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ISMP Med Safety Exchange

Presentation by the Natural and Non-prescription Health Products Directorate (NNHPD)

January 24, 2023

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Presentation Outline: Continuing to Work Towards the Self-Care Framework

Element I: Improved Natural Health Product Labelling

- NHP Labelling Implementation
- NHP Monograph Revisions

Element II: Risk-Based Approach for OTC Regulatory Oversight

- Non-Prescription Drug (NPD) Action Plan

Element III: Strengthening Oversight for NHPs

- Strengthened Post-Market Oversight for NHPs (Vanessa's Law)
- NHP Program Improvements
- Cost Recovery – Next Steps

Background

- Natural health products (NHPs) include a variety of products including vitamins and mineral supplements, probiotics, toothpaste, sunscreen, Homeopathic products and Traditional products (e.g Traditional Chinese medicines).
- More than 200,000 NHPs have been approved by Health Canada since 2004.
- In 2016, Health Canada introduced the Self-Care Framework (SCF), a series of regulatory, policy and operational initiatives to modernize Health Canada's approach to regulating lower risk health products.
- In 2021, the Commissioner of the Environment and Sustainable Development completed an audit of the NHP program, which found both strengths and areas for improvement. A number of the changes envisioned through the SCF align with the recommendations of the audit.
- The audit reinforced the need for the department to strengthen its oversight and be adequately equipped to address serious health risks. In response, Health Canada committed to undertaking certain activities to improve the safety of these products.
- In the past few years, in consultation with stakeholders, Health Canada has made significant progress towards its commitments to make the NHP market safer for consumers and help them make more informed choices.

NHP Labelling Implementation

In 2022, Health Canada introduced new requirements to make NHP labels easier for Canadians to read and understand:

1) Clearly and prominently displayed label text

- Minimum font and contrast requirements (black on white)

2) Standardized Product Facts Table

- Enable consumers and healthcare professionals to quickly identify key product information to reduce medication errors and easily compare products

3) Improved labelling of key allergens

- Priority food allergens, gluten, sulfites, and aspartame indications must be prominently displayed in the warnings section

4) Modernized contact information

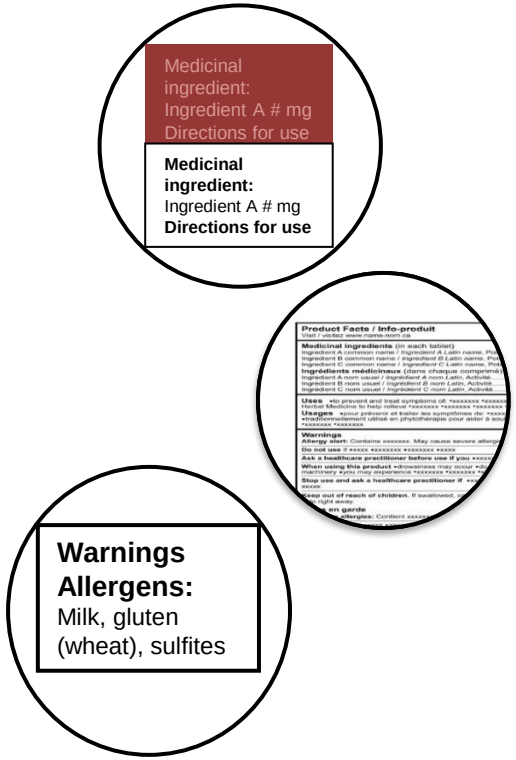
- Require the display of a telephone number, e-mail address, or website address of a contact person

5) Other labelling requirements

- Security packaging and labelling of exempted products

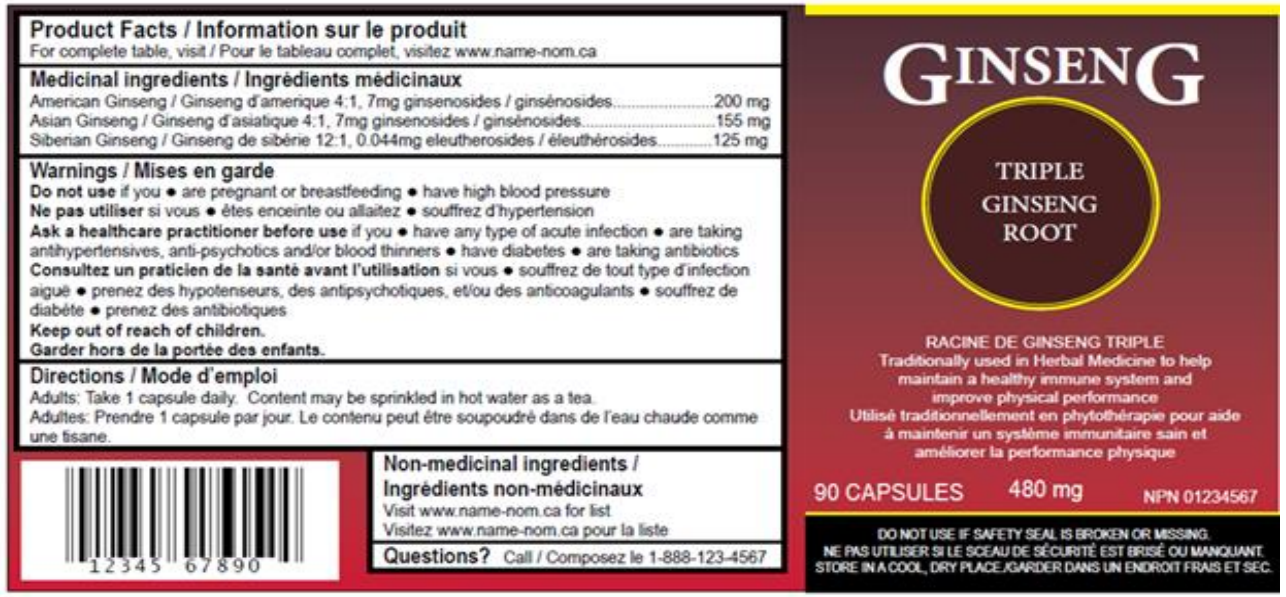
6) Homeopathic Products

- In addition to requirements above, HM statement and risk-based evidence standards.



