Regulation of Natural Health Products in Canada

Presentation at Dietary Supplement Public Meeting

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Health Canada

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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

Food and Drugs Act

- Cosmetics Regulations
- Natural Health Products Regulations
- Food & Drug Regulations Part C – Drugs
- Food & Drug Regulations Part B – Foods
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.
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 monograph\(^1\) 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/nhpdb-dgpsa/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

<table>
<thead>
<tr>
<th>Class</th>
<th>Duration</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>60 calendar days</td>
<td>• Products that comply with all parameters of an <strong>individual monograph</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Risk-based review</td>
</tr>
<tr>
<td>Class II</td>
<td>90 calendar days</td>
<td>• Products fully supported by a <strong>combination of monographs</strong></td>
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<tr>
<td></td>
<td></td>
<td>• Full review</td>
</tr>
<tr>
<td>Class III</td>
<td>210 calendar days</td>
<td>• Other Products</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• One or more non-monographed ingredients(^1), and/or</td>
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<tr>
<td></td>
<td></td>
<td>• Monographed ingredients but outside monograph parameters</td>
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<tr>
<td></td>
<td></td>
<td>(e.g. higher dose, different source, unacceptable claim, etc.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Full scientific review</td>
</tr>
</tbody>
</table>

1. 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

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 years\(^1\) 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)

• NHP Management of Applications Policy\(^1\) 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

Post-Market Activities: Reactive

Health Canada Post-Market Surveillance and Compliance Monitoring

- Foreign Product Alert
- Adverse Reaction Report
- New Pre-cleared Information
- New Scientific Evidence

Health Canada conducts risk assessment based on risk triggers.

Product removed from the market
(Risk could not be mitigated).

Product remains on the market
(Trigger had no impact on the product’s risk profile or the risk was sufficiently mitigated, for example, through the addition of new cautionary statements on the label).
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

- Product Categorization
- Product Claims and Evidence
- Improved product labelling
- Compliance Monitoring & Verification
- Site Licensing
- Quality Standard
- Vigilance
Proposal: Improved Labelling of NHPs

Requirements – Updates to the NHPR:

- Minimum font size
- Maximum contrast
- Standardization
# Product Facts Table

**Product Facts**
Visit www.name-nom.ca

<table>
<thead>
<tr>
<th>Medicinal ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient A common name / Ingredient A Latin name, Potency: XX mg</td>
</tr>
<tr>
<td>Ingredient B common name / Ingredient B Latin name, Potency: XX mg</td>
</tr>
<tr>
<td>Ingredient C common name / Ingredient C Latin name, Potency: XX mg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uses</th>
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</thead>
<tbody>
<tr>
<td>To prevent and treat symptoms of:</td>
</tr>
<tr>
<td><em>xxxxxx</em></td>
</tr>
<tr>
<td><em>xxxxxxx</em></td>
</tr>
<tr>
<td>Traditionally used in Herbal Medicine to help relieve:</td>
</tr>
<tr>
<td><em>xxxxxxx</em></td>
</tr>
<tr>
<td><em>xxxxxxx</em></td>
</tr>
<tr>
<td><em>xxxxxxx</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Warnings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergy alert: Contains <em>xxxxxxx</em>. May cause severe allergic reaction.</td>
</tr>
<tr>
<td>Do not use if <em>xxxxxxx</em></td>
</tr>
<tr>
<td>Ask a doctor or healthcare practitioner before use if you <em>xxxxxxx</em></td>
</tr>
<tr>
<td>When using this product <em>xxxxxxx</em></td>
</tr>
<tr>
<td>Do not drive a motor vehicle or operate machinery*</td>
</tr>
<tr>
<td>You may experience:</td>
</tr>
<tr>
<td><em>xxxxxxx</em></td>
</tr>
<tr>
<td><em>xxxxxxx</em></td>
</tr>
<tr>
<td>Stop use and ask a healthcare practitioner if <em>xxxxxxx</em></td>
</tr>
<tr>
<td><em>xxxxxxx</em></td>
</tr>
<tr>
<td>Keep out of reach of children, If swallowed, call a poison control centre or get medical help right away</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and children 6-12 years: take <em>xxxxxxx</em> every # hours up to # times a day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Information</th>
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<tbody>
<tr>
<td>Store between 15 - 27°C</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-medicinal ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient 1, Ingredient 2, Ingredient 3, Ingredient 4, Ingredient 5, Ingredient 6, Ingredient 7, Ingredient 8, Ingredient 9, Ingredient 10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Questions?</th>
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<tbody>
<tr>
<td>1-800-XXX-XXXX</td>
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</tbody>
</table>

- Quantitative list of product’s medicinal ingredients.
- Warnings to be included in prescribed order:
  - For external/rectal/vaginal use only
  - Reyn’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

- Includes storage instructions, special instructions (e.g. for disposal), or nutritional information.
QUESTIONS?