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# Health Canada's Red Tape Reduction Initiatives and International Collaboration

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## Objective

Provide an update on Health Canada's Health Product and Food Branch (HPFB) **Red Tape Reduction (RTR) initiatives**, including reliance, and outline the next steps.



# Key Updates

- **Red Tape Reduction Initiative**
  - Clinical Trials Modernization
  - Stakeholder Identified Burdens
- **Ministerial Reliance Order**
- **International Collaboration**
  - Access Consortium
  - Project Orbis
  - Regulatory Information Sharing (RIS) initiative
- **Other Burden Reduction Initiatives**



# Government of Canada Red Tape Reduction (RTR) Initiative

- In July 2025, The Government on Canada launched a RTR 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Board Secretariat, the RTR Initiative aims to modernize the federal regulatory framework by identifying and eliminating outdated and overly complicated regulations that raise costs, reduce productivity, and stifle economic growth.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.

# Overview of RTR initiatives

INITIATIVE	DESCRIPTION	WHY IT MATTERS?
Modernizing the framework for clinical trials	Drafting regulations to modernize the 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 and food approvals	Make regulations for human drugs and foods 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 Project Orbis, and rely on FRA decisions to facilitate improved access to drugs in Canada	Reduce burden for industry

## Overview of RTR initiatives (con't)

INITIATIVE	DESCRIPTION	WHY IT MATTERS?
Reducing red tape for natural health products (NHPs) and non-prescription drugs (NPDs)	Introducing simpler, flexible, risk-based approaches to regulating NHPs and NPDs	Encourage more products to be brought to the Canadian market
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
- Social media and awareness campaign
- 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

# **Stakeholder-Identified Irritants (Burden Reduction)**

# 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 July 2026** outlining a limited use scope, followed by consultation and introduction of additional flexibilities late 2026.

Short to  
Medium  
Term

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

- Eliminating the need for certain package inserts through a streamlined waiver process and risk assessment tool
- Piloting this process with prescription drugs completed in 2026, **planned for biologics in 2026/2027**
- Updates to the Plain Language Labelling Q&A document to reduce regulatory burden and improve efficiency. Results of completed consultation are being assessed.

# Addressing stakeholder-identified regulatory burdens

## 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**

Short to  
Medium  
Term

## Regulations

- Flexible risk-based post-market vigilance regulatory requirements for drugs (FDR) and natural health products (NHPR)
- Record retention reform for drugs (FDR) and natural health products (NHPR)

Medium  
to Long  
Term

# Key Updates

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# Background

- One of the actions identified in the RTR report is the development of a Ministerial Order made under section 30.06 of the *Food and Drugs Act (FDA)* that would deem that certain regulatory requirements related to drug submissions, for specific identified classes of drugs, are met based on decisions and documents produced by a foreign regulatory authority (FRA)
- This Order would be meant to facilitate work-sharing arrangements with like-minded FRAs, and would also provide support for reliance on foreign decisions / documents in the review of drug submissions filed directly to Health Canada

