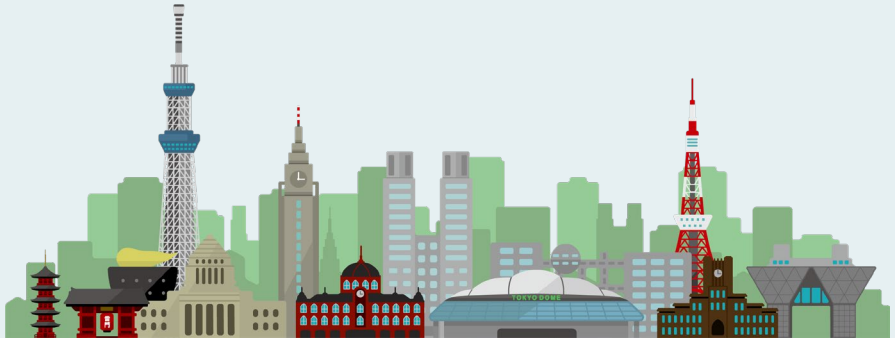
IMDRF International Medical Device Regulators Forum



Health Canada Regulatory and Policy Updates

Sally Prawdzik
Acting Director
Medical Devices Directorate

Overview

- Recent Regulatory and Guidance Publications
- Medical Device Regulation in Canada
- Performance Update

Health Canada Santé Canada

Recent Regulatory and Guidance Publications

Regulatory Amendment: Expanded Terms and Conditions for medical device licences

- The *Medical Devices Regulations* were updated to allow the Minister of Health to impose and amend terms and conditions at any point during a device's lifecycle.
- The new provisions come into force January 1, 2026

Final Guidance: Guidance on Terms and Conditions for Class II to IV Medical Devices

- Provides an overview of the regulatory authorities for terms and conditions (T&Cs) imposed or amended on medical device licences.

Recent Regulatory and Guidance Publications

Final guidance: Pre-market guidance for machine learning-enabled medical devices

- Outlines expectations for demonstrating safety and effectiveness for pre-market submissions

Draft guidance: Managing applications for medical device licences

- Explains how medical device licence applications submitted under the *Medical Devices Regulations* are managed
- Consultation open until April 21, 2025

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Regulating Medical Devices in Canada

Safety, effectiveness, and quality medical devices in Canada

MEDICAL DEVICES REGULATIONS (MDR)

PART I

LICENSING
Requirements to meet Canadian safety and effectiveness requirements

PART II

SPECIAL ACCESS
Requirements to access to custom-made devices or unlicensed devices if conventional therapies have failed or are unavailable/ unsuitable

PART III

CLINICAL TRIALS
Requirements to access a device for clinical trials involving human subjects

SERVICES

PRE-MARKET
Application screening
Scientific review
Fee processing

POST-MARKET
Licence renewal and amendment
Coordinating with surveillance teams

MEDICAL DEVICE PROGRAM

MEDICAL DEVICES DIRECTORATE
Licensing of Class II, III, and IV devices & in vitro diagnostic devices

Monitoring incidents once medical devices are on the Canadian market

MEDICAL DEVICE AND CLINICAL COMPLIANCE DIRECTORATE
Compliance & enforcement of the MDRs with the manufacturers/ importers/distributers

MARKETED HEALTH PRODUCTS DIRECTORATE (MHPD)
Incident reporting, safety signal detection, post-market surveillance

HEALTH PRODUCTS SHORTAGES DIRECTORATE
Medical device shortages

FEES 2024

- **New MD application** $171 - $29,405
- **Establishment licence** $5283
- **Right To Sell (Class II, III or IV)** $440

SERVICE STANDARDS (DAYS)

- Class II — 15 days — Medical Device Licence
- Class III — 75 days — Medical Device Licence
- Class IV — 90 days — Medical Device Licence
- Class I and all importers/distributors Establishment Licence — 120 days

