Agile Licensing Initiative: Understanding the application of expanded terms and conditions

Sally Prawdzik
Director, Bureau of Policy and International Programs
Medical Devices Directorate, Health Canada

CAPRA Medical Device & Combination Product Symposium
December 3, 2025

Health Canada Santé Canada

Canada

Objective

To describe expanded terms and conditions (T&Cs) for Class II–IV medical devices introduced through the Agile Licensing Initiative

- Background
- Key changes
- T&Cs Guidance
- T&Cs Benefits
- Transparency
- Next steps

Background: Terms and conditions

Terms and conditions on a medical device licence

- As per section 36 of the *Medical Devices Regulations* (MDR), Health Canada can impose T&Cs on a Class II to IV medical device licence.
- T&Cs are currently used to require additional medical device testing to ensure that devices continue to meet safety and effectiveness requirements.
- Through the Agile Licensing Initiative, Health Canada built on this existing authority in order to make T&Cs a more flexible mechanism for oversight.

Background: Agile Licensing Initiative

Agile Licensing Initiative

- Health Canada created new, targeted provisions and regulatory amendments to the *Food and Drug Regulations* (FDR) and MDR under the Agile Licensing Initiative to advance our modernization agenda and help reduce regulatory irritants and roadblocks to innovation.
- Health Canada expanded the authorities of T&C under subsection 36(2) of the MDR to help manage uncertainties and risks in medical devices, especially given the continued rapid pace of product innovation.
- Regulations were published in Canada Gazette, Part II (November 29, 2024).
- Expanded T&Cs provisions come into force on January 1, 2026.

Key Changes: Current and future state

Current State	Future State
What can T&Cs be used for?	
The MDR indicates that T&Cs can be used to require device testing (to ensure device safety and effectiveness continue to be met)	The scope of use of T&Cs is expanded. T&Cs can be used to request activities beyond tests and studies to meet objectives related to safety, effectiveness, risks and benefits
When can T&Cs be used?	
The MDR is written in a way that suggests T&Cs can only be imposed at licence issuance	The MDR clearly indicates that T&Cs can be imposed on a device licence at any time
What is needed to impose T&Cs?	
The Minister may impose T&Cs to ensure that the device continues to meet the applicable safety and effectiveness requirements	The Minister must consider specific factors before imposing or amending a T&C, including device uncertainties, the T&C objectives, technical feasibility, and burdensomeness
What are the possible consequences of non-compliance with T&Cs?	
Licence suspension	Licence suspension or prosecution

Key Changes: Regulations

Current MDR

36 (2) The Minister may set out in a medical device licence terms and conditions respecting

(a) the tests to be performed on a device to ensure that it continues to meet the applicable requirements of sections 10 to 20; and

(b) the requirement to submit the results and protocols of any tests performed.

(3) The Minister may amend the terms and conditions of the medical device licence to take into account any new development with respect to the device.

(4) The holder of the medical device licence shall comply with the terms and conditions of the licence.

Amended MDR

36 (2) The Minister may, at any time, impose terms and conditions on a medical device licence or amend such terms and conditions after considering

(a) whether there are uncertainties relating to the benefits or risks associated with the device;

(b) whether the requirements under the Act are sufficient for the following objectives to be met:

(i) maintaining the safety and effectiveness of the device,

(ii) optimizing the benefits and managing the risks associated with the device, and

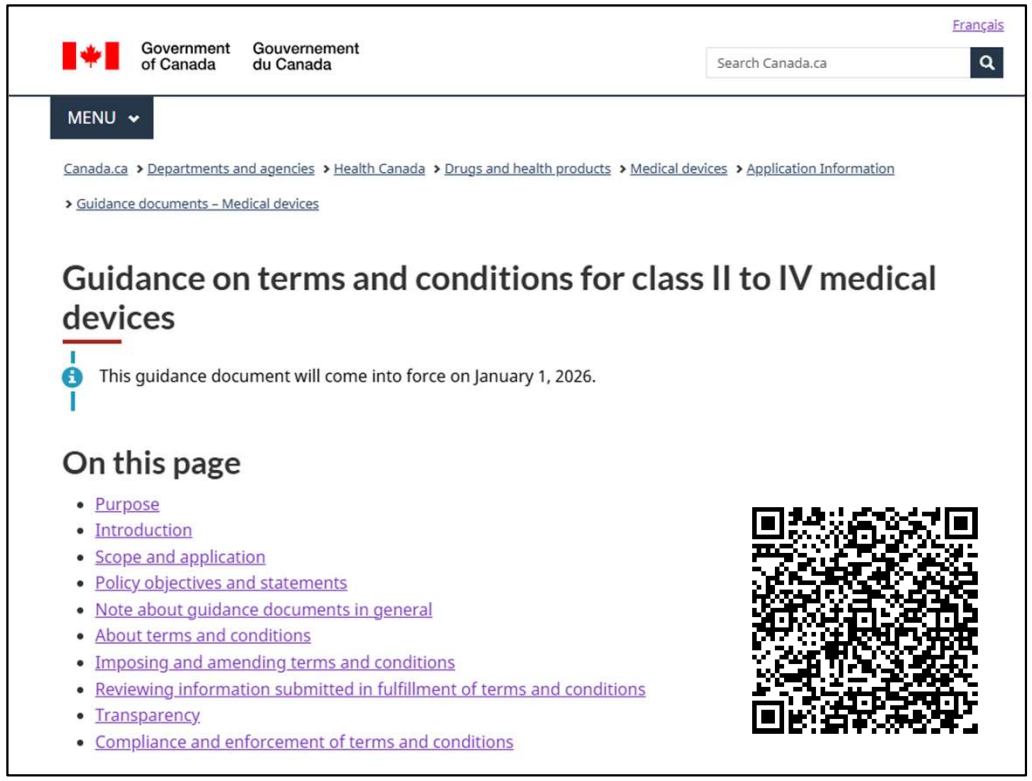
(iii) identifying any changes relating to those benefits and risks and managing uncertainties related to the benefits and risks;

(c) whether the proposed terms and conditions may contribute to those objectives being met;

(d) whether compliance with the proposed terms and conditions is technically feasible; and

(e) whether there are less burdensome ways for those objectives to be met.

