From Policies to Practices: Health Canada's approach to the modernization of CMC review

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Disclaimer

- The views expressed in this presentation are those of the presenter and do not convey official Health Canada policy

Significant Health Canada Updates

- Red Tape Reduction
- International Collaborations
- Updated Guidance Documents
- Ministerial Reliance Order – Christine Lefebvre; Session 2

Red Tape Reduction

Government of Canada Red Tape Reduction (RTR) Initiative

- In July 2025, the Government of Canada launched a review of regulations across federal departments and agencies with regulatory responsibilities.
- Led by the Treasury Board Secretariat, the RTR Initiative aims to modernize the federal regulatory framework by identifying and eliminating outdated and overly complicated regulations that raise costs, reduce productivity, and stifle economic growth.
- Acknowledging that red tape exists in both regulations and their execution, departments and agencies evaluated all aspects of regulations to find opportunities for reducing red tape, including regulatory text, administrative support programs, compliance and enforcement methods, and service delivery.
- A leaner, more focused government will make regulations more efficient, services more effective, and unlock more private capital for Canadian workers and businesses.

Health Canada's RTR Report

On September 8, 2025, Health Canada and the Public Health Agency of Canada published a report that outlines how the organizations are modernizing regulatory processes to reduce red tape and promote innovation and growth in the industries they regulate, while maintaining the highest standards to protect the health, safety, and security of people in Canada.

The Health Products and Food Branch will focus on a number of regulatory modernization initiatives in the coming three years aimed at lowering regulatory burden, fostering innovation and positioning Canada as a destination of choice for industry.

Out of the 25 regulatory and 17 non-regulatory initiatives put forward in the report, HPFB has put forward 5 major red tape reduction initiatives.

Health Canada/PHAC ’s RTR Report – 5 Themes:

Theme 1: International alignment and reduction of trade barriers	Theme 2: Improving client experience and service delivery	Theme 3: Risk-based regulating	Theme 4: Streamlining regulations, simplifying rules and enhancing flexibility	Theme 5: Enabling new products and technologies

HC/PHAC have a total of 42 initiatives: 12 initiatives completed or near completion, and 30 that should be completed over the next 2 years or beyond.

https://www.canada.ca/en/services/health/publications/health-system-services/report-red-tape-reduction.html

Overview of RTR initiatives – Health Products and Food Branch

Initiative	Description	Why it matters?
Modernizing Canada's clinical trials framework	Drafting regulations to modernize Canada's framework for clinical trials for drugs and developing associated draft guidance	Encourage clinical trials to be conducted in Canada and help increase access to novel therapies
Addressing stakeholder-identified health product and food regulatory burdens to support faster drug approvals	Make regulations for human drugs more flexible by introducing a risk-based approach and modernize processes, guidance and regulatory requirements	Enable stakeholders to adopt new technologies and respond to market needs more effectively
Increasing access to drugs through international collaboration, alignment and reliance	Leverage work-sharing with foreign regulatory authorities (FRA) through the Access Consortium, and rely on FRA decisions in certain circumstances to facilitate improved access to drugs in Canada	Reduce burden for industry

Overview of RTR initiatives (con't)

Initiative	Description	Why it matters?
Simplifying the Food and Drug Regulations	Streamlining authorization processes, addressing outdated and redundant requirements, increasing clarity, improving international alignment, and introducing flexibility and responsiveness to science and innovation	Help introduce new and innovative products onto the Canadian market

Clinical Trials Modernization

Clinical Trials Modernization

Key drivers informing modernization of the clinical trials regulatory framework

A one-size-fits all framework creates unnecessary burden	This approach does not consistently align requirements with risk, resulting in increased burden for sponsors
Innovative trial designs need flexibility	Greater use of adaptive and complex designs, and decentralized elements require regulatory flexibilities
Increasingly personalized and complex drugs are shifting risk management needs	Complex and targeted drugs (e.g., biologics, advanced therapies and radiopharmaceuticals) require a more adaptive risk-based approach to oversight
Advances in digital technologies and data are changing clinical trial delivery and oversight	Increased use of decentralized elements, e-consent, remote monitoring, real-world data and AI-enabled tools require modernized regulatory approaches
Global trials require greater international alignment and collaboration	Alignment with international guidelines and collaboration with like-minded regulators can reduce duplication and support consistent compliance and enforcement

Key Modernized Regulatory Requirements – At a Glance

The proposed Regulations introduce the following key changes to the regulation of clinical trials in Canada:

