IMDRF International Medical Device Regulators Forum | 26th Session

Health Canada Regulatory and Policy Updates

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Overview

- Medical Devices Program
- Precision regulating
- Post-market safety
- Shortages

Health Canada's Medical Devices Program

Health Canada

Health Products and Food Branch

Medical Devices Directorate

- Licensing of Class II, III, and IV devices
- Scientific reviews
- MDSAP
- Post-market safety risk evaluation

Marketed Health Products Directorate

- Incident reporting
- Detection of safety signals
- Post-market surveillance in collaboration with healthcare facilities

Regulatory Operations and Enforcement Branch

Medical Device and Clinical Compliance Directorate

- Compliance and enforcement
- Recalls
- Inspections
- Establishment licensing

Health Products Shortages Directorate

- Medical Device Shortages

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Precision Regulating: Overview

- Health Canada recently introduced amendments to the *Food and Drugs Act* to enable **precise, tailored regulatory solutions to emerging or ongoing issues**.
- This provides Health Canada with **adaptable tools** to address situations such as market disruptions, vulnerabilities and gaps that can impact availability of therapeutic products and food in Canada.
- If a situation requiring action is identified, the Minister will be able to create an Order (a type of regulation) to:
  - Exempt a product or class of products from specific regulatory requirements, adding conditions as needed;
  - Rely on information or decisions from select regulatory authorities to satisfy specific regulatory requirements; or
  - Put in place supplementary rules for specific therapeutic products to protect against potential health risks or adverse effects.

Precision Regulating: New Authorities

Exemption Authority

- Allows the Minister to make an Order to put in place targeted exemptions from specific regulatory requirements for certain therapeutic products or food, adding conditions as appropriate to ensure that health and safety standards are met

Reliance Authority

- Allows the Minister to make an Order so that Health Canada may rely on information or decisions from select foreign regulatory authorities to satisfy specific regulatory requirements for certain therapeutic products or foods

Supplementary Rules Authority

- Allows the Minister to make an Order to put in place supplementary rules for certain therapeutic products to protect against potential health risks from unintended product use or adverse effects to health or the environment

Strengthening Post-Market Safety

- Regulatory Amendments to Recall Framework & Medical Device Establishment Licensing
  - Registered June 17, 2024, and coming into force 180 days after
  - Amendments to Recall regulations include:
    1. Enshrining in regulations a 24-hour notification to Health Canada requirement
    2. Aligning internationally with removal of reportability of low-risk recalls, decreasing industry burden
    3. Creating regulations to facilitate recalls ordered by the Minister
  - New authorities to issue Terms & Conditions on a Medical Device Establishment Licence (MDEL) to mitigate risks to health and safety, and strategically target non-compliance

- Strengthening Inspections of MDEL Holders
  - Integrating hybrid and remote inspections with existing on-site inspections
  - Mapping and strengthening the supply chain
  - Increasing international inspections

What Are Medical Device Shortages?

What is a shortage

A medical device shortage occurs when a manufacturer of a medical device is unable to meet Canadian market demand for the device or for its components, accessories or parts. There are 2 types of shortages:

- **Actual**: when the current supply can't meet current demand
- **Anticipated**: when the future supply can't meet projected demand

Who must report

Manufacturers of Class I to IV devices and importers of Class I devices must report shortages and discontinuations to Health Canada. The requirements are outlined in sections 62.21 to 62.26 of the *Medical Devices Regulations*.

Reporting criteria

The following scenarios require reporting:

- Back order of 30 days or more (shortage report exemption when backorder is less than 30 days)
- No substitute devices readily available in sufficient quantities that can meet the Canadian demand (where the substitute devices are also in shortage)

*A Notice of Intent was recently published outlining our intent to amend the Regulations to help address and mitigate the harm to public health caused by health product shortages in Canada.

Medical Device Shortages

- New Health Products Shortages Directorate
  - Created in the Regulatory Operations and Enforcement Branch to bolster Health Canada's leadership on health product shortages, including medical devices
  - Lessons learned from drug shortages program to inform evolution of medical device shortage program
- Medical Device Shortage Program
  - Continue to develop and refine approaches and tools to:
    - Detect emerging signals and shortages
    - Case manage national critical medical device shortages
    - Refine regulatory tools to support mitigation strategies
    - Develop IT solutions to more efficiently manage shortage reporting data
- Continue to engage stakeholders domestically and internationally

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THANK YOU

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