Regulatory and Policy Updates
Therapeutic Products Directorate
Health Canada

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Overview

• Regulatory Review of Drugs and Devices
• Cost Recovery
• Guidances
Regulatory Review of Drugs and Devices

• Transformation into modern, agile regulatory system that supports better access to therapeutic products based on healthcare system needs
  – More timely access to drugs and devices
  – Enhanced use of Real World Evidence (RWE)
Building Better Access to Digital Health Technologies

• Develop a targeted review process for digital health technology (e.g. wireless medical devices, mobile medical apps, telemedicine, software as a medical device, etc.)

• Build capacity to review current and future applications for digital health technologies including emerging innovative technologies
Pre-Submission Scientific Advice for Medical Devices

• Develop tools and processes that will improve pre-submission meetings:
  – Influence the design of clinical trials for devices
  – Generate appropriate data to meet regulator needs
  – Improve communication between HC and medical device industry
Strengthening Post-Market Surveillance for Medical Devices

• Increase access to medical device safety and effectiveness information by:
  – Identifying RWE sources for medical devices
  – Acquiring RWE sources
  – Developing analytics tool to query RWE data sources

• Improve product lifecycle integration for medical devices
Cost Recovery

• Health Canada will begin consultations on proposal to modernize cost recovery framework for drugs and devices
  – All fees analyzed
  – Changes to fee lines
  – 75 day consultation period once posted
New Guidance Documents

• Draft Guidance on HIV Rapid Diagnostic Tests for use in point of care or for self-testing posted for public comments on July 31st.
Upcoming Documents

- Revisions to the Preparation of an Application for Investigational Testing (non-IVDDs)
- Guidance on Software as a Medical Device (SaMD)
- Consultation on Fee Proposal for Drugs and Medical Devices
Questions/comments

Thank you!