- Regulating the conduct of a clinical trial
- Applying a risk-based approach where appropriate, including allowing the use of Terms and Conditions (T&Cs)
- Updating Clinical Trial Application (CTA) requirements
- Enabling approvals by a National Research Ethics Board (REB)
- Expanding the scope of regulated health professions that can be CT investigators
- Adding flexibility for informed consent
- Updating sponsor's obligations:
  - adjusting notifications requirements
  - reducing record-keeping for adverse events for drugs with a well-understood safety profile
  - enhancing Health Canada’s ability to request an assessment of safety information (case and summary reports)
  - introducing targeted post-trial safety-related reporting obligation
- Modernizing Compliance and Enforcement (C&E)
  - direct regulatory oversight of service providers
  - introducing ability to suspend or revoke a part of an authorization

Clinical Trials Modernization – Timeline

Completed

- Pre-published regulatory package in Canada Gazette Part I (CGI) for 120-day public consultation in December 2025
- Published 3 draft guidance documents on Canada.ca
- Collected feedback via CGI, written submissions, online questionnaire
- 4 virtual stakeholder sessions

Ongoing

- Stakeholder feedback analysis
- “What We Heard” report: Summer 2026
- Finalization of the regulations
- CGII publication: June 2027
- 1-year delayed coming into force after CGII
- Possibility of a second regulatory package with additional flexibilities

Addressing Stakeholder-Identified Regulatory Burdens

Addressing stakeholder-identified regulatory burdens

Allow certain data to be submitted during a drug review

- Allow certain data to be solicited by Health Canada without needing to stop the review to issue a negative interim decision
- Increased flexibility which supports further international alignment and collaboration
- ***Planned publication of a Notice in August 2026*** outlining a limited use scope, followed by consultation and introduction of additional flexibilities late 2026.

Streamline drug labelling (including eliminating the need for certain package inserts)

Addressing stakeholder-identified regulatory burdens

Post-Market Vigilance (Marketed Health Products Directorate)

Guidance and Operations

- Remove requirement for industry to scan the Canada Vigilance Online Database – ***Complete***
- Update Notification of Foreign Actions Guidance Document – ***Final guidance publication anticipated Summer 2026***
- Update Preparing and Submitting Summary Reports Guidance Document – ***Final guidance publication anticipated Summer 2026***
- Moving from a product-based to a risk-based approach for risk management plans (Agile Regulations) – ***Final guidance publication anticipated Fall 2026***
- New Management of Post-market Vigilance Submissions Guidance Document – ***Final guidance publication anticipated Spring 2027***

Regulations (Long-term)

- Flexible risk-based post-market vigilance regulatory requirements for drugs (FDR)
- Record retention reform for drugs (FDR)

Simplifying the Food and Drug Regulations

Simplifying Part C of the Food and Drug Regulations

- The Food and Drug Regulations have been amended several times over the years to keep up with advances in science and Health Canada's evolving role related to the safety, efficacy and quality of health products and food.
- This has resulted in a complex set of regulations with some outdated requirements and gaps concerning current practices, international norms and other standards.
- The regulations are often inflexible to innovation and may be challenging for regulated parties to navigate.
- Stakeholders have indicated that they face undue burden due to overlapping or unclear regulatory requirements, complex regulatory approvals, and onerous reporting and information demands.

Simplifying Part C of the Food and Drug Regulations

Proposed Actions

Expected Outcomes

Health Canada plans to simplify Part C of the Food and Drug Regulations by:	Simplifying Part C of the Food and Drug Regulations is expected to:
• Streamlining authorization processes • Addressing outdated and redundant requirements • Increasing clarity • Improving international alignment • Introducing flexibility and responsiveness to science and innovation	• Improve predictability for regulated parties • Minimize interactions for regulated parties • Enhance service delivery for stakeholders • Reduce barriers to conducting business in Canada • Facilitate the introduction of new and innovative products onto the Canadian market

International Collaborations

International Involvement: Health Canada (BRDD)

Contributing to international collaborations is a key driver in maintaining and leveraging Health Canada's expertise

International engagement helps to support effort to work to internal and external harmonization

BRDD leadership and staff are actively involved in a number of international collaborations

- ICH
  - Management Committee, MEDRA, and the Technology Task Force,
  - Quality EWGs: ICH Q1, Q5E, Q6, M4Q, M16, and M18
- WHO Initiatives
- EDQM
- ICMRA PQKMS Pilot
- **Access Consortium**

Access Consortium - Overview

Access Consortium

- Formed in 2007, Access is a coalition of **like-minded medium-sized** regulatory authorities
- Aims to promote **faster and broader access** to medicines by our population, **better align regulatory systems** and **reduce unnecessary duplication** and differences
- Meets regularly to **work share** & exchange information on major regulatory issues/ challenges

Members

- Australia - Therapeutic Goods Administration (TGA)
- Canada - Health Canada
- Singapore - Health Sciences Authority (HSA)
- Switzerland - Swissmedic
- UK - Medicines and Healthcare products Regulatory Authority (MHRA)

Why Access Matters

Strategic Linkages:

