Regulatory and Policy Updates
Medical Devices Directorate
Health Canada

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A/Director General
Overview

- Organizational Change
- COVID-19
- Regulatory and Policy Initiatives
- Guidances
Organizational Changes

Director General

Senior Advisor

Science Advisor

Evaluation

ITA, SAP and Post-Market

Licensing Services

Policy and International

Planning and Operations

 Cardiovascular

Investigational Testing/Special Access

Regulatory Affairs

Policy

Quality Systems

Digital Health

Post-Market

Regulatory Screening

International Programs

Stakeholder Engagement

General and Restorative

Device Licensing

Musculoskeletal

In Vitro Diagnostic

Regulatory Affairs

Stakeholder Engagement
COVID-19

- Minister of Health signed the *Interim Order Respecting the Sale and Importation of Medical Devices Used in Relation to COVID-19* on March 18
  - Allows Health Canada to expedite the review of COVID-19 medical devices
  - Remains in effect for 1 year
  - Work is underway for developing transition interim order provisions
COVID-19

• Minister of Health signed the *Interim Order Respecting the Clinical Trials For Medical Devices and Drugs Relating to COVID-19* on May 23

  • expands the range of sponsors who may apply for a medical device clinical trial authorization.
  
  • more flexible with respect to the application format and some administrative requirements, without compromising patient safety or validity of trial results.
COVID-19

• As of September 3, Health Canada has issued Interim Order authorizations for 32 testing devices and 341 non-testing devices

• Guidances and notices have also been issued for different topics
  • Ventilators, personal protective equipment (PPE) such as gowns, gloves, respirators, face shields
  • 3D printed PPE
  • Reprocessing of single use respirators
  • Serological testing and test swab guidances
  • Face coverings
Regulatory and Policy Initiatives

- Publish final regulations to support the surveillance of medical device safety and effectiveness.
- Regulatory Modernization Work on developing agile, flexible licensing scheme for the Medical Devices Regulations.
- Met with patient groups to discuss vaginal meshes in mid-July and a risk assessment is anticipated in Fall 2020.
Planned Guidance Documents for Consultation

- Device Advice: Pre-submission meetings
- Clinical Evidence
- Wellness Policy
- AI/ML Static algorithms application
- Licence application type
- Significant Change
- Cybersecurity

Winter 2020
Spring 2021
Summer 2021

IMDRF
International Medical Device Regulators Forum
Questions/comments

Thank you!