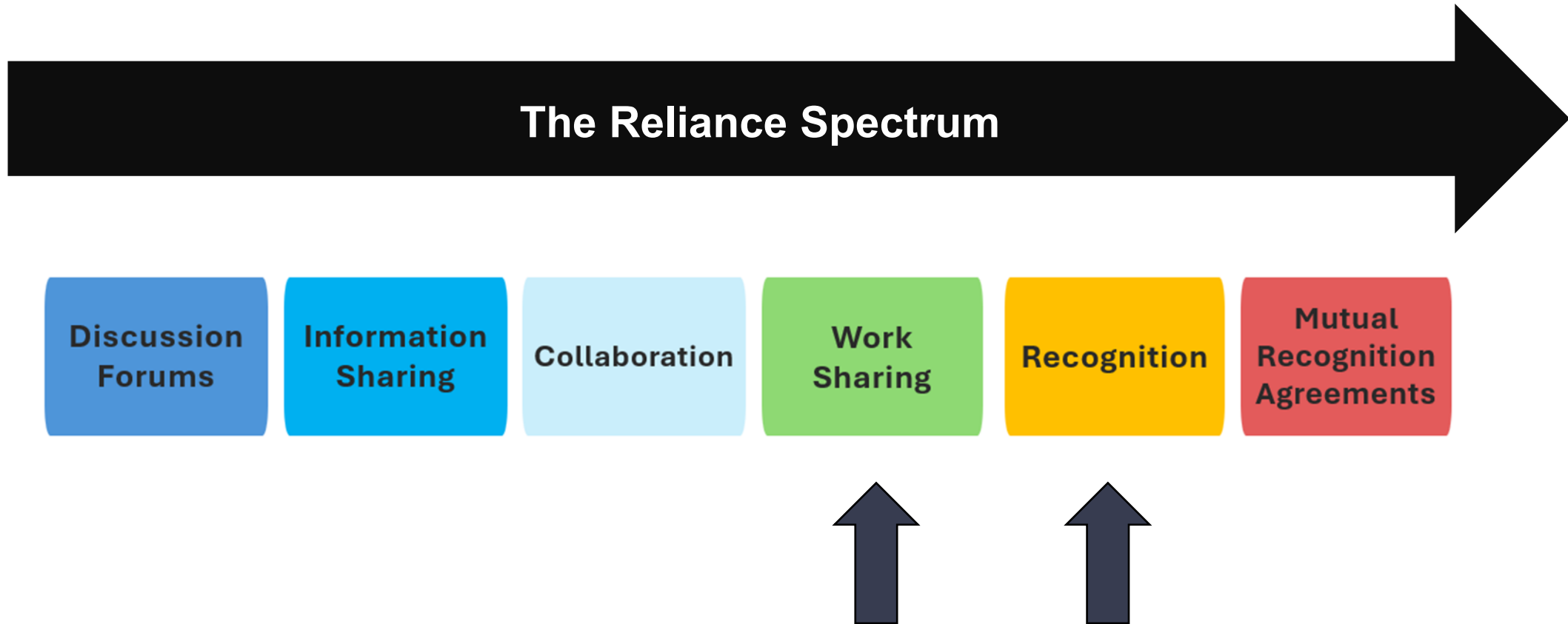
## Background – Reliance Orders in the *Food and Drugs Act*

- In 2024, new powers were added to the *FDA* which allow the Minister to make different types of Orders - considered to be Ministerial Regulations - including a reliance Order power.
  - A reliance Order may deem that specified requirements under the *FDA* or any subordinate regulations have been met on the basis of a decision of – or any information or document produced by – an FRA
  - They only apply to those products included in a specified class
  - A reliance Order can only be made if the Minister believes that it is necessary for a health and safety purpose or is otherwise in the public interest, and that it is unlikely to result in unacceptable health and/or safety risks, or an unacceptable degree of uncertainty respecting health and/or safety

## Context – Increasing global collaboration and alignment

- Health Canada is a partner in several global collaborative review schemes across product lines (e.g. Access Consortium)
- Health Canada has been focused on supporting international alignment through multilateral fora, such as the International Council of Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), drug clusters, and bilateral partnerships with FRAs
- Mid-sized regulators around the world have also been increasing their use of reliance and recognition to streamline therapeutics reviews and reduce duplication of effort

# Context – Reliance Spectrum



# Overview of Ministerial Reliance Order

## A tool that aims to:

- ✓ Allow Health Canada to leverage international partnerships—using a risk-based approach—to generate greater efficiencies in the review of some drug submissions
- ✓ Continue to strengthen and expand on information-sharing and decisions from foreign regulatory authorities with the longer-term goal of increased collaboration in regulatory decision-making
  - ✓ Incentivize sponsors to reduce delays in filing submissions for drugs in Canada
- ✓ Enable Health Canada to refocus resources as needed to support the health and safety of Canadians.