- HPFB's international strategic priorities
- Red Tape Reduction Report
- Reliance Order - Joint reviews
- Health Canada Departmental Plan
- Project Compass Interim Report
- Deputy Minister's Action Plan on Increasing Access to Drugs

Benefits:

- Value of established relationships with key trusted regulatory partners
- **Timely access to health products in Canada**

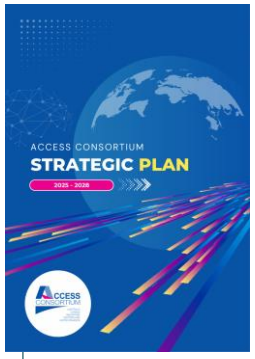
Challenges:

- Resources
- Time zones

Enabling regulatory harmonization and convergence

Access Timeline

CIRS RD Briefing 88 – New drug approvals in six major authorities 2013-2022: Focus on orphan designation and facilitated regulatory pathways



TGA Consultation Roadmap

Access Consortium GROWTH Manifesto

July 2023 | March 2024 | June 2025 | July 2025 | September 2025 | October 2025

Industry Perceptions and Experiences with the Access Consortium New Active Substance Work-Sharing Initiative (NASWSI): Survey Results and Recommendations

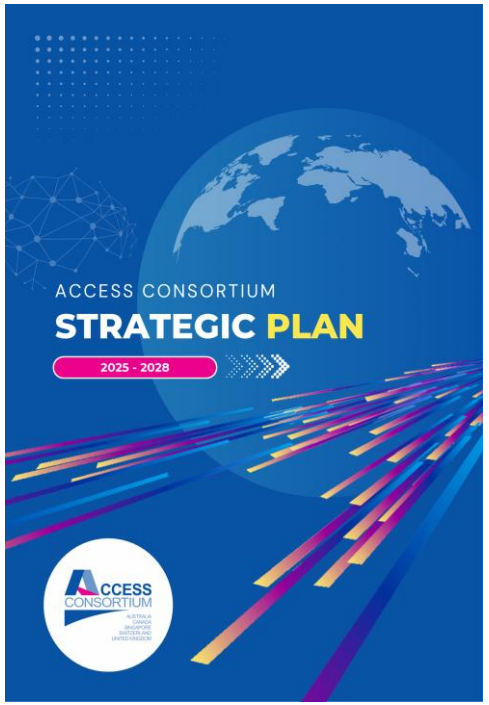
Leveraging the Access Consortium for efficient regulatory review
- Letter to HoA from industry associations

Potential Future of Access: Options Paper for long-term vision of Access Consortium
- MHRA paper

Strategic Plan for 2025-2028

1. Make Access a competitive and efficient submission pathway of choice for industry by strengthening Access work-sharing initiatives
2. Enhance Access collaboration throughout the health product lifecycle
3. Collaborate to enable timely access to innovative health products
4. Strengthen communication and consultation by enhancing engagement, transparency and reporting

Access one-stop website:
https://accessconsortium.info/



Access GROWTH Manifesto

VISION

To grow and advance regulatory cooperation and alignment to enable innovation, strengthen trust and accelerate access to safe, effective and high-quality health products to our patients

GROWTH – Our shared commitment

We aim to transform and shape a harmonized, trusted, forward-looking and patient-centric global regulatory ecosystem through close engagement and collaboration with the industry and its associations, where Access stands among the industries' preferred filing pathways

GROWTH manifesto encompasses six core principles:

1. Governance
2. Reliance
3. Openness
4. Worksharing
5. Transformation
6. Harmonization

Updated Guidance Documents

Guidance Updates of Note

- Biosimilars Guidance

Overview: Guidance on information and submission requirements for biosimilar biologic drugs - Canada.ca

- Division 4 Guidance (Biologics)

Requirements – Division 4: Guidance document on submission information for biologic drugs (Division 4, Schedule D) - Canada.ca

- Lot Release Guidance

Guidance on the Lot Release Program for Schedule D (biologic) drugs - Canada.ca

- Nitrosamines

Nitrosamine impurities in medications: Guidance - Canada.ca

Conclusions

Health Canada's CMC modernization agenda is translating policy into practice through:

- **Reducing regulatory burden** through targeted Red Tape Reduction initiatives and more flexible, risk-based approaches.
- **Modernizing clinical trial and regulatory frameworks** to better support innovation and emerging technologies.
- **Simplifying regulatory requirements** to improve clarity, efficiency, and international alignment.
- **Expanding international collaboration and reliance**, particularly through the Access Consortium, to enhance regulatory efficiency and timely access to medicines.
- **Updating guidance and operational practices** based on stakeholder feedback and evolving science.

GOAL: A modern, agile, and internationally aligned regulatory system that maintains Health Canada's high standards for quality, safety, and efficacy while supporting faster access to innovative therapies for Canadians.

Thank you