IMDRF International Medical Device Regulators Forum

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09:10 – 09:25

Canada

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Regulatory and Policy Updates Health Canada

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March 28, 2023

Overview

- Continuing to Enable Access to COVID-19 Devices
- Expanding Device Terms and Conditions
- New Guidance on Clinical Evidence Requirements
- Launch of Interactive Submission Tool: eSTAR
- Upcoming Public Consultations

Continuing to Enable Access to COVID-19 Devices

- Health Canada used temporary measures (Interim Orders No. 1, 2, 3) to expedite the review of, and access to, COVID-19 medical devices in Canada.
- On February 22, 2023, Health Canada introduced *Regulations Amending the Medical Devices Regulations (Interim Order No. 3)* to:
    - Enable COVID-19 medical devices to continue to be imported and sold after the expiry of Interim Order No. 3 on February 21, 2023.
    - Maintain most authorization flexibilities for authorizations where an urgent public health continues to exist.
    - Provide an expedited authorization pathway for new COVID-19 medical devices that are on the **List of Medical Devices for an Urgent Public Health Need in Relation to COVID-19** (UPHN list).

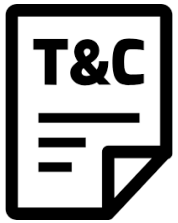
Continuing to Enable Access to COVID-19 Devices

- Edits to the UPHN list can be made by the Minister of Health and do not require regulatory amendments. This provides agility to address public health needs as they emerge.

Part 2. Categories of medical devices that have a UPHN related to COVID-19

Category of medical devices
testing devices that offer a multiplex feature for detecting COVID-19 and other respiratory pathogens (for example, influenza A, B and respiratory syncytial virus)
molecular or antigen tests that offer saliva sample types
testing devices that offer other unique sample types
testing devices that offer a unique feature that meets a clinical or accessibility need
testing devices that offer environmentally sustainable features
medical devices that do not belong to any other category of medical devices set out in Part 2 of the List for which an application for an authorization was submitted to the Minister under Interim Order No. 3 [1] before the day on which Part 1.1 of the MDR came into force, and in respect of that application: • no decision had been made under the Interim Order before that day, • no decision has been made under Part 1.1 of the Regulations, and • the applicant has not withdrawn the application.

Expanding Device Terms and Conditions



- As part of the **Agile Licensing** initiative, Health Canada is proposing expanded Terms and Conditions (T&Cs) regulations to support the life cycle approach for regulating medical devices.

- These proposed regulations provide us with authorities to:
    - expand the scope of use of T&Cs and;
    - impose or amend T&Cs at any time during the medical device's life

- The consultation on the proposed regulations and corresponding guidance document is open until the end of April.

- Health Canada also plans to publish information about the T&Cs that have been imposed on medical device licences, to increase transparency and communicate risks.

New Guidance on Clinical Evidence Requirements

- Guidance on Clinical Evidence Requirements for medical devices was published in November 2022.

- Guidance includes information on:
  - when clinical data/evidence is required
  - the common methods to generate clinical data
  - how to compare devices appropriately
  - sex, gender, and population considerations

Launch of Interactive Submission Tool: eSTAR

eSTAR is an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission.

- Features in this template include the integration of multiple resources, automatic verification and guided construction for each submission section.

On January 10th, 2023, Health Canada launched two eSTAR pilots:

- Joint Health Canada and U.S. Food and Drug Administration pilot:
    - Enables manufacturers to submit an application to both jurisdictions using a common submission building tool (eSTAR). While the content will be dictated by each jurisdiction's requirements, a common format will be used (IMDRF's Table of Contents structure).
    - The joint pilot is now full, having reached its total of 9 participants.

- Health Canada-only pilot program:
    - Provides opportunity for manufacturers to apply to Health Canada using the eSTAR tool.
    - Pilot is still accepting participants.

Upcoming Health Canada Public Consultations

Regulatory Proposal: Emergency Pathway	Proposal to amend the MDR to enable accelerated access to medical devices for which there is an urgent public health need in Canada.
Guidance: Licence Application Type	Helps manufacturers determine whether certain medical devices can be combined together and submitted as one device licence application.
Guidance: Machine Learning-enabled Medical Devices	Outlines supporting information manufacturers should consider when demonstrating the safety and effectiveness of machine learning-enabled medical devices as part of a medical device licence application.
Guidance: Interpretation of Significant Change of a Medical Device	Assists in the identification of "significant changes" to licensed Class III and Class IV medical devices, which may require an amendment to a medical device licence.

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Thank you/Questions

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