For drug submissions where a decision has already been made by an FRA



For drug submissions where the foreign decision is pending; must be filed in Canada within 120 days of being filed with the FRA



FRA = Foreign Regulatory Authority

# Overarching Design Elements

- The Order would be designed to allow for the deeming of one or a combination of:
  - Both clinical and chemistry and manufacturing (C&M);
  - C&M, without clinical; or
  - Clinical, without C&M.

# Overarching Design Elements

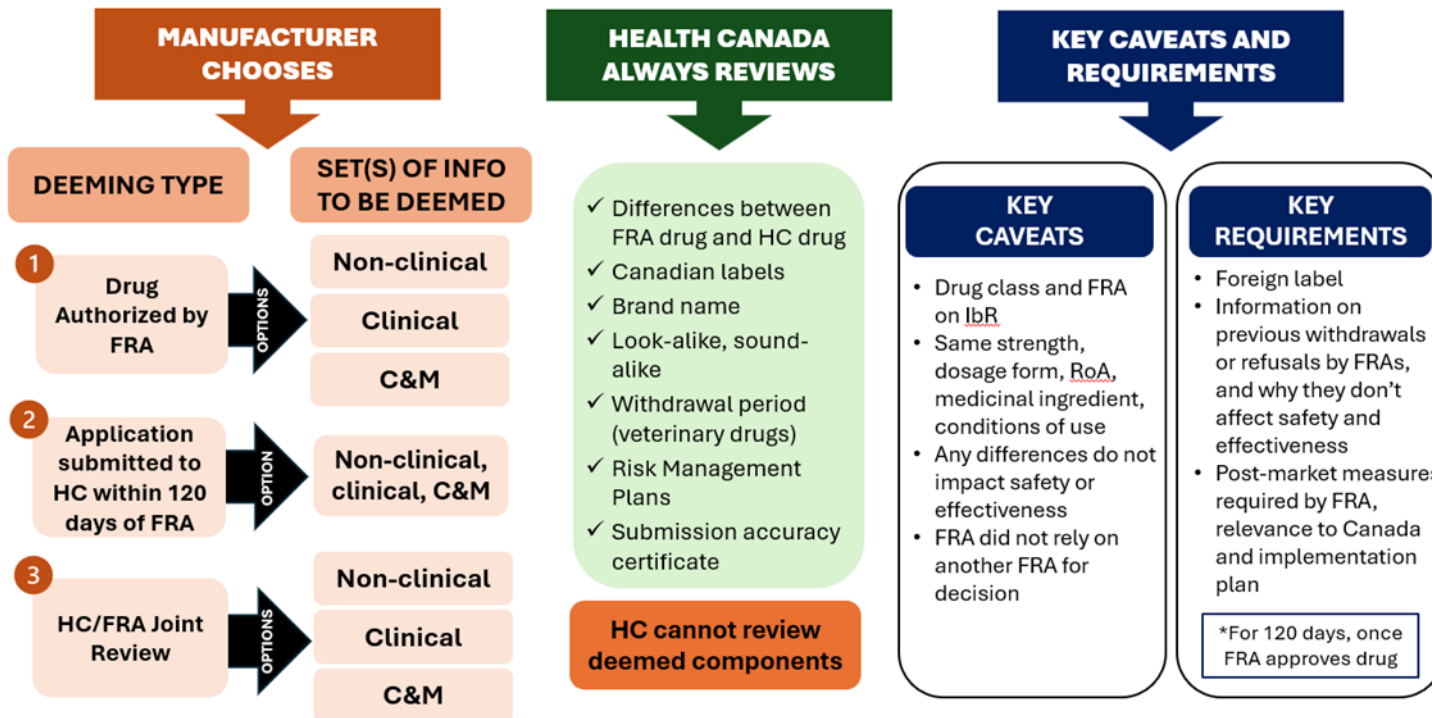
- A drug submission would need to:
  - Be a drug that is in a class identified on the Order's Incorporated by Reference (IbR) list
  - Meet the regulatory requirements in the FDR and the Order applicable to the submission type (e.g., NDS, ANDS, etc.)
- Existing intellectual property regimes continue to apply.

