Health Canada Santé Canada

Canada

What's New from Health Canada
Quoi de neuf à Santé Canada

Bruce Randall

Director General / Directeur général

Medical Devices Directorate

Direction générale des instruments médicaux

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Medical Devices Directorate
Direction des instruments médicaux

Bruce Randall
Director General

Senior Advisor/ Issues Management
Catherine Dion

Bureau of Evaluation
A/Deepak Sharma

- **Cardiovascular Devices** Kevin Day
- **Digital Health Devices** Marc Lamoureux
- **General and Restorative Devices** Constance Campbell
- **In Vitro Diagnostic Devices** Patrice Sarrazin
- **Musculoskeletal Devices** Weimin Zhao

Bureau of ITA SAP and Post-market
Roxanne Lewis

- **Investigational Testing** Bisi Lawuyi
- **Post-market** Emily Hollink
- **Post-market** A/Jason DiMuzio
- **Special Access** Peggy Seely

Bureau of Licensing Services
Colin Foster

- **Device Licensing** Serge Allard
- **Regulatory Affairs** Thomas Hazle
- **Regulatory Screening**

Bureau of Policy and International Programs
A/Sally Prawdzik

- **International Programs** A/Daniel Yoon
- **Policy** Maggie Graham

Bureau of Planning & Operations
Sarah Chandler

- **Quality Systems** Frédéric Hamelin
- **Admin** Rita Marinelli-Salvi, Véronique Larocque
- **Business Intelligence**

Government of Canada Red Tape Review initiative

- On July 9th, 2025, the Government of Canada launched an initiative for departments to review regulations and propose actions to reduce red tape.

- Ministers were asked to report to the President of the Treasury Board on their organizations' progress and next steps within 60 days

    - Health Canada and the Public Health Agency of Canada's report on red tape reduction was published on Sept 8th, 2025

Medical Devices - Key initiatives

Published Guidance

Terms and conditions for Class II to IV devices

Using standards to support compliance with the regulations

Machine learning – enabled medical devices

Application type

Guidance Finalization

Health Canada IMDRF table of contents (ToC)

Significant change

Management of applications

Policy Development

Unique device identification (UDI) system

Cost Recovery Decisions By Application Type

Application Type	Target	APR	MAY	JUN	JUL	AUG	SEPT	OCT	FYTD	2024-2025
Class II New	15	98% (181)	99% (168)	100% (134)	99% (107)	99% (134)	99% (111)	100% (140)	99% (975)	99% (1539)
Class II Amendments	15	98% (107)	100% (82)	95% (102)	100% (121)	99% (109)	100% (75)	100% (107)	98% (704)	99% (1355)
Class II, III & IV Private Label	15	100% (57)	100% (51)	95% (66)	100% (60)	94% (67)	100% (47)	100% (65)	98% (413)	99% (577)
Class III	60	99% (71)	100% (47)	99% (70)	100% (44)	100% (52)	100% (43)	100% (61)	99% (388)	99% (696)
Class IV	75	100% (12)	96% (24)	100% (17)	100% (24)	100% (20)	100% (7)	100% (29)	99% (133)	100% (205)

