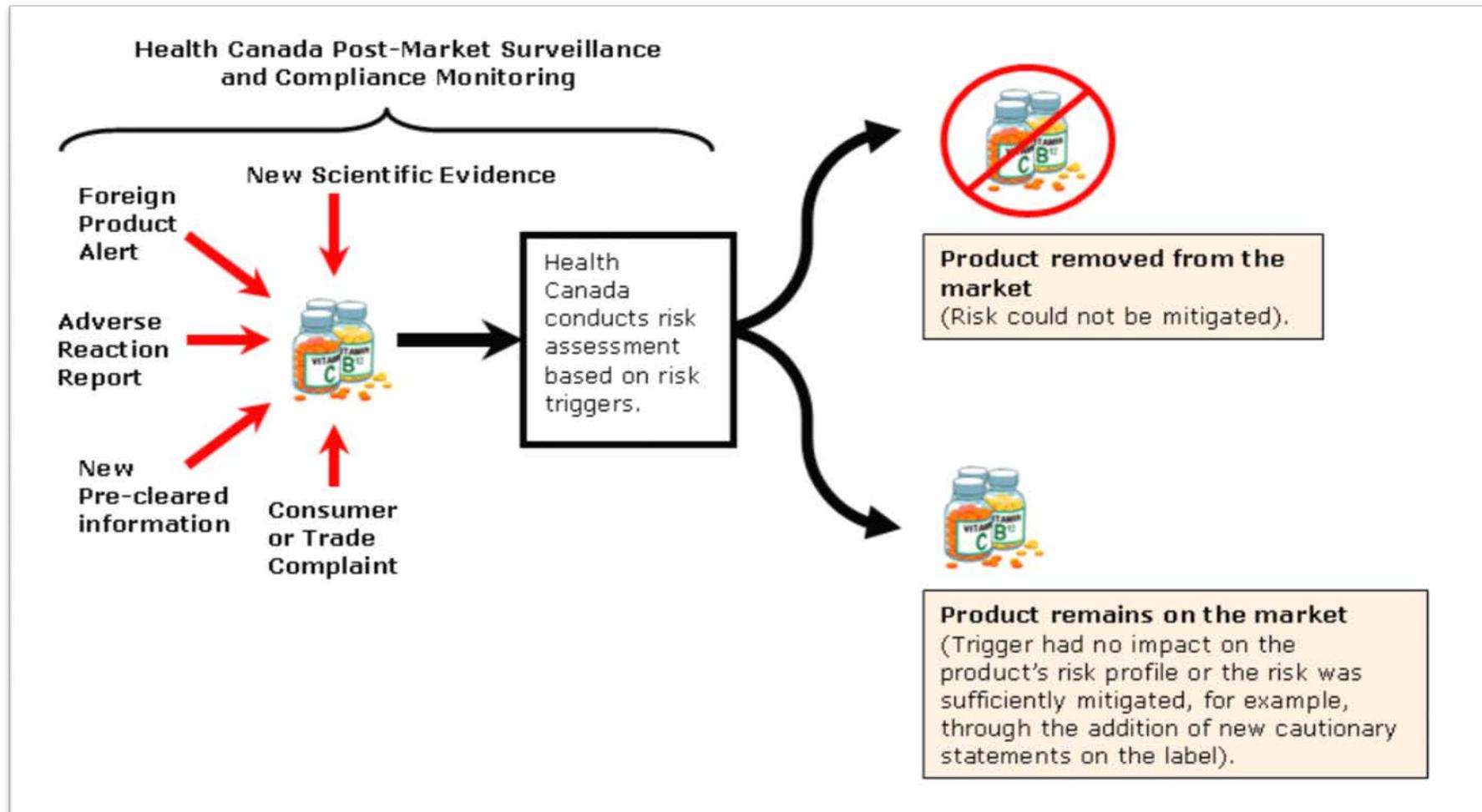
¹2017 Report on Compliance Monitoring: Natural health products at <https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/compliance-monitoring-reports/2017-reporting-compliance-monitoring-natural-health-products.html>

Processing Applications

- NHP Management of Applications Policy¹ updated in April 2019.
- Updates intended to achieve better outcomes for the health and safety of Canadians by ensuring that authorized NHPs meet all regulatory requirements. Changes also
 - Reflect evolving regulatory and market context
 - Align with current practice as well as with changes in the web-based application systems, i.e.
 - Attainable performance standards
 - Improved predictability of licensing application review outcomes through
 - Clear and precise application criteria; and automatic refusals when not met
 - No more paper applications
 - More efficient and comprehensive correspondence
 - No unsolicited changes

