A new era: Health Canada signals modernization in policy and regulatory reform

September 12, 2025

On Sept. 8, 2025, Health Canada and the Public Health Agency of Canada published their Report on Red Tape Reduction, outlining their key regulatory modernization initiatives aimed at improving efficiency, transparency and responsiveness within Canada's health system. This report marks a change in regulatory focus and is being hailed by some in the industry as a much-welcomed shift in policy. The stated aim of the initiatives detailed in the report is to create a regulatory environment that balances public health and product safety with economic competitiveness and innovation.

The report highlights Health Canada's progress and ongoing efforts to streamline administrative processes, reduce regulatory burdens, and enhance service delivery while shifting to a risk-based regulatory model. Ongoing and future initiatives have been organized into five themes: (1) increasing international alignment and reducing trade barriers; (2) improving stakeholder experience and service delivery; (3) risk-based regulating; (4) streamlining regulations, simplifying rules, and enhancing flexibility; and (5) enabling new products and technologies.

Key takeaways on themes:

- **International alignment and trade barrier reduction** : Health Canada recognizes that it regulates products that are also sold globally with different international requirements. Health Canada has signalled a move toward increasing the use of regulatory reliance and mutual recognition agreements with trusted international partners.
- **Risk-based regulation** : Health Canada's shift towards a risk-based regulatory model is aimed at ensuring that greater oversight is given to higher-risk areas while simultaneously streamlining the requirements for lower-risk products. Health Canada's stated goal is to create a more efficient and responsive regulatory approach that maintains public safety and reduces unnecessary administrative burdens. In line with this objective, Health Canada will be implementing streamlined approval processes for low-risk natural health products or over-the-counter medications that reflect the minimal public health risks.
- **Streamlined processes and better service** : Health Canada plans to enhance service delivery through introducing user-friendly platforms that will aim to make systems easier to navigate and allow consumers faster access to innovative

products. These changes will affect a broad scope of products including pest control products and cosmetics.

Implemented regulatory amendments:

Of relevance to product authorizations and safety, the report highlights several initiatives that regulators have already completed, or are close to completing, to attempt to reduce red tape:

- **Food and drug regulations** : The changes aimed to clarify Canada's relationship with international jurisdictions and reduce restrictions on novel or complex products to improve access through global partnerships. Under the revised regime, companies may be exempt from certain testing requirements in respect of novel and complex products (such as radiopharmaceuticals and biologics) when Health Canada has confidence in their product's safety. Health Canada anticipates approximately 60 novel and complex products will be eligible for available exemptions.
- **Medical devices regulations** : Health Canada has removed the requirement for reporting low-risk medical device recalls. This change is expected to save the industry about $375,000 (in 2022 dollars) every year.
- **Cannabis**: Health Canada is reviewing forms and guidance under the Cannabis Act to simplify documentation and clarify compliance expectations. Revised materials are expected to be released in 2026-2027 and will affect, among other things, licensing, production, packaging, labeling, and record-keeping. These changes aim to reduce the regulatory burden and compliance costs for companies.
- **Medical Device Establishment Licences (MDEL):** Health Canada implemented the use of terms and conditions on MDELs to permit it to respond more flexibly to medical device-related health risks and to manage non-compliance without disrupting access to the devices themselves. The goal of this initiative is to allow MDEL holders to continue operating while non-compliance issues are in the process of being addressed.
- **Machine-learning enabled medical devices (MLMD)** : Health Canada finalized pre-market guidance to help manufacturers navigate the licensing process for MLMDs. The guidance sets out the process for developing a predetermined change control plan which will allow companies to have their medical device changes approved in advance without needing additional review. We previously highlighted this guidance here.

Ongoing regulatory initiatives:

- **Natural health products (NHPs)** : Health Canada has issued a temporary exemption from its new labeling requirements for NHPs licensed between June 21, 2025 and June 21, 2028 while it creates flexible labeling requirements. Companies with NHPs licensed in this period may rely on previous labeling requirements.
- **Simplifying the food and drug regulations** : Future amendments aim to improve predictability and minimize interactions between Health Canada and regulated parties.

- **Modernizing clinical trials** : New regulations will establish a modern and flexible regulatory framework for clinical trials that is proportionate to risk. The framework aims to encourage clinical trials to be conducted in Canada and to help increase access to novel therapies.
- **Cosmetics** : As part of a larger scale modernization of the Health Canada IT system, the system for cosmetics notifications will be streamlined to reduce the administrative burden. Companies needing to notify Health Canada of their cosmetics sales will be able to do so in an automated fashion with minimal intervention from Health Canada.

Through these amendments Health Canada aims to reduce administrative burdens while maintaining high standards of safety and oversight. We will continue to monitor these developments closely and assess their implications for stakeholders across the health and life sciences sectors.

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