RISK-BASED MEDICAL DEVICES CLASSIFICATION

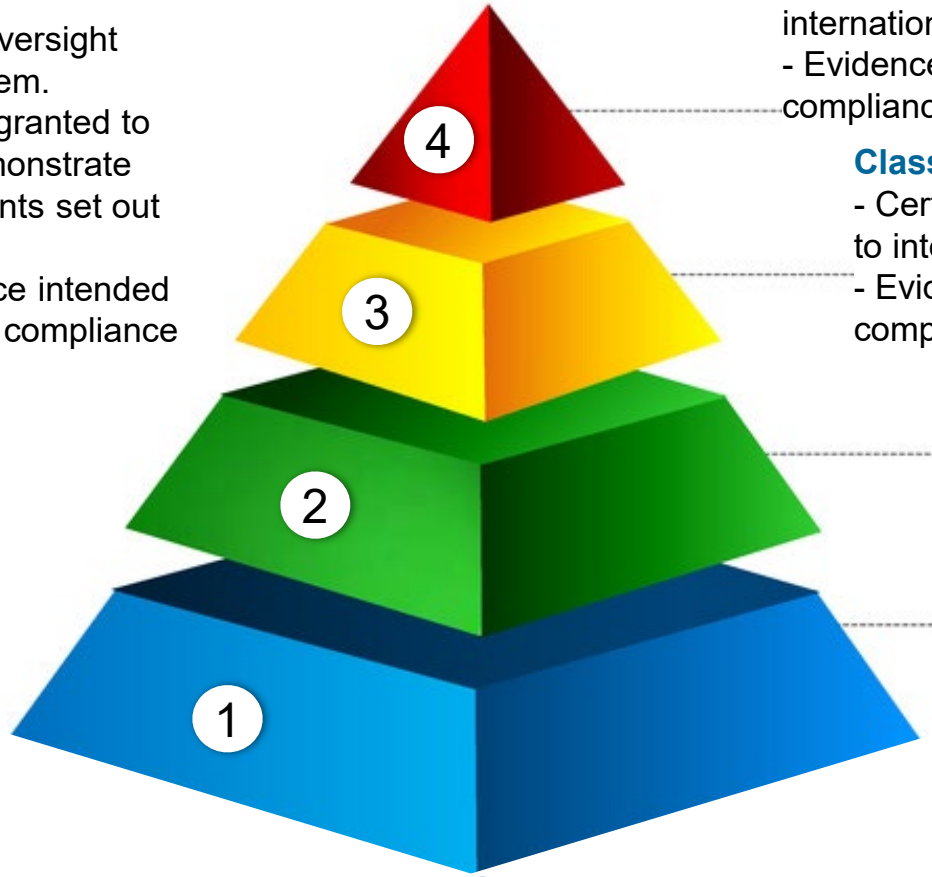
Classification Indicators
Duration of contact • Expertise of intended user • Potential for transmission of infection • Impact of results on the person/public • Invasiveness • Importance of information for diagnosis • Energy exposure • Transmissibility/mortality rate of disease

RISK and OVERSIGHT

CLASS I	CLASS II	CLASS III	CLASS IV
Wheelchair	TENS unit	Dialysis Units	Bone graft
Hospital bed	Contact lens	Dental crowns	HIV test kit
Gauze bandage	Surgical glove	Orthopedic implant	Pacemaker
Surgical /dental instrument	Digital thermometer	Insulin infusion pump	Tissue heart valve
	Powered toothbrush	Blood glucose monitor	Neurosurgical shunt

Risk-Based Regulatory System

Premarket regulatory oversight based on licensing system. Market authorization is granted to manufacturers who demonstrate conformity to requirements set out in MDR.
Post-market surveillance intended to enforce and promote compliance with MDR



Class IV
- Certification that device is designed and manufactured according to international Quality Management System standard (MDSAP).
- Evidence of safety, effectiveness & labelling reviewed to validate compliance with MDR. More in-depth review than Class III.

Class III
- Certification that device is designed and manufactured according to international Quality Management System standard (MDSAP).
- Evidence of safety, effectiveness & labelling reviewed to validate compliance with MDR.

Class II
- Certification that device is manufactured according to international Quality Management System standard (MDSAP).
- Manufacturer's attestation that device satisfies the safety and effectiveness requirements in MDR. Label reviewed.

Class I
- Oversight based on establishment licensing and compliance with applicable sections of the MDR. No device-specific licence issued