¹NHP Management of Applications Policy at <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-health-products/legislation-guidelines/guidance-documents/management-product-licence-applications-attestations.html>

Post-Market Activities : Reactive



Post-Market Activities : Proactive Monitoring

- Legislative prohibition against false, misleading or deceptive

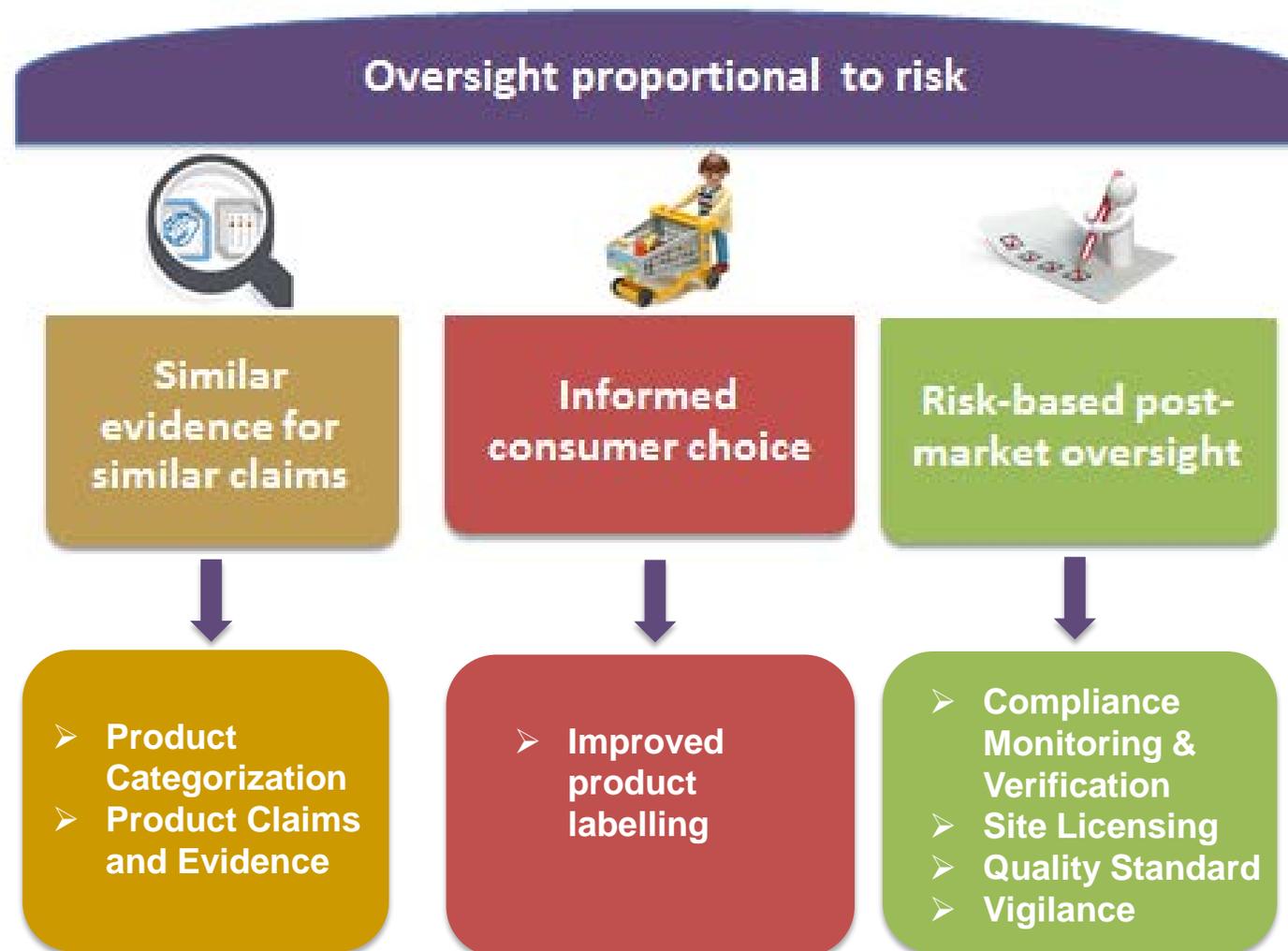
s.9 of the *Food and Drugs Act* :

“No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety”

