IMDRF International Medical Device Regulators Forum

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

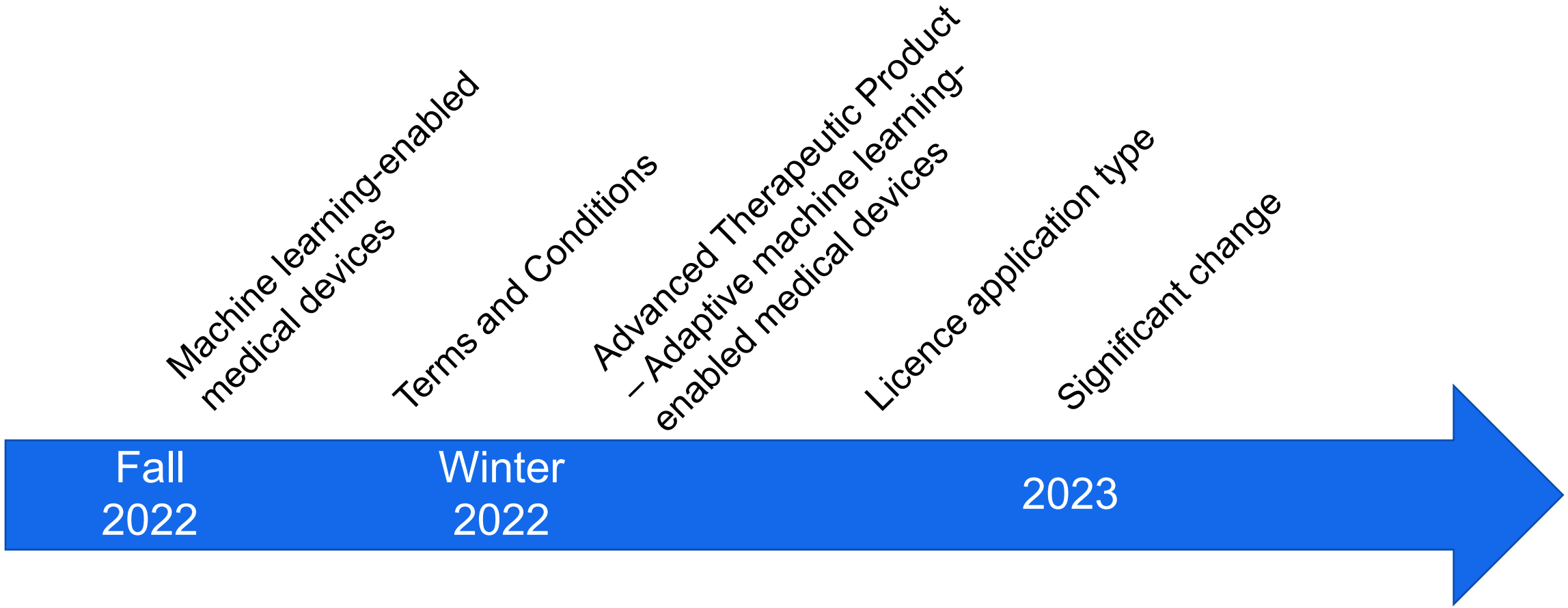
COVID-19

- 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



Pending final guidance documents

- Clinical evidence requirements for medical devices
- Device advice: Medical device meetings

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Thank you/Questions

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