Regulatory Amendments

Matthew Ryan, Manager
Regulatory Operations & Enforcement Branch

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Canada

Overview of Presentation

- Overview of ROEB's Regulatory Role
- Drivers for Regulatory Changes
- Overview of Recent Activities to Update Regulations
- Timelines and Next Steps

Supply Chain View of ROEB's Role

- Regulate activities of import and distribute via MDEL
- Conduct post-market C&E activities including; recalls, complaint follow-up, compliance verification, etc

HPFB (pre-market)

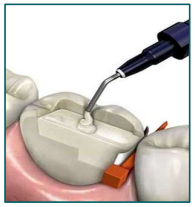
ROEB

ROEB & HPFB
(post-market)

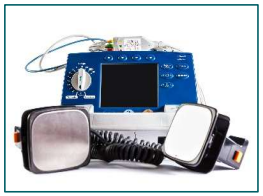
Situating the Regulatory Operations & Enforcement Branch (ROEB)

Health Products & Food Branch

- Review medical device applications for safety & effectiveness
- Issue Medical Device Licenses (MDL)
- Conduct post-market monitoring of safety and effectiveness including lifecycle management of MDL
- Oversees manufacturer compliance with ISO13485 Quality Management Systems (QMS)



Class III



Class IV

Regulatory Operations & Enforcement Branch

- Oversees importers and distributors
- Issue MDEL and conduct inspections
- Oversees certain post-market C&E activities, including recalls, compliance verification for manufacturers, importers & distributors

<u>How we deliver our work</u>:

- Issue and maintain MDEL
- Conduct inspections
- Recalls
- Risk communications

Quality

Policy Drivers for ROEB's Regulatory Changes

Drivers for Regulatory Amendments

- Tightening effectiveness of recalls
  Birth Control Pills Recall
- 2018-2019 Targeted Regulatory Sectoral Reviews
  The Health & Biosciences Sector Regulatory Review Roadmap
- Align with foreign jurisdictions on post-market safety
- Pandemic & Lessons Learned:
  - ✓ Terms and Conditions are a more prominent tool for regulators as they become more agile
  - ✓ Facilitates patient access & ongoing safety & effectiveness

Summary: Regulatory Packages Amending the Medical Device Regulations

ROEB Package 1	ROEB Package 2
• Notice of Intent Published on Dec 11, 2021 • CG1 publication on April 15, 2023 • Consultation Period Feb 9th – March 9th 2024 • CG II publication on June 17, 2024 • Came into Force on Dec 14, 2024	• Notice of Intent Published Nov 21, 2024 • CG1 publication on November 8, 2025 • **70-day consultation period is OPEN** • CG II publication in early 2027 • Coming into Force after six months

Summary of Regulatory Package 1

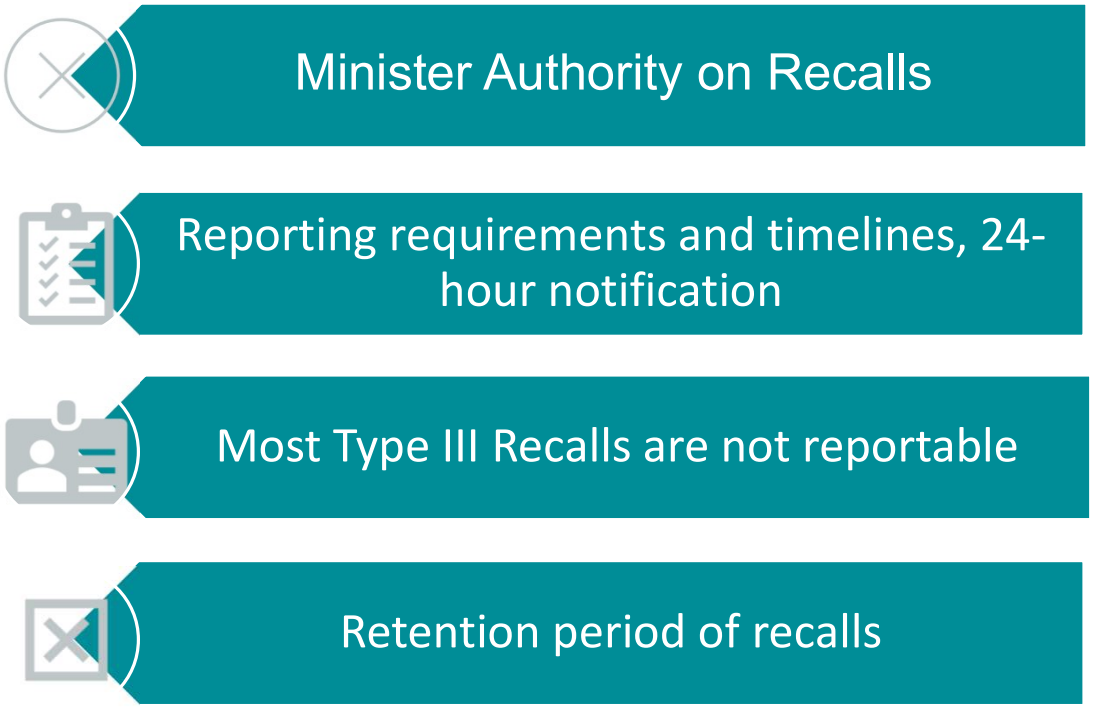
- Introduce greater flexibility & tools to enhance capacity to regulate MDEL holders based on risk
- Enhance Canada's regulatory alignment with the United States, the European Union, the United Kingdom, Australia, and Switzerland