- Proactive monitoring of marketed NHPs in development:
 - Proactively monitor products on the Canadian market to identify possible non compliance issues; and
 - Take action as appropriate
- Health Canada also works in collaboration with independent advertising preclearance agencies to educate and promote compliance on advertising

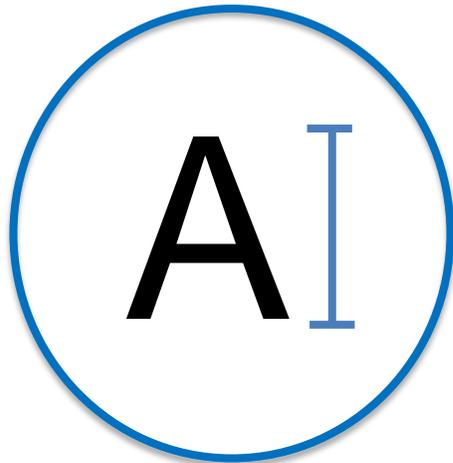
Current Modernization Efforts

Regulation of NHPs, Non-Prescription Drugs and Cosmetics

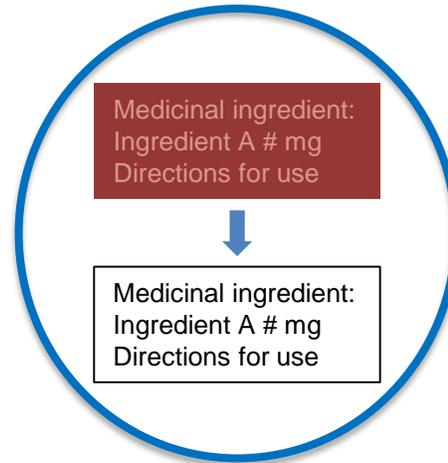


Proposal: Improved Labelling of NHPs

Requirements – Updates to the NHPR:



Minimum font size



Maximum contrast



Standardization

Product Facts Table

Title: 8 pt sans serif font bold	A	Product Facts Visit www.name-nom.ca	Quantitative list of product's medicinal ingredients.
Headings: 7 pt sans serif font bold	B	Medicinal ingredients Ingredient A common name / Ingredient A <i>Latin name</i> , Potency.....XX mg Ingredient B common name / Ingredient B <i>Latin name</i> , Potency.....XX mg Ingredient C common name / Ingredient C <i>Latin name</i> , Potency.....XX mg	Warnings to be included in prescribed order: <ul style="list-style-type: none"> • For external/rectal/vaginal use only • Reye's syndrome • Allergy alert • Flammability warning • Choking warning • Alcohol/liver/stomach bleeding warning • Sore throat warning • Dosage warning • Sexually Transmitted Diseases (STD) alert • Do not use • Ask a doctor or healthcare practitioner before use if you • When using this product • Stop use and ask healthcare practitioner if • Other warnings • Keep out of reach of children
Subheadings: 6 pt sans serif font bold	C	Uses •to prevent and treat symptoms of: •xxxxxxx •xxxxxxx •traditionally used in Herbal Medicine to help relieve •xxxxxxx •xxxxxxx •xxxxxxx •xxxxxxx	
Body text: 6 pt sans serif font	D	Warnings Allergy alert: Contains xxxxxxx. May cause severe allergic reaction.	
Weight of rules: 1.5pt	E	Do not use if •xxxx •xxxxxxx •xxxxxxx •xxxx Ask a doctor or healthcare practitioner before use if you •xxxxxxx •xxxxxxx xxxxx •xxxxxxx	Includes storage instructions, special instructions (e.g. for disposal), or nutritional information.
	F	When using this product •drowsiness may occur •do not drive a motor vehicle or operate machinery •you may experience •xxxxxxx •xxxxxxx •xxxxxxx	
	G	Stop use and ask a healthcare practitioner if •xxxxxxx •xxxxxxx xxxxxxxxxxx •xxxxxxx xxxxx	
	H	Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
	I	Directions •Adults and children 6-12 years: take xxxxxx xxxxxx every # hours up to # times a day	
	J	Other information Store between 15 - 27°C.	
	K	Non-medicinal ingredients Ingredient 1, Ingredient 2, Ingredient 3, Ingredient 4, Ingredient 5, Ingredient 6, Ingredient 7, Ingredient 8, Ingredient 9, Ingredient 10	
	L	Questions? 1-800-XXX-XXXX	

QUESTIONS?