# Overarching Design Elements

- Where differences exist between the drug submission in Canada versus what was approved by the FRA:
  - Manufacturer would provide a description of the differences and demonstrate that those differences would not result in an unacceptable risk to health or safety
  - Health Canada would examine any identified differences and the information provided by the manufacturer to determine whether it has been demonstrated that there are no differences that could lead to an unacceptable health or safety risk
  - Differences could include:
    - For C&M, including inherent differences in the drug (e.g., colourant)
    - Clinical differences (including differences that reflect the Canadian context)

# Ministerial Reliance Order – Proposed implementation for human drugs

## RELIANCE – CGI PROPOSAL



## Proposed Implementation Plan – Human Drugs

### Phase 1

To be implemented with the coming into force of the MRO in July 2026

- **General deeming** will focus on classes of drugs to address therapeutic gaps that have been identified; specifically, human drug classes with pediatric conditions of use.
- **Joint reviews** will be fully implemented in Phase 1, leveraging existing processes and expertise.

### Phase 2

This phase would include classes of drugs for 120-day filing via a targeted approach. Pending further engagement, general deeming would expand to include additional classes of human drugs to the IbR list for consideration during this phase.

### Phase 3

This phase would include classes of drugs for **abbreviated new drug submissions**.

## Next Steps

- The [Ministerial Reliance Order \(MRO\)](#) was published in *Canada Gazette*, Part I, on December 20, 2025, for an 84-day consultation period.
- [Notice of Intent](#) was published on May 5, 2026, to seek feedback on the proposed phased implementation process for developing and updating the incorporated by reference (IbR) list. The list would set out the classes of drugs and the foreign regulatory authorities (FRAs) for the MRO.
- Targeting publication in *Canada Gazette*, Part II, in Summer 2026.
  - MRO would come into force upon publication
- In addition to the Ministerial Reliance Order, Health Canada is actively engaging with international peer regulators on other ongoing initiatives to improve access to drugs for people in Canada.

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# 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

Building on regulatory harmonization and convergence

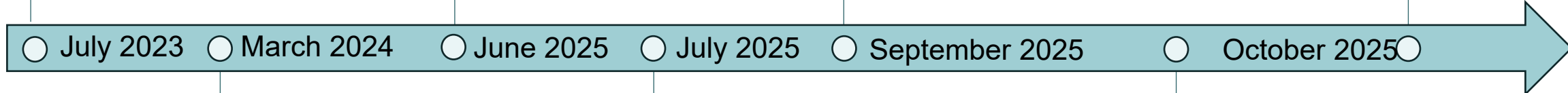
# Access Timeline

[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**



[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

## Key Access Metrics

	Innovative drugs	Generic drugs
Total number of approvals to date: 40 (in the ~8 years since program inception)	40	6
Submissions filed in calendar year 2025	15	1
Approvals in calendar year 2025	6	0
Submissions filed in calendar year 2026*	3	0
Approvals in calendar year 2026*	4	0
Submissions currently in review*	14	1