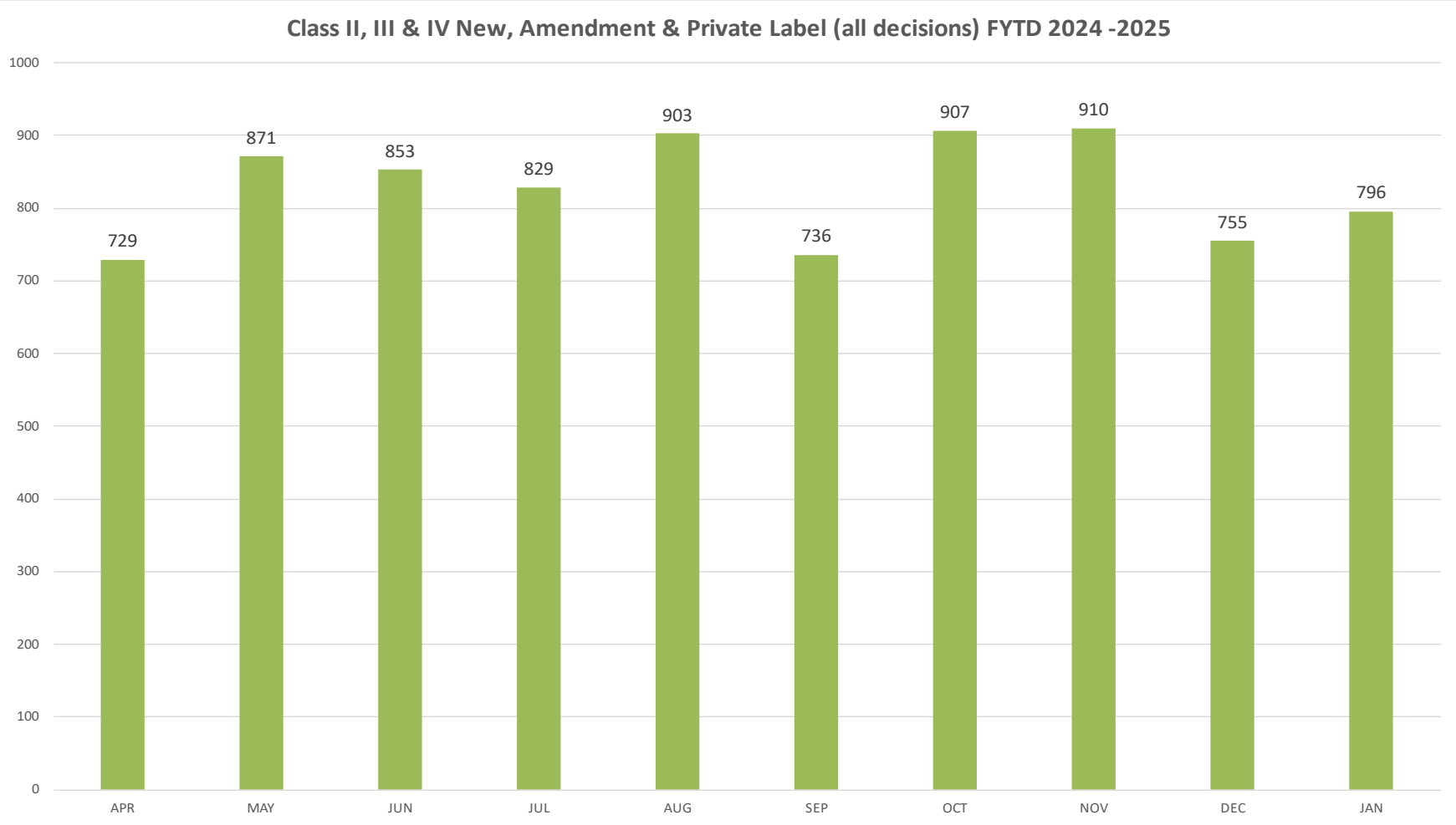
Medical Device Fees and Performance Standards (Cost Recovery)

Fee	Fee Amount (CAD) (as of April 1, 2024)	Performance Standard (calendar days)
Fees for the Examination of an Application for a Medical Device Licence (MDEVAL)		
Class II licence	$615	15
Class II licence amendment	$316	15
Class III licence	$13,559	60
Class III licence (near patient)	$28,884	60
Class III licence amendment – Changes in manufacturing	$4,279	60
Class III licence amendment – Significant changes not related to manufacturing	$10,884	60
Class IV licence	$29,405	75
Class IV licence amendment – Changes in manufacturing	$4,279	75
Class IV – Significant changes not related to manufacturing	$15,558	75
Class II, III or IV licence or licence amendment - Private label medical device	$171	15
Annual Fee for Right to Sell a Licensed Class II, III or IV Medical Device		
Right to Sell	$440	20

Performance By Medical Device Application Type (Cost Recovery)

Application Type	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC	JAN	2024-2025 FYTD
Class II New	100%	99%	99%	99%	100%	100%	99%	100%	99%	99%	99%
Class II Amendment	98%	99%	100%	99%	100%	100%	99%	100%	100%	99%	99%
Private Label	100%	100%	98%	100%	100%	93%	100%	100%	100%	99%	99%
Class III	100%	100%	100%	100%	99%	100%	100%	100%	100%	99%	99%
Class IV	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Number of Licence Decisions per Month