Amendments to the *Medical Devices Regulations*

Recalls	Update the definition of recall to include recalls ordered by the Minister, establish a regulatory framework for recalls of medical devices ordered by the Minister, and clarify the industry's reporting and record keeping obligations for firm-initiated recalls.
MDEL Application	Modernize the Medical Device Establishment Licence (MDEL) application requirements to reflect existing practices.
MDEL Terms and Conditions	Provide the Minister with the ability to issue terms and conditions on a MDEL to mitigate risks to health and safety and strategically target non-compliance.

Regulatory Package I: Updated Documents

- Health Canada has drafted revisions to the Guide to Recall of Medical Devices (GUI-0054) to increase predictability and transparency for industry



MDEL Terms & Conditions Policy (POL-0156)

Regulatory Modernization Continued: Part 2

Key Drivers

- 2018-2019 Sectoral Consultations: Industry stakeholders noted elements of HC's regulatory frameworks were limiting competition and were not aligned with other jurisdictions.
  - HC committed to modernizing regulatory frameworks by adopting risk-based approaches to reduce burden and enable innovation
  - *Health and Biosciences : Targeted Regulatory Review – Regulatory Roadmap - Canada.ca*

- HC has also heard from industry stakeholders that the MDEL requirements for distributors outside of Canada are burdensome, redundant, and could negatively affect the supply of devices in Canada.

- A robust and transparent supply chain plays a critical role in mitigating risks for products distributed on the market, and responding to supply disruptions

Regulatory Package #2: An Overview

- Canada Gazette 1 published Nov 8, 2025
- Consultation period is OPEN
- The objectives of the regulatory amendments are to:

Risk-Based Licensing	Supplier Information	Documented Procedures
• Adopt a **risk-based approach** to licensing foreign distributors to help **reduce administrative burden** for stakeholders and **facilitate greater international alignment**	• Improve HC's ability to efficiently identify persons selling into and within Canada and **enable risk-based and targeted C&E action** by requiring supplier information	• Provide certainty around the interpretation of the MDR by making **explicit provisions for documented procedures** to manage health and safety risks of medical devices imported and/or sold in Canada

Foreign MDEL Requirement for Distribution: S44(3)

- Current Regulation
  - *Any person who imports a medical device shall ensure that the person from whom they import it holds an establishment licence.*

- *Proposal* to repeal foreign distributor licensing requirement

- Benefits

ROEB will take a risk-based prioritization approach to section 44.3

Eliminate duplication in supply chain

Removes barriers to Market Access

Decrease regulatory burden

Medical Device Establishment Licensing: Supplier Lists

- Supports oversight & transparency of supply chains

- Supplier
  - Any person, other than the manufacturer, who sells a medical device to an MDEL holder
  - Includes Cdn importers, domestic distributors & foreign distributors

