



IMDRF

International Medical
Device Regulators Forum

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- Draft Guidance on HIV Rapid Diagnostic Tests for use in point of care or for self-testing posted for public comments on July 31st.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



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Questions/comments

Thank you!