Health Canada's Workload Management in Human Drug Submission

Presentation to CAPRA Education Day 2026

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Outline

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3. How we are Addressing the Issue
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Context

Health Canada's recent achievements demonstrate resilience and global leadership despite growing pressures.

- Aligned reviews with domestic Health Technology Assessment organizations (HTAs)
- WHO-Listed Authority designation[1]
- Centre for Innovation in Regulatory Science (CIRS) DR Briefing 101 Report[2] shows strong performance for Health Canada in the following area:
  - Shortest median for priority reviews in 2024
  - Top 3 for shortest median submission approval time
  - Shortest median for expedited reviews
- Increased monthly decision output amid resource pressures

1: WHO designates new WHO-Listed Authorities, strengthening global access to quality-assured medical products
2. *RD Briefing 101 – New drug approvals by six major authorities 2015-2024*

Context (Cont.)

Since 2022, Health Canada's Pharmaceutical Drugs Directorate (PDD) and Biologic and Radiopharmaceutical Drugs Directorate (BRDD) have been managing a growing submission backlog driven by:

- Steady year-over-year increases in the number of drug submissions filed;
- Rapid scientific advances are increasing for deeper review. submission complexity and the need
- Incomplete data packages and gaps in required information; and
- Staffing limitations.

Health Canada implemented important efficiency measures, but despite these efforts, the capacity remained insufficient to meet the growing demand, prompting increased attention and feedback from industry stakeholders.

Key Metrics: Pharmaceutical Drugs Directorate (PDD)

Innovators

- Between 2016 and 2025, PDD experienced a 23% increase in new drug submissions (NDS) and 44% increase in changes to marketed new drugs (SNDS) received.
- Average number of review hours per new drug submission over the past 5 years has risen by 45%.
- NDS New Active Substance (NAS) average submission review hours peaked in 2024-25 with 3,221 hours – a 44% increase from 2020-21.
- Despite this, in FY2024-25, PDD maintained on-time performance, completing 97% of NDS and 99.8% of SNDS within established timelines.

Generics:

- There are several hundred generic submissions in review at any given time.
- Between 2016 and 2025, Health Canada experienced a 43% increase in Abbreviated New Drug Submission (ANDS) and more than 200% increase in Supplement to an Abbreviated New Drug Submission (SANDS).
- Average number of review hours per new generic submission over the past 5 years has risen by 30%.
- Average monthly decision targets have increased to 42 submissions for FY2024-25 and continue to increase. Historically, it was approximately 25 decisions targeted.

Key Metrics: Biologic and Radiopharmaceutical Drugs Directorate (BRDD)

- BRDD's NDS submissions have increased by 110%, including an increase of 63% for NDS NAS, while SNDS have increased by 115%.
- Since 2018, average review hours for NDS have increased by 40% (1,761 to 2,475), peaking in 2022-23 with 2,917 hours.
- NDS NAS average submission review hours peaked in 2022-23 (3,651 hours) and has decreased by 16% by 2024-25 attributable to review efficiencies.
- Since 2018, the average number of review hours for Biosimilars has increased by 25%, attributed to increasing complexity.
- Despite this, in FY2024-25, BRDD maintained on-time performance, completing 93.2% of NDS and 96.9% of SNDS within established timelines, while resources remained relatively constant.

How we are Addressing the Issue: Initial Activities

Maximizing Capacity

Temporary reallocation of resources, hiring contractors.

Process Optimization

Analyzing workflows, streamlining reviews, bundling.

Support for Submission Quality Improvement

checklists, training.

Increased International Collaboration

Access Consortium, Project Orbis, information sharing, reliance.

Stakeholder Engagement

Discussions at multiple fora

How we are Addressing the Issue: Activities with Longer-Term Impacts

Some of the Ministerial commitments include:

- **Red Tape Review**: Report published on September 8, 2025, underscores a commitment to regulatory efficiency, with actions underway to modernize processes, reduce burden, and support backlog reduction.
- Publication of the **Ministerial Reliance Order** (CGI, December 2025: for consultation) for expanding use of foreign reviews and reliance with foreign regulatory authorities.

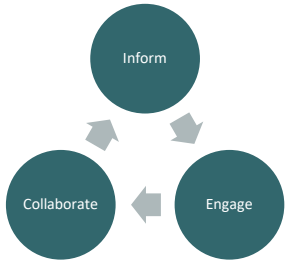
Other:

- Increase use of **AI**
- **Pharmaceutical and Life Sciences Sector Task Force**
- Publication of the **Biosimilars Guidance**
- Implementation of **ICH Q12** including new and updated guidance documents (Post-notice of Compliance Changes).

