IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

Medical Devices Directorate

Health Canada

David Boudreau

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

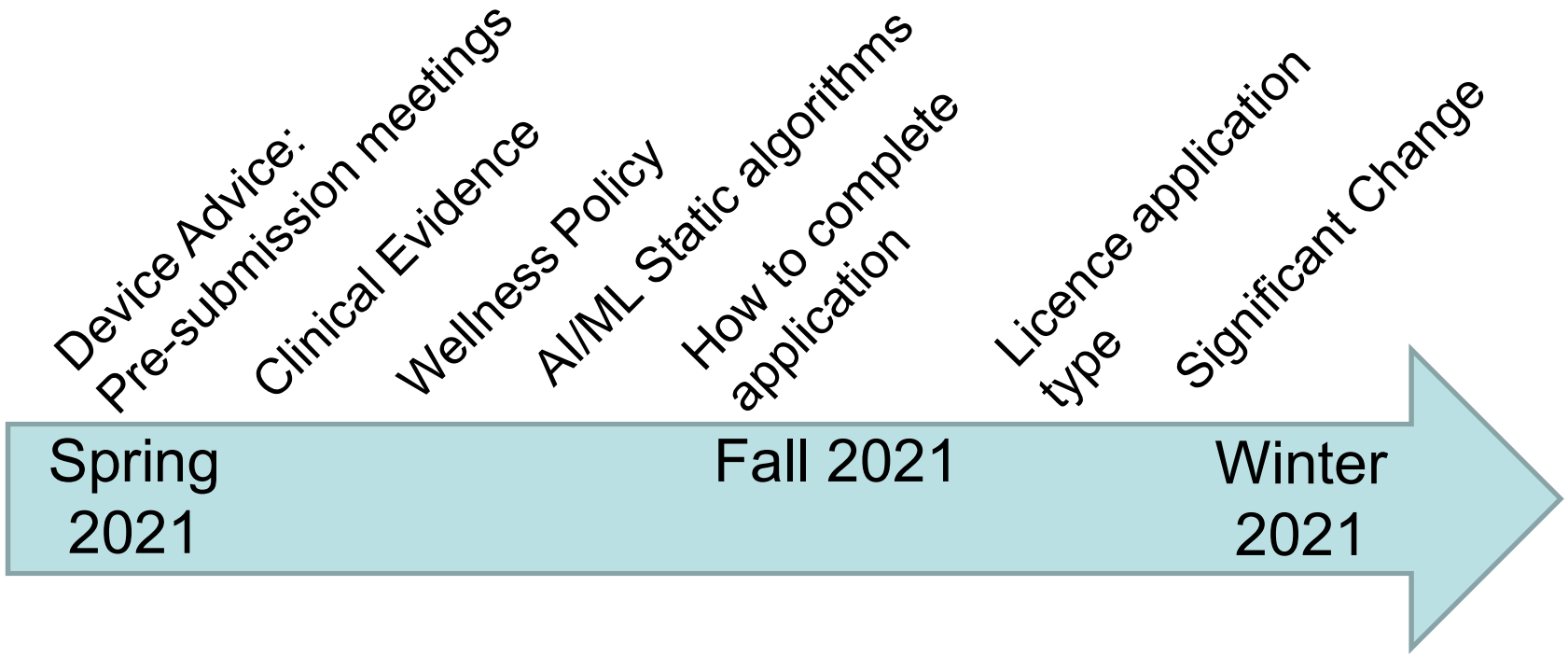
New Post-Market Surveillance Regulations

- 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



Questions/comments

Thank you!