IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

Medical Devices Directorate
Health Canada

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A/Director General

Overview

- Organizational Change
- COVID-19
- Regulatory and Policy Initiatives
- Guidances

Organizational Changes

COVID-19

- Minister of Health signed the *Interim Order Respecting the Sale and Importation of Medical Devices Used in Relation to COVID-19* on March 18
  - Allows Health Canada to expedite the review of COVID-19 medical devices
  - Remains in effect for 1 year
  - Work is underway for developing transition interim order provisions

COVID-19

- Minister of Health signed the *Interim Order Respecting the Clinical Trials For Medical Devices and Drugs Relating to COVID-19* on May 23
  - expands the range of sponsors who may apply for a medical device clinical trial authorization.
  - more flexible with respect to the application format and some administrative requirements, without compromising patient safety or validity of trial results.

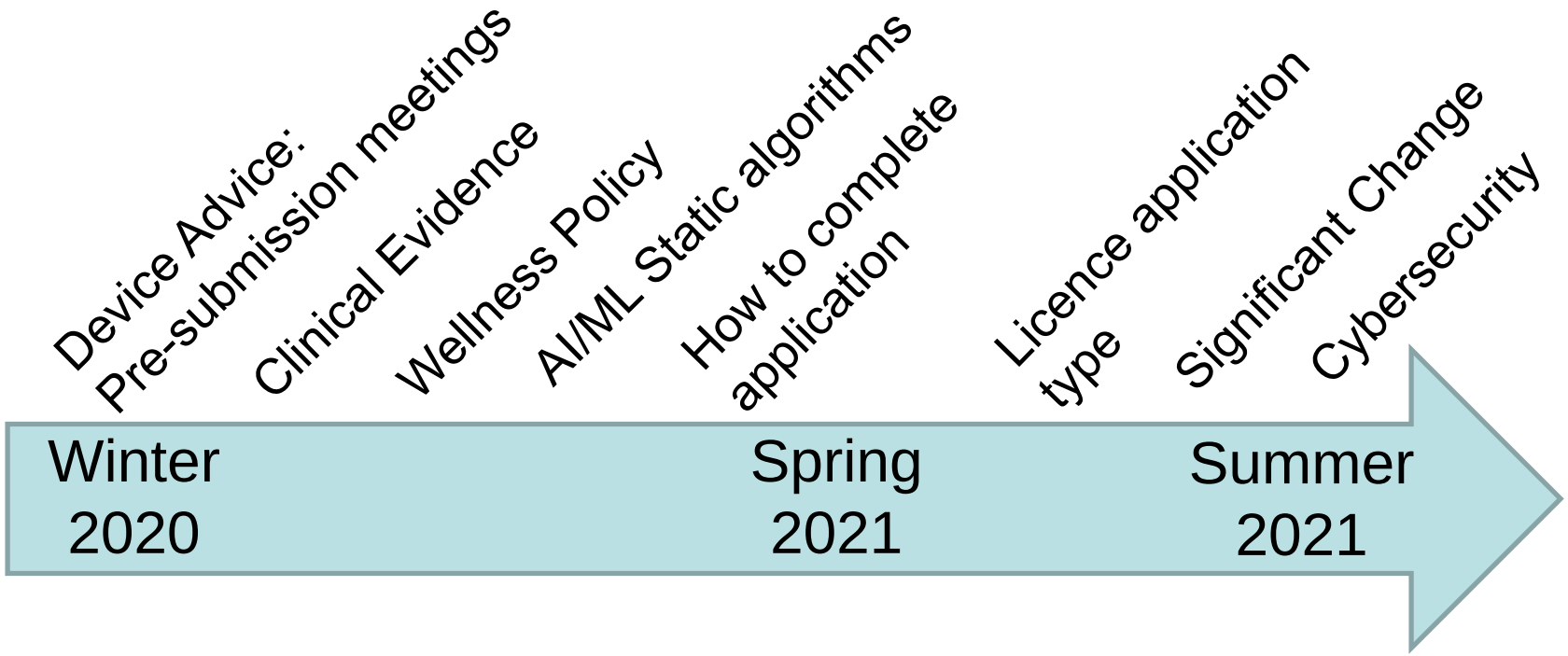
COVID-19

- As of September 3, Health Canada has issued Interim Order authorizations for 32 testing devices and 341 non-testing devices
- Guidances and notices have also been issued for different topics
  - Ventilators, personal protective equipment (PPE) such as gowns, gloves, respirators, face shields
  - 3D printed PPE
  - Reprocessing of single use respirators
  - Serological testing and test swab guidances
  - Face coverings

Regulatory and Policy Initiatives

- Publish final regulations to support the surveillance of medical device safety and effectiveness.
- Regulatory Modernization Work on developing agile, flexible licensing scheme for the Medical Devices Regulations.
- Met with patient groups to discuss vaginal meshes in mid-July and a risk assessment is anticipated in Fall 2020

Planned Guidance Documents for Consultation



Questions/comments

Thank you!