Regulatory Update from Health Canada

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Overview

• Addressing Future Public Health Emergencies
• Advancing Agile Licensing for Medical Devices
• Recent Public Consultations
• Recent Scientific Advisory Committee Meetings
• Piloting eSTAR Functionality
Addressing Future Public Health Emergencies

• In February 2023, Health Canada introduced a permanent regulatory framework under Part 1.1 of the *Medical Devices Regulations* to allow faster access to COVID-19 medical devices for which there is an urgent public health need.

• In January 2024, we have broadened these regulations to apply to future public health emergencies.
  • To provide more information, a guidance on *medical devices for an urgent public health need* was also published.
Advancing Agile Licensing for Medical Devices

- As part of our Agile Licensing initiative, Health Canada is proposing expanded Terms and Conditions (T&Cs) to support the life cycle approach for regulating medical devices
  - Health Canada also plans to publish information about T&Cs that have been imposed on medical device licences, to increase transparency and communicate risks
- In Spring 2023, we held a public consultation on the proposed regulatory amendments to broaden the scope of terms and conditions on Class II to IV medical devices
  - Overall, stakeholders were supportive of the proposed regulatory changes
  - Work continues to finalize the regulations and accompanying guidance
Recent Public Consultations

In the Fall 2023, we held public consultations on two draft guidance documents:

- **Draft Guidance: Machine Learning-enabled Medical Devices**
  - Outlines expectations for demonstrating safety and effectiveness for pre-market submissions

- **Draft Guidance: Medical Device Application Type**
  - Assist applicants in determining whether certain devices, including components and parts, should be combined and submitted as one application
Recently, we launched a new public consultation:

- **Draft Guidance: Interpretation of "significant change"**
  - Assists manufacturers in determining when a proposed change is significant and requires a licence amendment
  - Updates reflect Health Canada's current thinking and provide additional examples
  - **Public consultation** launched on February 7, 2024, and closes April 22, 2024
Recent Scientific Advisory Committee Meetings

• SAC-Digital Health Technologies (January 2024)
  • Discussion topics included:
    ➢ Transparency considerations around machine learning-enabled medical devices
    ➢ Monitoring of machine learning models throughout the lifecycle

• SAC-Medical Devices Used in the Cardiovascular System (November 2023)
  • Discussion topics included:
    ➢ Pulse field ablation
    ➢ Portable and home use devices in cardiovascular medicine
Piloting eSTAR Functionality

- eSTAR: dynamic template to help build comprehensive device submissions
- Health Canada is conducting two pilots to assess the tool’s functionality:
  - Joint pilot with the U.S. FDA for submissions sent to both jurisdictions
  - Health Canada-only pilot
- Participants are being surveyed on their experience
Thank you!
Questions?

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