Regulation of Natural Health Products: An Update - October 2025

The Natural Health Products Regulations (NHPR) were developed in response to a demand from Canadians. They wanted access to high quality natural health products (NHPs) that were safe, effective and respected traditional forms of health and healing. Previously, the regulatory system focussed on conventional medicines and was not appropriate for NHPs. This changed in January 2004 when a specific regulatory approach for NHPs came into effect. The NHPR were developed following extensive national consultations hearing from Canadians and based on the recommendations of an Expert Advisory Committee.

The NHPR have been in place for over two decades and there have been many changes made to both how the NHPR are implemented and the regulatory environment in which they exist. The last five years have been particularly dynamic with many changes proposed and implemented. This article will provide an update on three key areas: Red Tape Reduction Initiative, Plain Language Labelling, and Cost Recovery.

Red Tape Reduction Initiative

Though based on an act of Parliament from 2015, the Red Tape Review was announced by the Secretary of the Treasure Board in July 2025. This cross federal government initiative "requires all departments to review their regulations and propose measures to eliminate burden, such as removing outdated rules, reducing duplication with provincial regulations, and streamlining processes". Red Tape is defined as "unnecessary and overly complicated regulations" with this review intended to "support economic growth, improved efficiency, and make it easier for Canadians and businesses to interact with government services".

In response, Health Canada and the Public Health Agency of Canada published a report presenting 42 initiatives either completed, almost completed or that should be completed in the next 2 years.

Regarding NHPs, Health Canada has committed to reducing regulatory burden by introducing a simpler registration process, and adopting a flexible, risk-based approach to monitoring. There is a plan to table amendments that support more flexible labelling requirements (see Plain Language Labelling below) and to move Health Canada oversight, when appropriate, from post market to premarket.

More information about the Health Canada/PHAC report can be found at: https://www.canada.ca/en/services/health/publications/health-system-services/report-red-tape-reduction.html

Plain Language Labelling (PLL)

Since their inception, the NHPR contained provisions required for NHP labels developed through extensive consultations. However, the federal government, launched three years of closed-door consultations with stakeholders on labelling. This culminated in 2021, when Health Canada published a public consultation initiative to include NHPs within a broader Over-the-Counter medicine labelling initiative called Plain Language Labelling. Health Canada's stated aim for this process was to "address poor communication of key information on health products label that can lead to in correct purchases and preventable harm". These proposed labelling changes fell within four basic areas:

- inclusion of a mandatory table format for product information
- clarifying existing allergen labelling requirements to include priority food allergens
- clearly and prominently displayed label text, and
- allowing for civic addresses to be replaced with websites for company contact information.

So, the Plain Language Labelling initiative, did not focus on simplifying the language of labels.

Major concerns were raised by many stakeholders not only about the effectiveness of these changes in reducing risk and supporting informed choice but also the decision to prioritise these changes over other more serious issues and the feasibility of their implementation. In addition, concerns were raised about how seriously Health Canada took the feedback provided over the previous years of closed-door and open consultation.

Despite these stakeholder concerns, Health Canada moved ahead with a slightly modified approach which was passed into law in July 2022. Recognising that these new regulations would require extensive changes to NHP labels, Health Canada required implementation of the changes for new products to be done within 3 years and, for existing NHPs, required label changes to be made within 6 years.

A more detailed description can be found in a previous ISURA articles: *Improved Labelling for Natural Health Products – The Final Regulations*.

While these new labelling regulations have not changed, in the face of significant lobbying and push back from stakeholders notably the NHP industry, Health Canada modified the implantation timeline with a temporary compliance exemption. This allows companies to follow the previous labelling requirements for NHPs licensed between June 21, 2025 and June 21 2028. While this compliance exemption is in place, Health Canada has committed to work with industry as part of the Red Tape Reduction Initiative to address issues and to introduce "flexible labelling requirements through targeted regulatory amendments". This will be part of the Reducing Red Tape initiative identified above.