Guidance: Understanding expanded terms and conditions



Français

Government of Canada | Gouvernement du Canada

Search Canada.ca

MENU

Canada.ca > Departments and agencies > Health Canada > Drugs and health products > Medical devices > Application Information > Guidance documents – Medical devices

Guidance on terms and conditions for class II to IV medical devices

This guidance document will come into force on January 1, 2026.

On this page

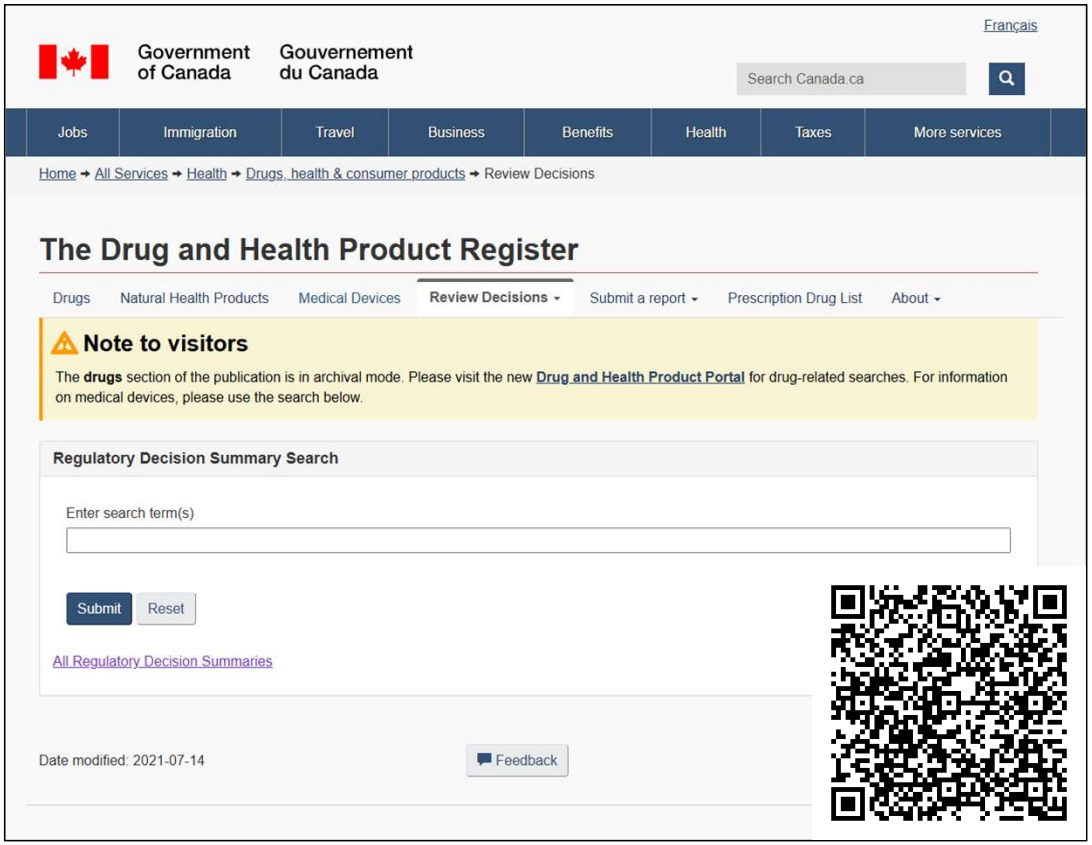
- Purpose
- Introduction
- Scope and application
- Policy objectives and statements
- Note about guidance documents in general
- About terms and conditions
- Imposing and amending terms and conditions
- Reviewing information submitted in fulfillment of terms and conditions
- Transparency
- Compliance and enforcement of terms and conditions

- The Guidance on terms and conditions for class II to IV medical devices was published at the same time as the amendments to the MDR.
- It explains how expanded T&Cs will be used in practice and what to expect.
- The Guidance will be in effect upon the coming into force of the amended regulations on January 1, 2026.

Benefits of expanded T&Cs

- Supports Health Canada's ability to oversee and assess a device throughout its lifecycle.
- Helps ensure that devices maintain a favorable benefit/risk profile and continue to meet safety and effectiveness requirements.
- Allows consumers to have *continued access* to medical devices that meet safety and effectiveness requirements, as T&Cs will allow for improved oversight and reduction in risk/uncertainties allowing devices to stay on the market.

Publishing T&Cs to enhance transparency



- T&Cs imposed or amended on a medical device licence on or after January 1, 2026 will be published in both official languages on the Regulatory Decision Summary (RDS) page.
- We will aim to update content regularly, including when T&Cs have been removed.

Next Steps

Planned updates to the T&C guidance (following coming-into-force)

- Adding additional information on transparency measures
- Using the regulatory enrolment process for stakeholders to:
  - submit a response during the opportunity to be heard process; or
  - request amendments to existing T&Cs
- Publishing a PDF version of the guidance document

Updates to other guidance documents to reflect expanded T&Cs

- Guidance on clinical evidence requirements for medical devices
- Pre-market guidance for machine learning-enabled medical devices

Thank you