Health Canada Santé Canada

Canada

Health Canada –alignment and collaboration

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Transforming how we regulate

Objective: An agile regulatory system that supports better access to therapeutic products based on healthcare system needs

Expanded collaboration with health partners

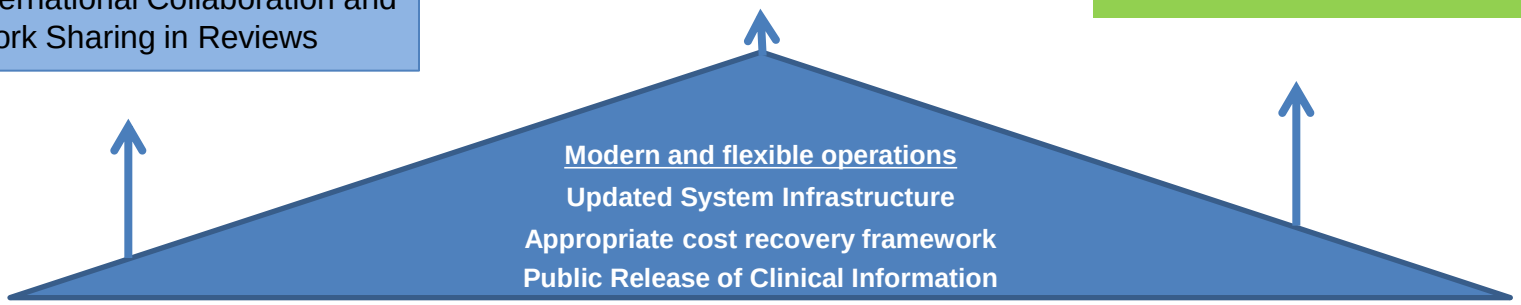
- Alignment of the Health Technology Assessment (CADTH) Review with Health Canada Review
- Implementing a Mechanism for Early Parallel Scientific Advice
- Use of Foreign Reviews/Decisions
- International Collaboration and Work Sharing in Reviews

More timely access to drugs and devices

- Expansion of Priority Review Pathways
- Improving Access to Biosimilars and Biologics
- Improving Access to Generic Drugs
- Building Better Access to Digital Health Technologies
- Pre-Submission Scientific Advice for Medical Devices
- Special Access Programme (SAP) Renewal and Block Release

Enhanced use of real world evidence

- Leveraging Data for Assessing Drug Safety and Effectiveness
- Strengthening the use of real world evidence and regulations for medical devices



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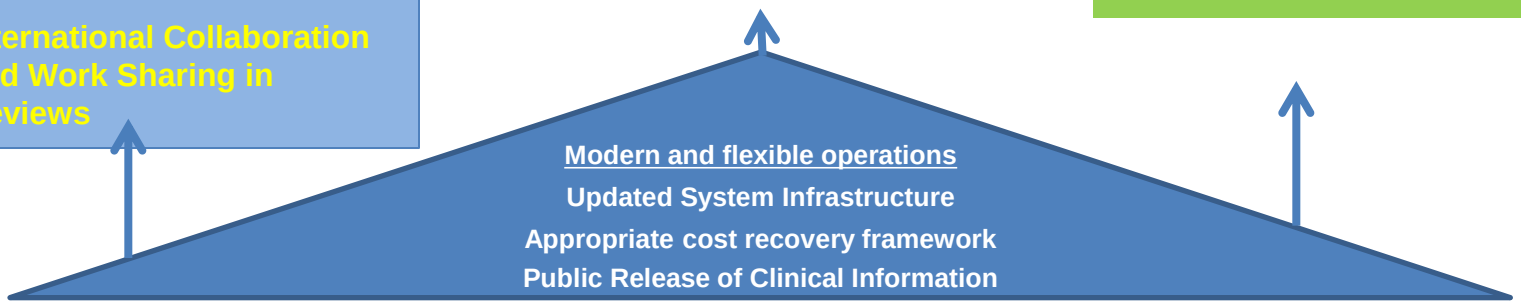

Expanded collaboration with health partners

Early parallel scientific advice

- Opportunity for drug sponsors to get product development advice from HC and CADTH jointly
- Process formally launched in February, 2019

Aligned reviews with CADTH and INESSS

- Established mechanisms for aligned regulatory and health technology assessment reviews, with potential to save overall time to market
- Available as a standard submission pathway since June 2018
  - 19 aligned reviews completed, 9 ongoing, ~75% are new drugs

International alignment and collaboration

- Created processes to share submission review with other regulators
  - 2 reviews completed, more ongoing (partnering with Australia)
  - Ongoing discussions about worksharing between members of ACSS

Other international engagement

- ICH
- FDA/EMA/other regulators cluster meetings

Drug review prioritization

New Drug Submission/Supplementary New Drug Submission – review for safety, quality efficacy

- Target review time – 300 days [similar review for generics = 180 days]

Priority review policy

- Unmet medical need, serious, life-threatening or severely debilitating disease
- Requirement for “substantial” evidence of effectiveness
- Target review time – 180 days

Notice of Compliance with Conditions policy

- Unmet medical need, serious, life-threatening or severely debilitating disease
- “Promising” evidence of effectiveness
- Target review time – 200 days
- Manufacturer agrees to conduct confirmatory studies

R2D2 proposal – expand priority review

Proposal: to include consideration of “healthcare system needs”

- Consultation to be launched soon

- Key elements of draft proposal:
  - Combine priority review and NOC/c into single accelerated review pathway with 180 day review timelines
  - Expand product eligibility criteria to include:
    - Products with same characteristics and indication, if they are submitted within one year of marketing of the first (would not currently be eligible)
    - Healthcare system needs such as:
      - benefits for public health (e.g, products for antimicrobial resistance, opioid crisis)
      - reduction of treatment burden for patients (e.g., due to administration, hospitalization),
      - targeting specific populations (e.g., pediatrics, rare diseases)

- Responds to results from extensive consultation across the healthcare system

Optimizing the Use of Real World Evidence (RWE)

- Health Canada is working with its partners, including CADTH and INESSS, to optimize the use of RWE for regulatory decisions in order to improve access to prescription drugs in Canada.
  - An joint action plan is being developed as a first step to outline how the organizations will work together to accomplish this goal (anticipated to be published this fall).

- Health Canada is building internal capacity to evaluate the appropriate use of RWE as supportive and (in rare cases) pivotal evidence for regulatory decision making.

- “Elements of Real World Data/ Evidence Quality throughout the Prescription Drug Product Life Cycle” will be published by Health Canada to provide overarching principles on the quality of RWD/RWE.
  - It outlines elements of protocol development, reflective of the current guidance from international organizations, as well as key elements characterizing RWD quality.

- Notice to Industry to be issued by Health Canada to invite drug submissions using high quality RWE.

Where Next? Updates from Budget 2019

- Regulatory roadmaps to support innovation in the health and bio-sciences
  - Creation of “regulatory sandboxes” to support innovative products that don’t fit well into existing regulatory frameworks

- Modernizing clinical trial regulation
  - To become more risk-based and agile

- Proposals to support implementation of national pharmacare
  - Canadian drug agency – assessment, pricing negotiation
    - HC to lead transition office to support development
  - National formulary
  - National strategy for EDRDs – up to $1B over 2 years in 2022-23, $500M ongoing

Broader system collaboration which has been started under R2D2 will continue to support ongoing modernization.