Cost Recovery

Cost recovery is a mechanism by which a regulator can charge fees to either completely or partially cover their costs for operating a regulatory framework. Currently a cost recovery system exists in Canada for all approved medicines with the exception of NHPs. Food regulatory programs are also not subject to cost recovery. In May 2023, Health Canada posted a proposed approached with suggested fees. This proposed framework would apply to NHP product licence applications, NHP site licence applications, and post-market activities captured under a fee called Right to Sell (RTS). These fees would apply to any organisation with a Health Canada regulatory requirement such as sponsors, manufacturers, distributors and importers of NHPs. The framework also included a mitigation for small businesses, performance standards for Health Canada with penalties if the standards are not met, and the creation of a new category: Class III novel applications not defined in regulation or guidance documents. The initial, proposed implementation date for the framework was April 1, 2025, with an estimated annual cost to industry of $100.8M.

More details together with a comparison with key international jurisdictions can be found in a previous ISURA article: *Comparing NHP Regulations from Canada and Australia*.

In April 2024, in response to consultation and following focussed workshops with key stakeholder groups, Health Canada posted an updated approach for the Cost Recovery initiative with a modified fee scale. The basic approach was to focus on recovering costs for existing program activities and postponing system improvements such as the use of IT systems, quality review of submissions and audit functions; strengthening the review of efficacy date for products making claims for strengthening diseases; strengthening oversight of online advertising; and increasing capacity for processing and education. It is estimated that this would reduce annual costs from $100.8M to $51.1M. None of the proposed system improvements are predicted by government to have an impact on review times, costs, or other metrics of improvement. In addition, pertinent details were lacking including how references to clinical terms would be defined, how strengthened compliance would be administered, and challenges with past education programs would be addressed.

This modified approach would:

- Lower the fee setting ratio, or the portion of costs included in the fee charged to industry versus that paid by taxpayers, for the first 4 years:
- Phase in fees over a 7-year period based on a coming into force on December 1, 2025;
- Remove the proposed Class III- Novel category; and
- Reduce the number of fee categories associated with annual site licensing from 5 to 3.

The current cost recovery document can be found at:
https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation/cost-recovery/revisions-proposed-fees.html

Following the spring 2025 federal election, this initiative was paused but not officially abandoned. A proposed start date of December 1, 2025 was the last implementation date posted publicly.

Final Thoughts

When the Natural Health Products Regulations were developed and implemented in the early 2000s they were rather unique with few international examples from which to learn. Much has changed in the past couple of decades and, in hindsight, some things could have been done differently. At their core the NHPR are solid. Many of the problems facing the public today are related to the government's interpretation of the wording of the regulations and its implementation of them over the past decade than the regulations themselves.

Under the Red Tape Reduction Initiative, the opportunity exists to again make the Canadian approach a global gold standard. This could include:

- Using IT and online functions to replace the current complicated people and paper heavy process.
- Leveraging existing initiatives to streamline the number of inspections of NHP manufacturing sites.
- Developing a public system, much like food nutrition programs, for communicating both the benefits and appropriate use of NHPs.
- Working with international partners to reflect a global marketplace.

The possible changes outlined in the red tape reduction report are only in play due to the strong advocacy of the Canadian Health Food Association and from NHP companies. In addition, recent changes in government priorities have left a number of loose ends, notably around cost recovery and the new labelling requirements which are now in law. While the Red Tape Reduction Initiative provides an opportunity to effectively resolve these loose ends, the NHP community must remain vigilant to ensure that government remains committed to tangible positive improvements in the sector and for Canadians.

About the author:
Michael Smith trained as a pharmacist and as a naturopathic doctor. He is recognized internationally as an expert in natural health products and complementary & alternative medicine. For more than 10 years, he worked in senior regulatory positions at the then Natural Health Products Directorate, Health Canada, and the Therapeutic Goods Administration in Australia. In addition to his international work as a consultant, he is an Adjunct Professor at the National Center for Natural Products Research at the University of Mississippi, USA and an Adjunct Associate Professor at the National Centre for Naturopathic Medicine at Southern Cross University, Australia. He is a member of ISURA's Scientific Advisory Committee.