Red Tape Reduction for Natural Health Products: Simple Registration and Opportunities for Burden Reduction

Stakeholder meeting

Natural and Non-prescription Health Products Directorate

December 11, 2025

Health Canada Santé Canada

Canada

Session Overview

1. Purpose of the session
2. Overview of red tape reduction initiatives
3. Implementing a registration pathway: Considerations and discussion questions
4. Industry burden and irritants: What we have heard so far and other suggestions
5. Regulatory timelines and next steps

Purpose

- Gather early feedback on the development of a registration system for certain natural health products

- Provide an opportunity to discuss additional opportunities to reduce burden

Reducing Red Tape for Natural Health Products (NHPs)

- On September 8, 2025, the Government published the Health Canada and the Public Health Agency of Canada's report on red tape reduction committing to:

> "…*introduce a* ***simple registration process for certain NHPs*** *and NPDs, along with flexible risk-based monitoring for all NHPs and NPDs. The department plans to amend the regulations for NHPs by making labelling requirements more flexible and reducing authorization requirements in areas where oversight is more appropriate after the product is authorized*."

Red Tape Reduction Initiatives for NHPs: Overview

What: Address one-size-fits-all approach to regulating NHPs and labelling implementation concerns.
Why:
- Increased flexibility
- proportionate oversight
- Expedited pathways to market and reduced burden

Today's session

Simple registration process for certain products

What: NHPs with higher certainty (e.g., based on a monograph)

Why:
- Proportionate oversight
- Enable faster market access
- Reduce regulatory & administrative burden
- Create a sustainable regulatory program

Prioritizing NHPs that benefit Canada

What: NHPs that are sold or made in Canada

Why:
- Focus public resources on products that benefit people in Canada

Simplified labelling requirements

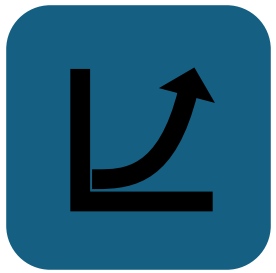
What: All NHPs

Why:
- Facilitate implementation for industry while maintaining consumer outcomes by prioritizing key information on labels
- Incorporation of outcome-based language, where appropriate, to offer flexibility and support innovation

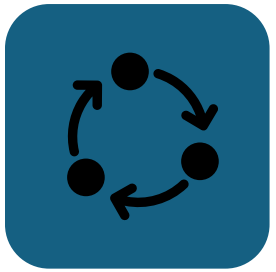
Red Tape Reduction Initiatives for NHPs: Policy Objectives

Proposed changes will aim to reduce overall burden, while maintaining consumers' health and safety. Specifically, this would be achieved by:

Aligning level of oversight for NHPs with certainty and reducing administrative requirements



Focusing program resources where needed to support the Canadian economy



Incorporating modern tools to respond to emerging health risks and adapt to new evidence and advancing technology

Part 1: Implementing a Registration Pathway

Hélène Lowell, Senior Policy Analyst

Implementing a Registration Pathway: Considerations

Scope	At a minimum, products for which there is a high-certainty of safety and efficacy when used under established conditions of use within the monographs
Registration Process	Quicker and less administrative burden than current Class I process; No pre-market review or Ministerial decision for higher certainty products
Post-Market Changes	Less burdensome than current requirements; Minimize post-registration notification requirements

Consideration: Market Access

Context

- Health Canada is considering registration models for higher certainty products, including notification to the department either pre-market (e.g., 30 days prior to first sale) or post-market (e.g., 10 days after first sale).
- The assumption is that products would be market-ready at the time of registration.

Discussion Questions

1. What are the benefits and risks we should consider when determining the timing of registration (i.e., pre- or post-market)?

2. What challenges, if any, might arise in providing site licence information at the time of registration?

Consideration: Product-specific numbers

Context

- Health Canada is considering no longer issuing licenses or NPNs for registered products since it would no longer be an authorization process.
- We are considering alternatives for distinguishing licensed and registered products. For example, *product-specific registration numbers* or *monograph-based numbers* that would apply to all products meeting that monograph.