\* = As of May 12, 2026

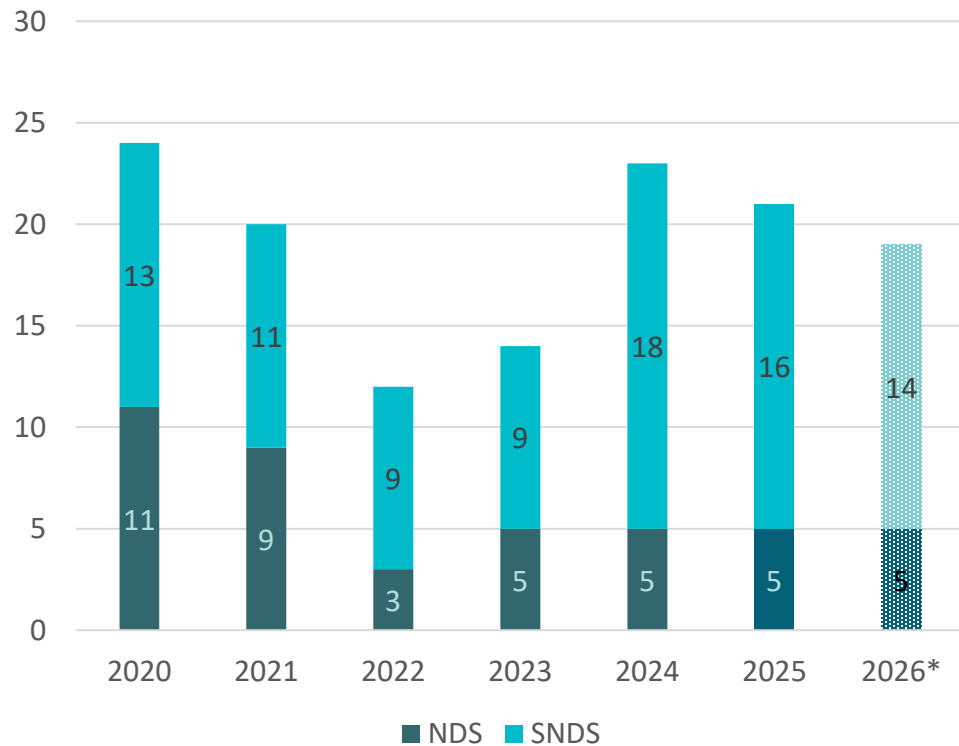
# Project Orbis at Health Canada: Overview

- Project Orbis is a US FDA Oncology Center of Excellence (OCE) initiative for **oncology products**, providing a framework for parallel submission review and information sharing among international partners
- Project Orbis aims to give Canadians, and patients around the world, earlier access to promising cancer treatments
- Health Canada has been a partner in Project Orbis since its inception in May 2019 and worked with the US FDA and Australia's TGA on the first ever Project Orbis submission
  - The submission sought market authorization for Lenvima and Keytruda combination therapy for the treatment of advanced endometrial carcinoma, resulting in simultaneous regulatory decisions in all three countries
- In addition to the US FDA, Project Orbis partners include:
  - Therapeutic Goods Administration (TGA) of Australia
  - National Health Surveillance Agency (ANVISA) of Brazil
  - Health Products and Food Branch (HPFB) of Health Canada, Canada
  - Ministry of Health (IMoH) Pharmaceutical Administration of Israel
  - Health Sciences Authority (HSA) of Singapore
  - Swiss Agency for Therapeutic Products (Swissmedic) of Switzerland
  - Medicines and Healthcare products Regulatory Agency (MHRA), of the United Kingdom (U.K.)