Legend	<90%	90-99%	100%

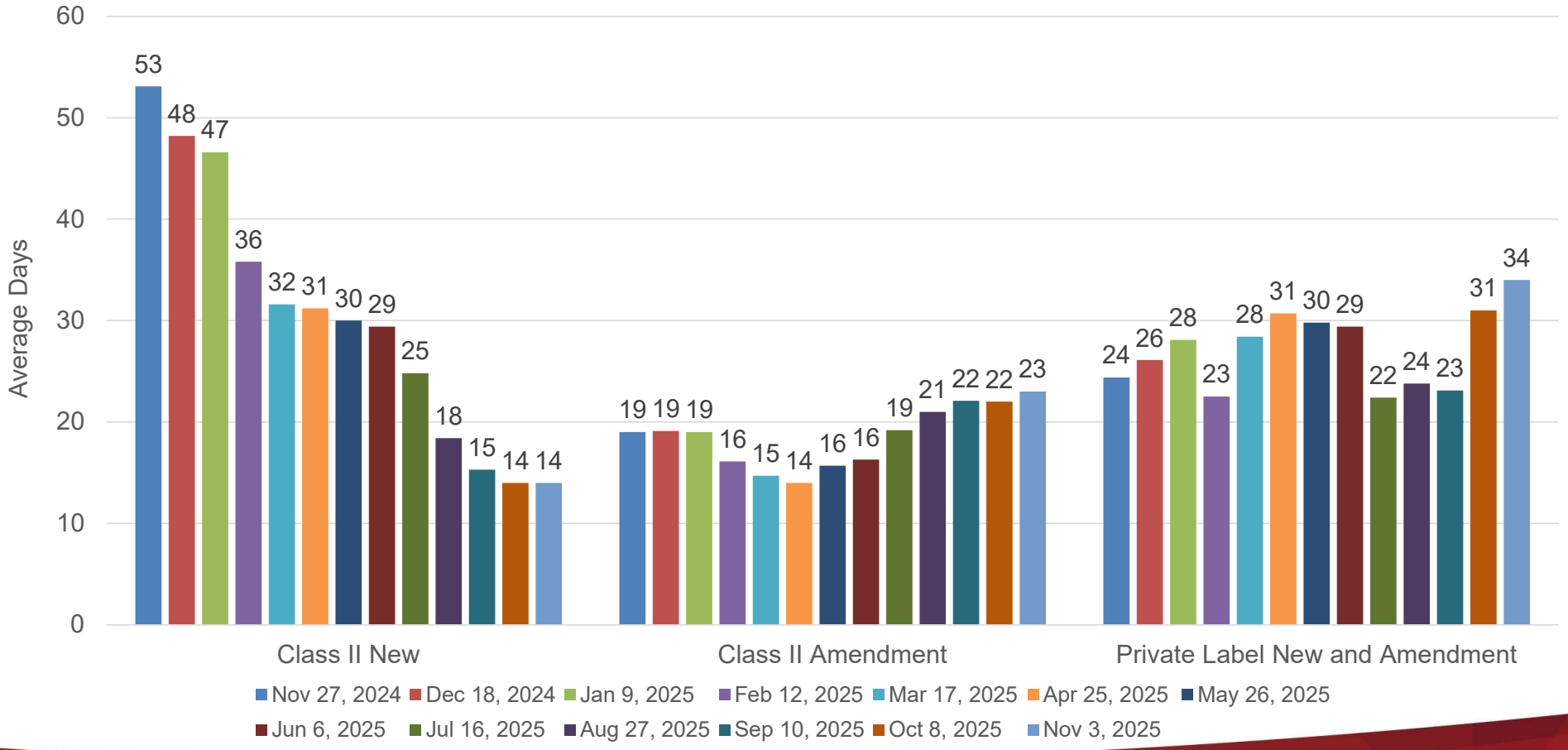
Non-Cost Recovery Performance By Application Type

Application Type	Target	APR	MAY	JUN	JUL	AUG	SEP	OCT	FYTD	2024-2025
Class II (2nd, 3rd, etc, decisions)	15	58% (252)	92% (179)	54% (164)	56% (194)	49% (247)	95% (157)	84% (148)	67% (1340)	50% (2471)
Screening Class III & IV	15	91% (117)	86% (140)	71% (136)	66% (115)	73% (97)	77% (105)	86% (132)	78% (842)	68% (1312)
Minor changes	7	98% (604)	99% (544)	96% (392)	98% (722)	81% (350)	86% (502)	72% (173)	91% (3719)	90% (5891)
Special Access	3	89% (448)	94% (432)	97% (470)	97% (393)	95% (429)	98% (477)	98% (563)	94% (3253)	86% (4330)
New ITA	30	90% (63)	89% (57)	90% (59)	96% (51)	94% (52)	80% (40)	100% (59)	92% (381)	96% (640)
ITA Modifications	30	86% (44)	95% (43)	100% (44)	100% (30)	93% (21)	100% (26)	100% (21)	95% (214)	95% (422)