Engaged Stakeholders: What we heard from Industry

Industry stakeholders emphasized the importance of implementing measures to help alleviate workload pressures and address challenges related to backlogs, including the following areas:

- Predictability and Transparency
- Flexibility in the Review Process
- International Collaboration
- Guidance and Policy Updates



Stakeholder Engagement Workshops: *Advancing Solutions Together*

- Health Canada organized a series of stakeholder workshops in Fall 2025 with representatives from innovator and generic/biosimilar industry associations.
- Designed to foster a collaborative, solution-focused dialogue to identify both immediate and longer-term improvements to the drug submission review process.

Desired Outcomes

- Surfacing a clear set of short-term ideas that could be explored or tested quickly.
- Identifying longer-term opportunities that warrant further consideration.
- Building shared understanding and trust.
- Establishing a foundation for continued collaboration.

Stakeholder Engagement Workshops: Outcome

Action Plan:

A shared commitment to activities that will enhance transparency and predictability and support efficient reviews.

Communication

Workload Management

Backlog Reduction

Action Plan: *Communication*

Activity	Target	Status
Broaden outreach to include Industry stakeholders beyond associations, for example, by presenting at the annual DIA meeting.	Ongoing	In-Progress & ongoing
Develop a streamlined and proactive **communication framework** that considers needs, provides clear and timely information to industry, and minimizes repetitive or ad hoc inquiries to Health Canada.	Spring 2026	Completed. Implementation summer 2026
Assess ability for Biologic and Radiopharmaceutical Drug Directorate innovator submissions to leverage the Pharmaceutical Drug Directorate's process for sharing **status report information**.	Spring 2026	Completed. Implementation fall 2026
Optimize use of pre-submission and pipeline **meetings.**	Winter 2027	In-Progress. Project Plan being developed
Explore the possibility of using of **AI chatbot** to respond to routine stakeholder questions to improve response times and client service.	Spring 2027 (Project initiation)	Project initiation Spring 2027

Action Plan: *Workload Management*

Activity	Target	Status
Develop **workload management principles** framed around our commitment to serving Canadians, for example, responding to public health issues.	Winter 2027	Draft Completed. Stakeholder engagement summer 2026
Assess feasibility allow Health Canada to **solicit data during reviews.**	Fall 2026	In-Progress. Implementation target Dec. 2026
Share **guidance tools** to assist with file completeness (e.g. checklists).	Summer 2026	In-Progress and ongoing. Summer 2026
(Industry): Facilitate **knowledge exchange** among members to share lessons learned and best practices, with the goal of improving the quality of submissions.	Ongoing	Ongoing
Introduce clear **parameters for extension requests** granted during the review process to support timely decision-making.	Summer 2026	In-Progress. Summer 2026

Action Plan: *Backlog Reduction*

Activity	Target	Status
Establish a risk-based framework for the application of **Reliance Order** as it relates to drug reviews	Summer 2026	In-Progress. CGII July 2026
Enhance and standardize **protocols** to support the **effective and consistent use of foreign regulatory information** during drug reviews.	Spring 2026	In-Progress. Ongoing
Expand the use of AI-tools in drug reviews.	Ongoing	Ongoing
Consider targeted, time limited **hiring.**	Fall 2026	Many additional resources already hired. Training is ongoing.

Unclassified / Non classifié

Health Canada Communications Protocol for Human Drug Submissions Nearing Review Target

Guiding Communications between the Pharmaceutical Drugs Directorate/ Biologic and Radiopharmaceutical Drugs Directorate and Sponsors.

The Issue

- Stakeholders want predictability and advance notification if a submission will miss target, but responding to submission status requests diverts Health Canada resources from review.

At a Glance

- Introduces milestone notifications for NDS and (S)NDS submissions to provide earlier and more predictable communication to sponsors when a file is at risk of missing its review target, while outlining shared responsibilities between Health Canada and stakeholders.

