Regulatory and Policy Updates
Medical Devices Directorate
Health Canada

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Director General
Overview

- COVID-19
- New Post-Market Surveillance Regulations
- Regulatory Initiatives
- Guidances
COVID-19

• The *Interim Order Respecting the Sale and Importation of Medical Devices Used in Relation to COVID-19* expires on March 18, 2021

• HC has consulted stakeholders on a second Interim Order that will extend the emergency provisions and transitional regulations
COVID-19

• The *Interim Order Respecting the Clinical Trials For Medical Devices and Drugs Relating to COVID-19* expires on May 23, 2021

• HC is working on a second Interim Order to extend the emergency provisions
COVID-19

• As of February 17, Health Canada has issued Interim Order authorizations for 55 testing devices and over 600 non-testing devices

• Guidance on respirator safety and performance requirements updated to include information on new certification programme from Canadian Standards Association
COVID-19

- Webpages, such as those on test kits, updated to include information on variants

- Public advisory on UV lights and wands to warn against unsubstantiated COVID-19 claims
New Post-Market Surveillance Regulations

• Published December 23, 2020

• Allows HC to order licence holders to
  – Conduct an assessment
  – Compile information, conduct tests or studies or monitor experience
  – Notify HC when risk mitigation actions are taken outside Canada relevant to devices marketed in Canada
  – Conduct analysis
  – Prepare summary reports for Class II devices every two years and for Class III & IV devices every year, and notify HC of any changes to benefits and/or risks
New Post-Market Surveillance Regulations

• Guidance documents have been published:
  – Amendments to the *Food and Drugs Act*: Guide to New Authorities, including power to require assessment and power to require tests, studies, etc.
  – Foreign risk notification for medical devices
  – Incident reporting for medical devices
  – Summary reports and issue-related analyses of safety and effectiveness for medical devices
Regulatory Initiatives

• Clinical Trial modernization
  – Will provide a risk-based, flexible framework for drugs, biologics, vaccines, natural health products, and medical devices

• Advanced Therapeutic Products framework
  – Intended for novel, complex products that challenge existing regulatory frameworks
  – Pilot candidate expected by 2022
Planned Guidance Documents for Consultation

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

Spring 2021  Fall 2021  Winter 2021
Questions/comments

Thank you!