Discussion Questions

3. What are the operational considerations for companies related to issuance of a “non-NPN” number for registered products?

4. If including the number on the label, how far in advance of market entry would a number be needed?

Consideration: Supporting Compliance with Monographs

Context

- The current web-based product licensing application form (web PLA) and validation tool were developed to support applicants in complying with monograph parameters for Class 1 submissions and to facilitate a more efficient licensing process within NNHPD.
- Under a registration system, we assume that the product would be market-ready at the time of registration and that compliance promotion tools would be needed earlier in the product development process.

Discussion Questions (continued on the next slide)

5. What are the barriers to complying with the parameters of a monograph?

6. What role do industry associations play in helping members market compliant products?

Consideration: Supporting Compliance with Monographs

Discussion Questions (continued)

7. How useful is the label text generator in supporting the development of product labels?

8. Would your members support a registration form with fewer information requirements without a validation tool, or would the compliance support benefits of the current web PLA outweigh the burden reduction benefits? Please elaborate.

Part 2: Industry Burden and Irritants

Sara German, Policy Development Manager

Industry Burden and Irritants

Context

- As part of the red tape reduction (RTR) initiatives, Health Canada is looking at reducing burden and irritants across the NHP lifecycle, including for products that would continue to be reviewed and licensed.
- We are considering suggestions shared with the department so far (summarized on the next slide) through:
  - RTR submissions
  - Ongoing engagements
  - Formal consultations (e.g., updates to the Management of Application Policy)

What We Heard

- Apply risk-based principles to application reviews, including relying on previous decisions and evidence, as well as ingredients used safely in other products (e.g., food ingredients).
- Reduce submission timelines and application refusals.
- Remove the requirement to submit finished product specifications in product licence and amendment applications.
- Reduce the number of post-market submissions needed.
- Build flexibility into the amendment/ notification/ fundamental change regulations and operational processes; manage changes based on risk/ type rather than class of the original product submission.
- Develop a formal process and provide guidance for industry to request monograph and NHPID modifications.
- Improve transparency in operational processes (e.g., timelines) and submission classifications; introduce flexibility for class II submissions to include products similar to those already approved.
- Align oversight for similar products that may be regulated under multiple regimes.
- Provide clear guidance for regulatory requirements for NHPs across their lifecycle.

Proposed Areas for Industry Input

- Process improvements suggested through the consultation on the Management of Applications Policy (MAP) are under consideration; we will be seeking additional stakeholder input early in the new year on the following topics:

  - **Scope of Class II product licence applications (PLAs):** expanding the definition of Class II PLAs to allow a broader range of applications under this class, including:
    - ✓ Allowing common spices, herbs, and tea ingredients
    - ✓ Applications that reference NPNs already approved by Health Canada

  - **Refusal of Class II and Class III PLAs:** examining use of refusals, including:
    - ✓ The use of Information Request Notice (IRN) versus direct refusals
    - ✓ Refusals based on IRN responses regarding the removal or revision of proposed claims

  - **Pause-the-clock for Class II and Class III PLAs:** introducing pause-the-clock, including:
    - ✓ Understanding common scenarios for responding to an IRN, to inform how to pause-the-clock
    - ✓ Impacts on service standards and reporting implications

Industry Burden and Irritants

Discussion Question

9. Are there other process or regulatory irritants you would like to raise at this time?

Regulatory Timelines and Next Steps

Fall 2025	Winter – Spring 2026	Fall 2026	Winter- Spring 2027	Fall 2027

NHP

Policy Development

Initial engagement sessions

Regulatory Development

Targeted engagement (as required)

Targeted CGI publication *(formal consultation)*

- The Department is planning engagement sessions for early 2026 to discuss proposals for NHPs under the Red Tape Reduction initiatives
- Stakeholders will have the opportunity to provide feedback during the sessions, in writing and at the public CG Part I consultation

Thank You

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