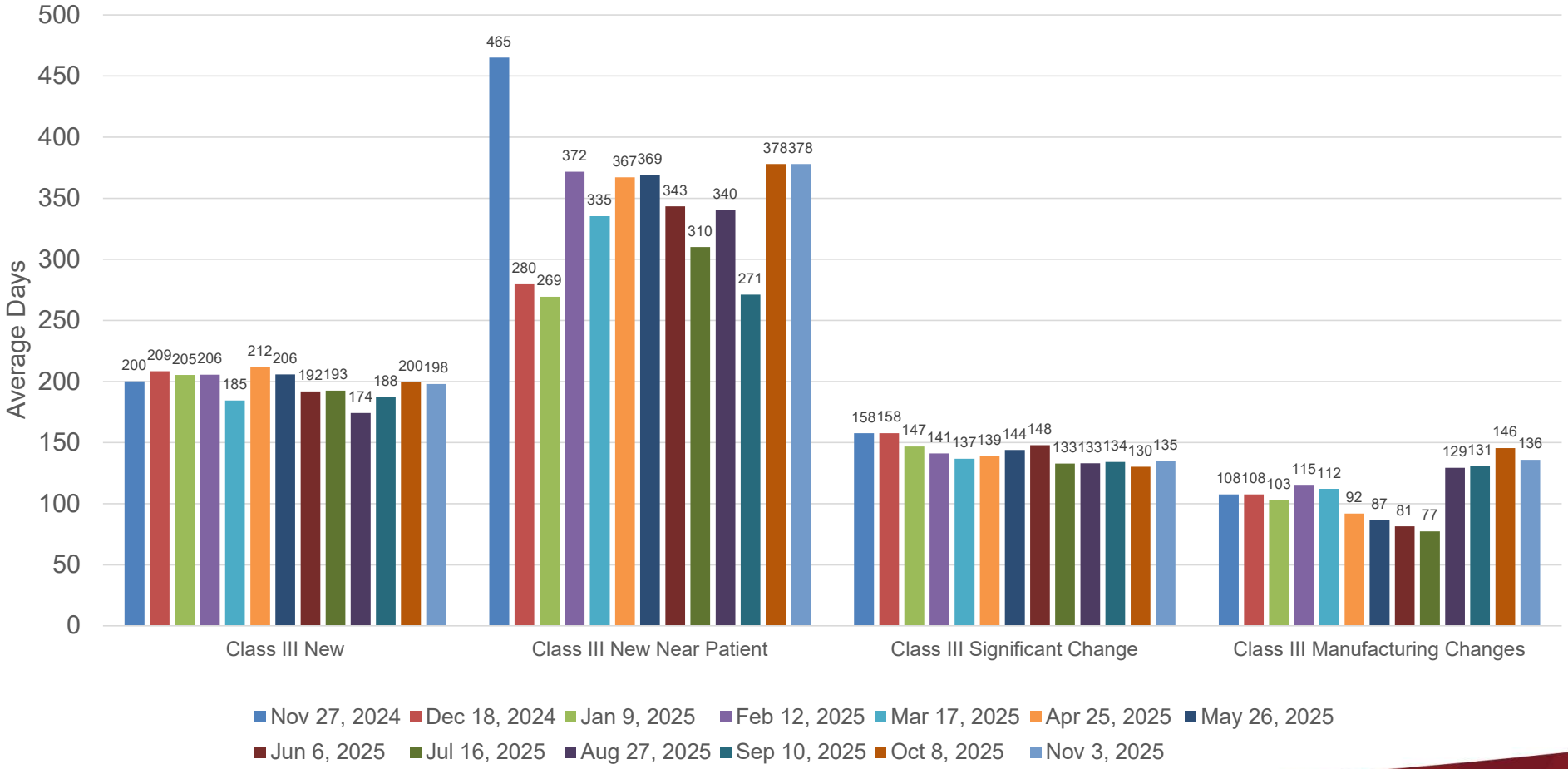
Legend	<80%	80-89%	90-100%

Average Market Authorization Time - Class II & PL

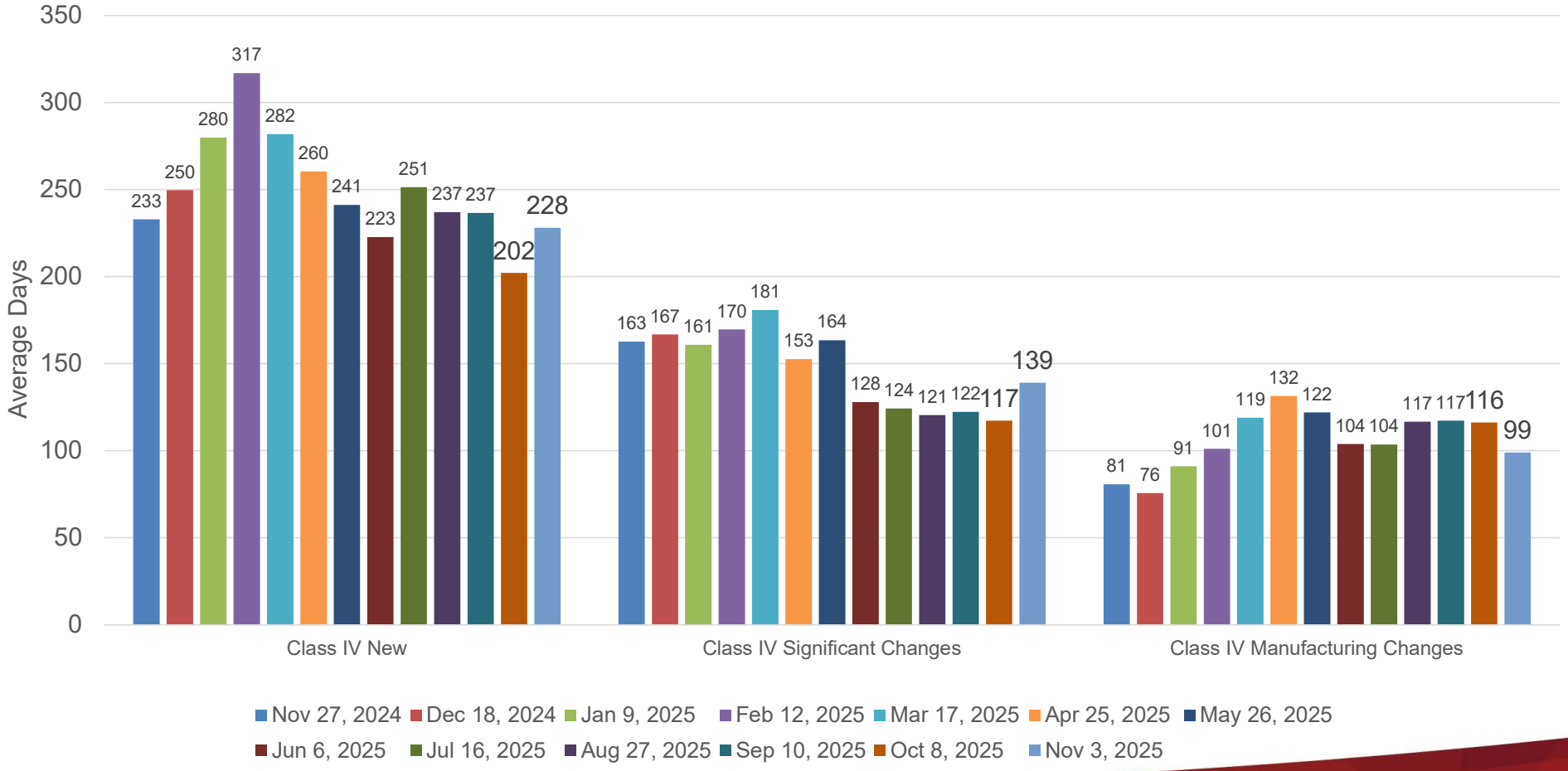
Medical devices – market authorization time / Instruments médicaux - temps d'autorisation de mise en marché - wiki



Average Market Authorization Time - Class III



Average Market Authorization Time - Class IV



Stay Informed

What's new: Medical devices

Files added to the web site are also posted here in the **What's New** section for three weeks. Once you have browsed through the entire site, all you need to do to keep current is make sure you visit this page more than once every three weeks.

Subscribe to the RSS feed

Health Canada provides RSS (Really Simple Syndication) feeds of our news releases and advisories, warnings and recalls. One of our RSS feeds brings you to up-to-date information on medical devices.

Our services

Device Advice e-learning

Interactive learning platform covering: risk classification, licensing and labelling requirements, required submission documents, licence application types, licence amendments, and management of applications, etc.

General inquiries

meddevices-instrumentsmed@hc-sc.gc.ca

General Enquiries (classification decisions, pre-submission meetings, significant change assessments, etc.)

Our services – Three meeting types

Innovation	Opportunity to engage with manufacturers of novel technologies well in advance of the application process (investigational testing or licensing).
Pre-clinical	Opportunity to present relevant data and discuss concerns and issues regarding device development strategy. Advice received at these meetings can influence the requestor's design of the investigational testing protocol.
Pre-submission	Opportunity to present relevant data and discuss the information and evidence manufacturers intend to use to support a medical device licence application.

Questions?

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