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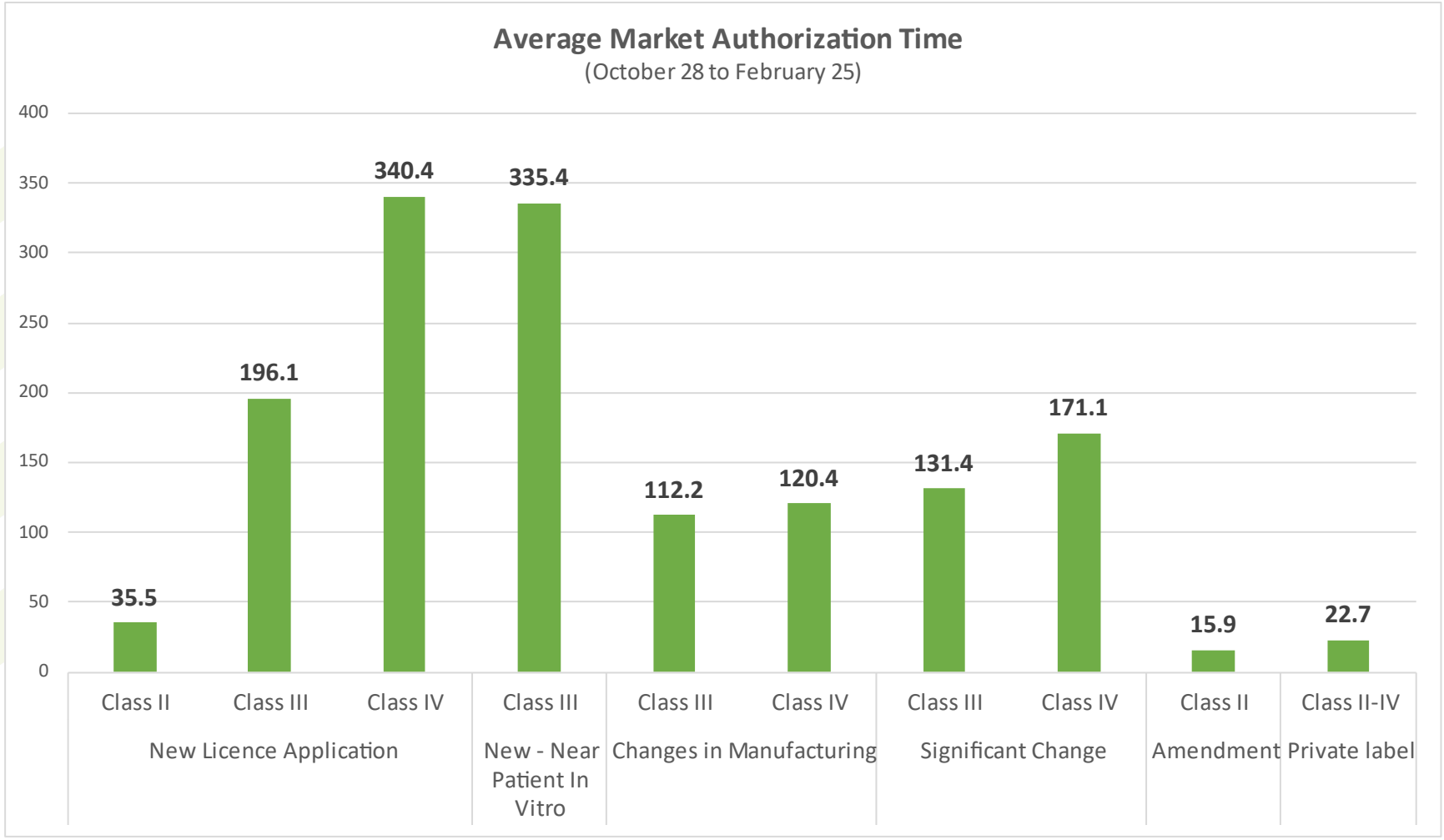
Average Market Authorization Time



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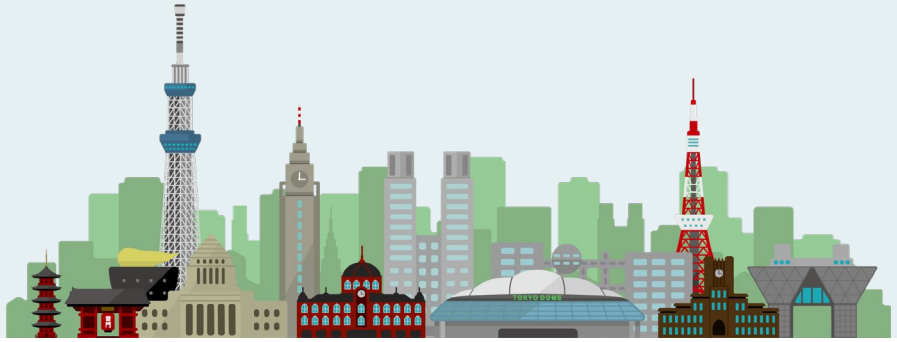

Thank you/Questions