Previous label:

New label:



NHP Labelling Implementation (cont'd)

- Planned implementation timelines are as follows:
  - **Products that are authorized by Health Canada prior to June 21, 2025, will have until June 22, 2028**, to comply with the new labelling requirements
  - Product licence applicants wishing to have a product authorized prior to June 21, 2025, should consider approval timelines for product licence application approval when planning the timing of their submission
  - Products that are authorized by Health Canada on or after June 21, 2025, are expected to comply with the new labelling requirements immediately
- **Next Steps:** Progress through the NHP monograph revision process and continue to work with stakeholders throughout the transition period to implement the new labelling requirements

NHP Monograph Revisions

- To support the implementation of NHP labelling, Health Canada is actively working on updates to product monographs.
- The revisions will focus on:
  - Improving conciseness, clarity, accuracy, and ensuring consistency between monographs;
  - Updating some monographs to mitigate potential risks identified by NNHPD;
  - Including examples of product facts tables in each monograph;
  - Expanding the scope where possible: addition of medicinal ingredient(s) and/or claim(s) for which NNHPD has collected enough evidence and is comfortable with its availability through compendial
- The monograph revision process is expected to be completed in January 2025.

Product monograph: a factual, scientific document on the medicinal ingredient(s) that, devoid of promotional material, describes the properties, claims, indications, and conditions of use for the medicinal ingredient(s), and that contains any other information that may be required for optimal, safe, and effective use of the medicinal ingredient(s).

Non-Prescription Drug (NPD) Action Plan

- We continue to advance work on the NPD Action Plan, which was initially launched December 2022
- The NPD Action Plan proposes policy and operational solutions to address barriers to marketing NPDs in advance of regulatory changes
- Short term solutions were introduced in December 2022:
  - Updates to the recommended and optional Canadian Drug Facts Table sub-headings;
  - Additional guidance on the product monograph and patient medication information leaflet; and,
  - Additional guidance for label mock-up requirements
- Our goal is to share medium term solutions in early 2024:
  - Providing clarity on post-authorization submissions for quality-related changes;
  - Clarifying NPD inactive ingredient expectations and the application of INCI names on NPD labelling; and
  - Consulting on an oral cold, cough and flu monograph to support licensing of non-prescription drugs (Finalization targeted by summer 2024)
- Future regulatory amendments would introduce a risk-based approach to the oversight of NPDs in regulation

Strengthened Post-Market Oversight for NHPs (Vanessa's Law)

- On June 22, 2023, Bill C-47 received Royal Assent and included amendments to the *Food and Drugs Act* to extend the *Protecting Canadians from Unsafe Drugs Act* (also known as Vanessa's Law) to NHPs

- Upon Royal Assent, many provisions came into force immediately and gave Health Canada tools to respond to serious health and safety risks:

  - order a recall of NHPs that present a serious or imminent risk of injury to human health
  - require a label change or package modification, if necessary, to prevent serious injury to health
  - impose higher fines and penalties for non-compliance
  - order a person to provide information to determine if a product presents a serious risk of injury to human health
  - disclose confidential business information when there is a serious risk of injury to human health or for the protection or promotion of human health or the safety of the public
  - incorporate by reference
  - prohibit false or misleading statements or information to the Minister

- These new authorities will only need to be used if a serious risk to health is identified or if a company refuses to take voluntary actions to address the risk. Compliant companies would not be impacted by these new authorities.

- Some provisions that require regulations are not yet in force (e.g., terms and conditions, mandatory hospital reporting), and Health Canada would consult with stakeholders on any further regulatory changes needed to support these authorities

NHP Improvements

- In addition, as part of our work to advance the Self-Care Framework and respond to the CESD audit recommendations, we are advancing initiatives to improve the NHP program:
  - **Risk-based quality screening** will be applied to new product licence and quality amendment applications submitted as of November 1, 2023, and will focus on ingredient quantity tolerance limits
  - **Consultation on updates to NHP guidance documents** (Quality of NHPs Guide and NHP Good Manufacturing Practices Guidance Document) targeting consultation and implementation in 2024
  - **Proactive inspection program:** In 2021-2022, Health Canada conducted a **pilot inspection program** to assess whether NHP manufacturers and importers were following regulatory requirements for GMPs. The findings of the pilot reinforce the need for a permanent, proactive, risk-based inspection program to verify compliance with GMPs as part of ensuring that the NHPs sold in Canada are safe and of high quality.

Cost Recovery for NHPs – Next Steps

- Health Canada's consultation on an initial fee proposal NHPs closed on August 10, 2023
- We consulted on proposed:
  - Fee structure and fee amounts
  - Performance standards and penalties for missed standards
  - Fee mitigation measures for small businesses
  - Timeline for implementation (April 1, 2025)
- We are actively working to address stakeholders' concerns and arrive at a proposal that mitigates impacts on small businesses while supporting Health Canada's efforts in providing market access to a variety of safe and effective health products.

Questions

Natural and Non-Prescription Health Products Directorate (NNHPD)

Contact us directly at:

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For more information on NHP regulation in Canada, please visit: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation.html