Regulatory and Policy Updates
Health Canada

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Overview

COVID-19

Regulatory Consultations

Guidance Documents
COVID-19

• The Interim Order No. 3 Respecting the Sale and Importation of Medical Devices Used in Relation to COVID-19 (IO No. 3) was signed on February 21, 2022

• Health Canada is developing amendments to the Medical Devices Regulations that will enable COVID-19 medical devices to continue to be imported and sold after the expiry of IO No. 3
COVID-19

• The *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations* came into force February 27, 2022

• These Regulations ensure
  – the continuation of clinical trials authorized under the interim order
  – all authorizations, suspensions and exemptions for clinical trials issued under the interim order remain in effect
COVID-19

• As of September 1, Health Canada has issued interim order authorizations for 131 testing devices and 667 non-testing devices
Planned guidance documents for consultation

- Machine learning-enabled medical devices (Fall 2022)
- Terms and Conditions (Winter 2022)
- Advanced Therapeutic Product - Adaptive machine learning-enabled medical devices (Winter 2023)
- Licence application type
- Significant change
Pending final guidance documents

- Clinical evidence requirements for medical devices
- Device advice: Medical device meetings
Thank you/Questions

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