Aiming for Summer 2026 implementation

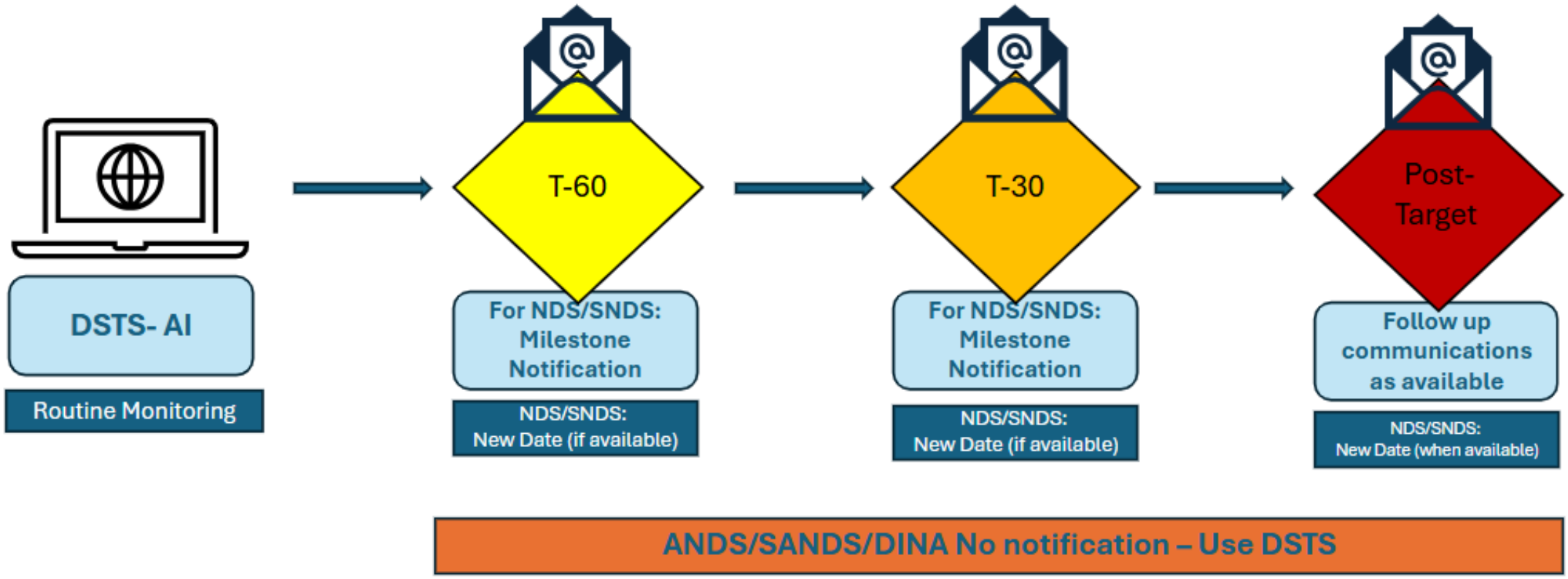
Guiding Principles

Transparency: Communication will be triggered by identified issues, risks, and/or defined communication milestones.

Predictability: Sponsors will be informed at pre-defined points in time during the review process, or when there is a significant change in review status. This will support consistent expectations.

Timeliness: Information will be shared when it is made available as defined in this protocol.

Shared responsibility: Effective communication relies on adherence to agreed timelines and expectations by both Health Canada and sponsors.



PROCESS FLOW FOR SUBMISSIONS AT RISK OF MISSING TARGET DATE

Roles and Responsibility

Health Canada	Maintaining DSTS-IA up-to-date Status updates at defined milestones
Sponsors	Monitoring DSTS-IA. Limiting *ad hoc* status enquiries Using established communication channels
Shared	Adhering to protocol Working collaboratively to address issues

Conclusion: What you can do for a Successful Outcome

- Share pipeline information to support better planning and facilitate earlier engagement on complex or high-priority files.
- Engage Health Canada via Pre-Submission communication to clarify expectations, address potential issues early, and align on submission strategy.
- Consider work-sharing or international submission pathways.
- Provide foreign review reports and information when available.
- Provide submissions that are complete and of high-quality.
- Share lessons learned and apply insights to improve future submissions.
- Use established communication channels and avoid *ad hoc* duplicative requests.

Conclusion (cont.)

- **Collaboration** and engagement with industry partners is key, sharing responsibility for timely drug approvals.
- Multiple ongoing projects: Balancing **immediate action** with long-term **sustainability.**
  - Continue to engage with Industry and providing more advance notice to stakeholders when a file is at risk of missing target timelines
  - Continued implementation of internal efficiencies, including early submission assignment, resource reallocation, branch-wide analysis of workload and priorities, expansion of pilot projects.
  - Prioritize international collaboration and incorporation of foreign information in reviews, where appropriate.
  - Pursue longer-term initiatives, including Ministerial Reliance Order and initiatives under Red Tape Review.

Thank you!

Merci!