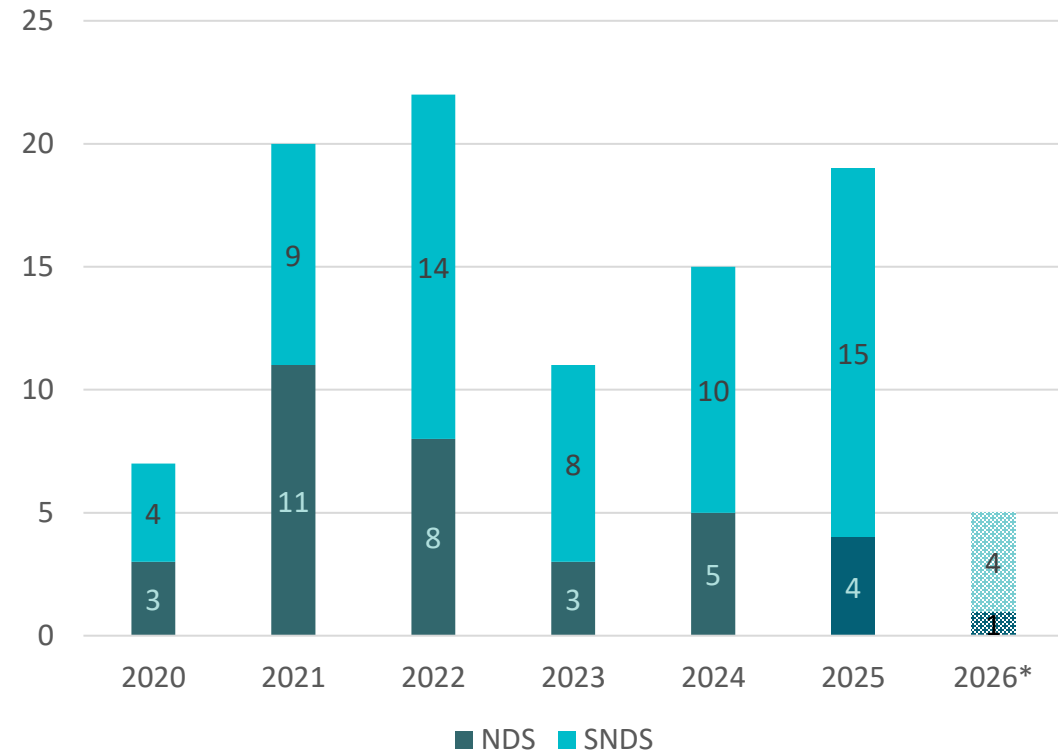
# Projet Orbis Metrics

Submission filing and approval volume trends from 2020 to 2026\*

Volume of **Submissions Received** Over Time (Calendar Year)



Volume of **Approvals** Over Time (Calendar Year)