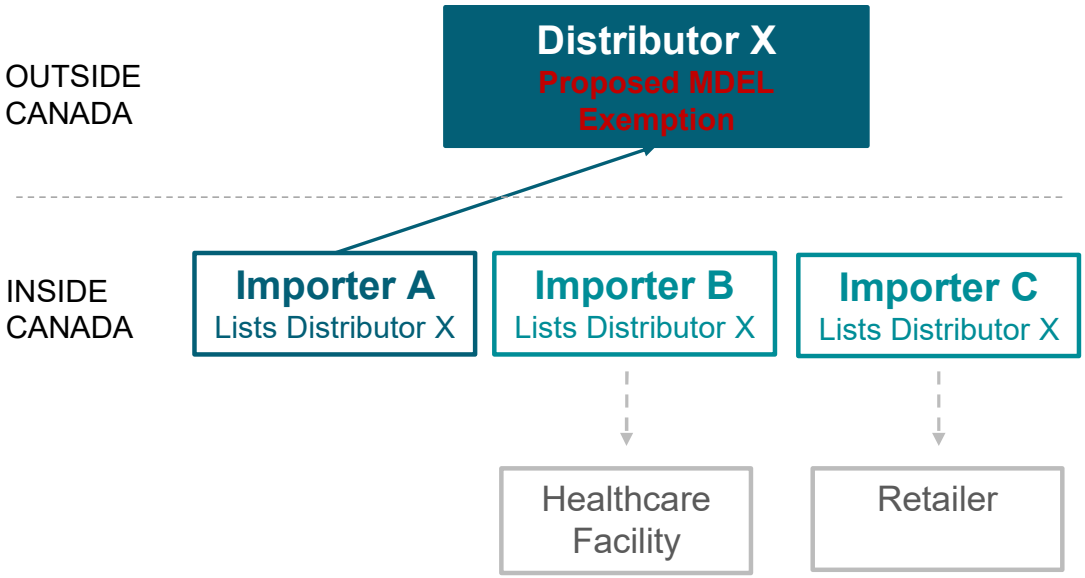
- Benefits
  - In the event of a risk, Industry and HC can better trace supply from MDEL holder back through supply chain
  - Risk mitigation measure

When to Submit

- ✓ With amendments to license
- ✓ Minimum – during ALR
- ✓ Supplier lists – part of current business practices

How Health Canada would use Supplier Lists

Supplier lists would allow HC to identify MDEL holders who may be importing and/or selling non-compliant devices to take targeted C&E action & quickly reduce risks to patients and users



1. HC learns Importer A is selling non-compliant devices imported from Distributor X
2. HC uses supplier lists to determine who else Distributor X sold to in Canada
3. HC targets follow-up with Importers B and C who imported from Distributor X, instead of contacting all importers

Strengthening Requirements - Standard Operating Procedures (SOPs)

- Amend the MDRs to include explicit requirement for MDEL holders to establish, implement & maintain all documented procedures

- Benefits
  - Allow HC to assess that the MDEL holder is adequately managing risks associated with their licensable activities and can conduct a timely and effective recall when needed.
  - Provides stakeholders with certainty with respect to their regulatory obligations under the MDR

The MDEL framework of post-market safety management rests on procedures being up to date, thorough and implemented

Medical Device Regulations: ROEB Regulatory Priorities

Health Canada is committed to modernizing the Medical Device Establishment Licensing (MDEL) Framework

- Health Canada Forward Regulatory Plan (2024-2026)
- Improving oversight of the medical devices supply chain remains a priority
- Red Tape Reduction Report
- Regulatory amendments to help address and mitigate harm to public health caused by shortages and better prevent health product shortages, where possible.
    - Aim to publish in the Canada Gazette, Part II, in 2026.

Safe and Effective Medical Devices via a Strong-Compliant Supply Chain

Majority of medical devices manufactured outside of Canada

- e.g. 42% of imported medical devices from USA

- **Canadian importers & distributors**
  - ✓ Play a critical role in supply
  - ✓ Key knowledge holder of origin of supply
  - ✓ Critical role in mitigating risk of product **before** and **after** distribution
  - ✓ Key role in quality of medical devices

- **Manufacturers (inside & outside of Canada)**
  - ✓ Significant regulatory obligations
  - ✓ Key role in medical device safety and effectiveness
  - ✓ Strong partnership with importers and distributors
  - ✓ Key role in medical device quality

Questions?