Health Canada Santé Canada

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WCBP 2018 ICH Workshop
Health Canada Challenges & Opportunities

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Health Canada's Plan for Regulatory Transformation

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

Expanded collaboration with health partners

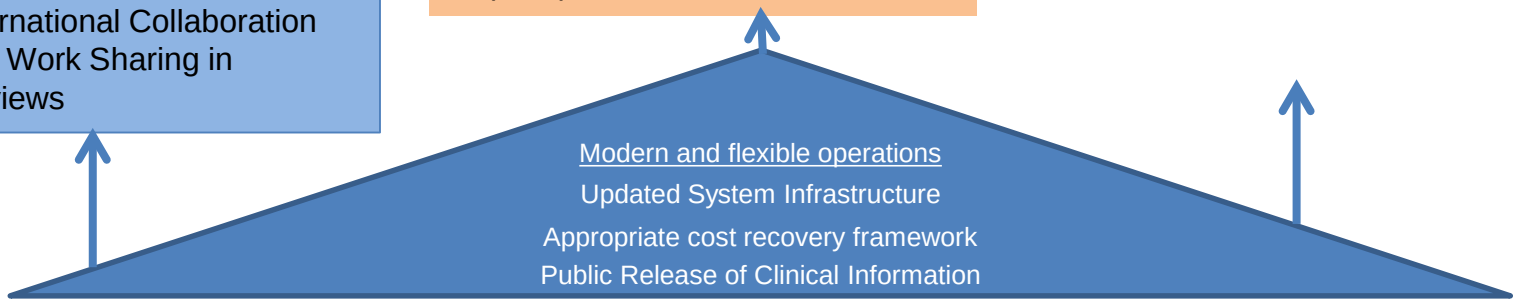
- Alignment of the Health Technology Assessment Review with Health Canada Review
- Implementing a Mechanism for Early Parallel Scientific Advice
- Use of Foreign Reviews/Decisions
- International Collaboration and Work Sharing in Reviews

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

Enhanced Use of real-world evidence

- Leveraging Data for Assessing Drug Safety and Effectiveness
- Strengthening Post-market Surveillance of Medical Devices



Current Quality Challenges & Opportunities

- Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
  - Step 2 guideline recently published for consultation will be a challenge to implement globally.

- Opportunity to open scope of ICH guidelines to include Vaccines and Radiopharmaceuticals

- Potential Future Topics:
  - Quality Overall Summary
  - Assessment and Control of Extractables and Leachables (E&L) for Pharmaceuticals and Biologics
  - Continuous Manufacturing
  - Harmonizing Quality and Safety Standards for [Novel] Excipients [and conventional excipients for new uses]
  - Analytical Methods/Procedures
  - Quality Management for Oligonucleotide Therapeutics

Additional Challenges & Opportunities

Current Challenges:

- GCP Renovation: A challenge that was realised in 2016 and now being addressed with revision to E8(R1) and subsequent annexes to E6(R1).
- E17 – Multi Regional Clinical Trials: Recently finalised guideline will be challenging to effectively implement across regions. IWG formed to facilitate the development of global training.
- E9(R1): Addendum to Statistical Principles for Clinical Trials – Estimands and Sensitivity Analysis in Clinical Trials - New concept that will be challenging to implement.

Potential Future Opportunities:

- Adaptive Clinical Trials
- Real World Data
- Paediatrics: New extrapolation topic just launched, potential for future topic on modelling and simulation)
- Data Standards: Global uptake of Identification of Medicinal Product (IDMP) Standard