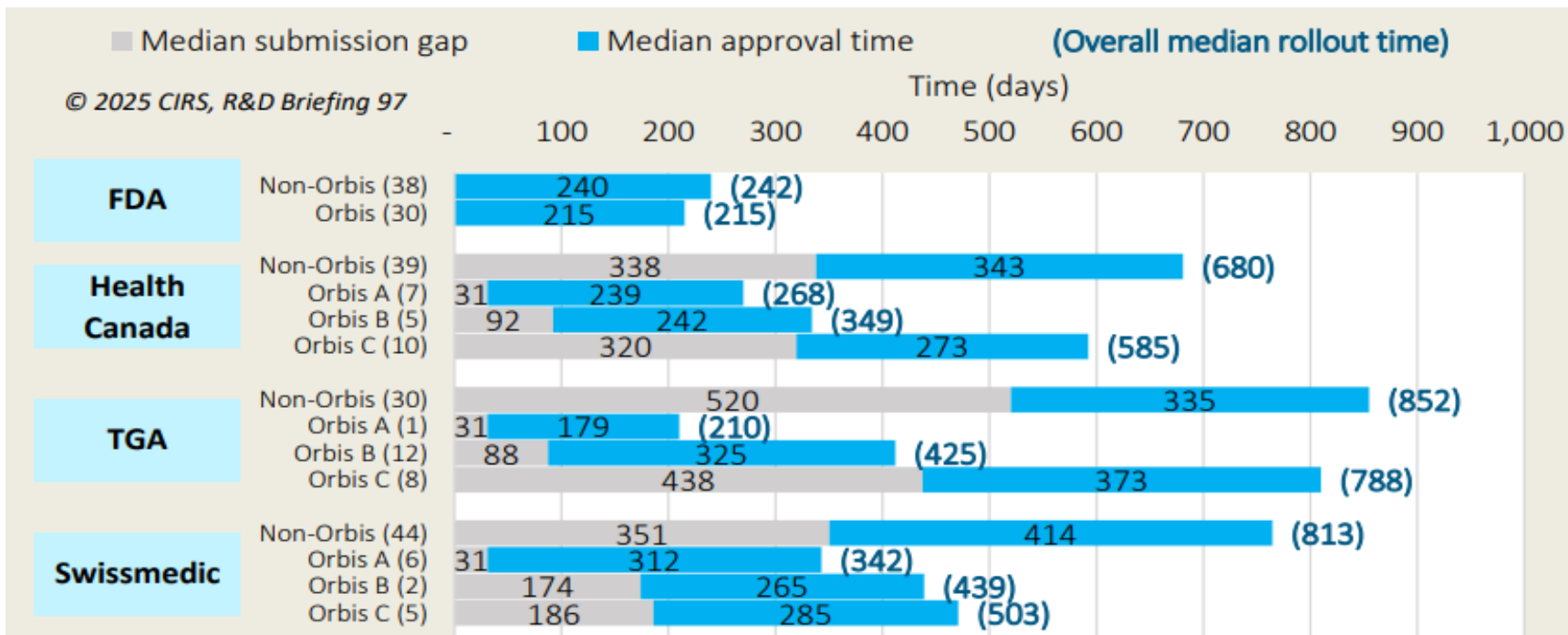


\*2026 Calendar year represents only approvals, submissions received, or submissions expected as of the data available on May 12, 2026. Volume is expected to increase throughout the remainder of the calendar year.

# Projet Orbis Metrics

## Submission Gap and Review Time Analysis (2019-2023)

- According to an analysis conducted by the Centre for Innovation in Regulatory Science (CIRS), we see a significant reduction in the time between submission filing to the first country globally and submission filing to Health Canada.
- Earlier submission filing means earlier regulatory decisions from Health Canada, enabling earlier access to new oncology treatments for Canadian patients.



Source: Centre for Innovation in Regulatory Science (2024) R&D Briefing 97: Access Consortium and Project Orbis New Active Substance Approvals Across Eight National Regulatory Authorities. A Five-Year Comparative Study. Centre for Innovation in Regulatory Science. London, UK.

## International engagement - Regulatory Information Sharing (RIS) initiative

- On December 1, 2025, Health Canada and the U.S. Food and Drug Administration (FDA) formalized what had been a pilot program, to enhance the exchange of regulatory information to facilitate review processes for generic drugs.
- The objective is to support regulatory alignment and enhance patient access to high-quality, safe and effective generic medicines in both countries. Participation in this program is entirely voluntary and subject to the agreement of the applicant, U.S. FDA and Health Canada.
- To date, 27 submissions have successfully gone through the RIS initiative.

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# Revised Biosimilars Guidance Document

- On May 19, 2026, Health Canada published a revised version of its *Guidance on information and submission requirements for biosimilar biologic drugs* (Biosimilars Guidance).
- The guidance is intended to assist sponsors in meeting the requirements of the *Food and Drug Regulations* for the authorization of biosimilars.
- It has been revised to reflect Health Canada's experience in reviewing biosimilar submissions since the last comprehensive review of the guidance in 2016, and to better align with the current state of science and international developments.

# Key Changes and Implications

- Most notably, the Biosimilars Guidance now indicates that comparative clinical efficacy trial(s) are no longer typically required when a biosimilar candidate and its reference product can be compared and extensively characterized by appropriate analytical studies.
- The revised guidance, thus, places greater emphasis on establishing analytical comparability and provides further information on considerations in this regard.
- Removing the default requirement for clinical efficacy studies is expected to facilitate biosimilar development programs by providing significant time and costs savings to sponsors, likely accelerating market entry and lowering biologic drug costs.

# Revisions to the Nitrosamine Guidance

Health Canada's Health Product and Food Branch and Regulatory Operations and Enforcement Branch will publish a revision of the '*Nitrosamine Impurities in Medications*' guidance



Providing increased flexibility and resources for market authorization holders (MAHs), further aligning with the approach of other regulators. Publication in May/June 2026

**Health Canada's change in expectation for reporting on the detection of nitrosamine impurities:**



No longer requires MAHs to inform HC every time an elevated level of a nitrosamine impurity is detected. MAHs are only expected to notify HC if a decision to initiate a recall is made and reporting should be conducted as specified.



No longer requires nitrosamine risk mitigation-related changes to be filed as Level I (Supplement) submissions by default. These changes should be classified and filed in accordance with HC's Post-Notice of Compliance Change guidance, using a risk-based approach.



Reduces regulatory burden for low-risk nitrosamine mitigation strategies and supports faster implementation of risk mitigation measures, leading to increased drug product safety.

