



**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

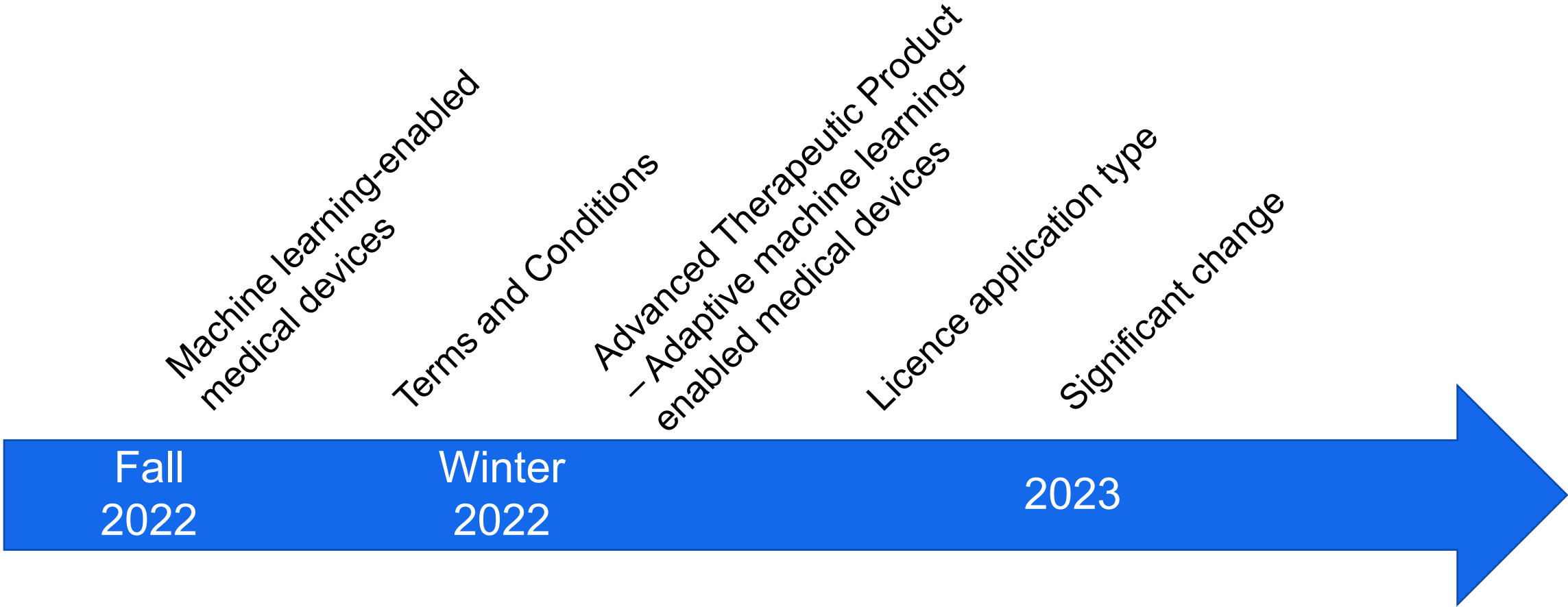
# COVID-19

- 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

# Thank you/Questions

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