Health Canada Santé Canada

Draft guidance document: Terms and conditions for medical devices

Canada

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This document provides guidance to manufacturers on how Health Canada will exercise the authority to impose or amend terms and conditions (T&Cs) on Class II to IV medical device licences. This is in accordance with proposed amendments under section 36 of the *Medical Devices Regulations* (MDR).

Introduction

The *Food and Drugs Act* (FDA) and its regulations give Health Canada the authority to regulate food, drugs (including natural health products), medical devices and cosmetics. As a medical device regulator, our role is to verify that regulatory requirements for the safety and effectiveness of medical devices are met through a combination of pre-market scrutiny, post-market surveillance, and compliance and enforcement activities.

Health Canada takes a risk-based approach to the regulation of medical devices where the level of review before licensing depends on the risk presented by the device. The safety and effectiveness evidence required to support a medical device licence application is in proportion to the risk of the device. This approach balances the need to provide the population of Canada with timely access to new and innovative technology with the need for appropriate levels of pre-market oversight of safety and effectiveness evidence.

Since 1998, under section 36 of the MDR, Health Canada can impose terms and conditions (T&Cs) on a Class II to IV medical device licence. T&Cs have been used as regulatory tools to help ensure that medical devices in Canada continue to meet safety and effectiveness requirements of sections 10 to 20 of the MDR.

In 2014, the *Protecting Canadians from Unsafe Drugs Act* (*Vanessa's Law*) introduced amendments to the FDA. *Vanessa's Law* improved Health Canada's regulatory authority to collect data about a therapeutic product before or following market authorization. (Note: Under the FDA, a therapeutic product is a drug or device or any combination of drugs and devices. It does not include a natural health product within the meaning of the *Natural Health Products Regulations*.)

Vanessa's Law also conferred powers to take immediate action to protect the health and safety of people in Canada when a risk with a therapeutic product is identified. It further provides Health Canada with the necessary authorities to implement a life cycle approach to regulating drugs and medical devices by providing the authorities to make regulations under the FDA.

To this end, Health Canada is proposing expanded T&Cs regulations to support the life cycle approach for regulating medical devices. These proposed regulations provide us with authorities to:

- expand the scope of use of T&Cs and
- impose or amend T&Cs at any time during the medical device's life cycle

Scope and application

This guidance document applies to T&Cs imposed on Class II to IV medical device licences under subsection 36(2) of the MDR. The term "medical device," as used in this document, is defined in the MDR as follows:

- **medical device** means a device within the meaning of the Act [FDA], but does not include any device that is intended for use in relation to animals (section 1)

This guidance document does not address the following T&Cs:

- those imposed on a "lot of *in vitro* diagnostic devices" (section 37 of the MDR) or
- those imposed on medical devices authorized under interim orders for the importation and sale of medical devices for use in relation to COVID-19

For more information on interim order authorizations, please refer to:

- Interim Order No. 3

Policy objectives and statements

Policy objectives

This guidance document explains the purpose of T&Cs. It also outlines the process that will be applied when T&Cs are:

- imposed on Class II to IV medical device licences or
- amended (includes the removal of T&Cs)

The objective is to ensure that:

- T&Cs are imposed and amended fairly and consistently
- regulated parties are given an opportunity to voice their concerns or submit suggested modifications to the T&Cs before the T&Cs are imposed

Policy statements

The proposed regulations will give the Minister the power to impose and amend T&Cs on a Class II to IV medical device licence at any time in the device life cycle. This will compel medical device manufacturers, through T&Cs, to take steps to address the safety, effectiveness, risks and benefits of their medical devices.

This will enhance Health Canada's ability to oversee and assess devices as well as enhance communications with manufacturers from licensing to the post-market stage. The sooner that issues are identified, the sooner they can be addressed. The oversight provided by T&Cs and the reduction in risks and uncertainties will allow consumers to have continued access to safe and effective medical devices.

Health Canada is not changing the issuance requirements for medical device licences. When an application for a medical device licence (or a licence amendment) is submitted to the Minister, the Minister determines whether the device meets safety and effectiveness requirements of sections 10 to 20 of the MDR. As required by subsection 36(1) of the MDR, it is only when these requirements are met that the Minister shall issue or amend a medical device licence. T&Cs are not intended to enable the licensing of a medical device that has not met the safety and effectiveness requirements of sections 10 to 20 of the MDR.

Currently, the Minister may impose T&Cs on a medical device licence requiring that manufacturers:

- conduct tests on a device to ensure it continues to meet the safety and effectiveness requirements of sections 10 to 20 of the MDR
- submit the results and protocols of any tests performed

Currently, the Minister also may amend T&Cs imposed on a medical device licence to take into account any new developments with respect to the device.

Under the proposed amendments, T&Cs may be imposed on a Class II to IV medical device licence at the time of licensing or at any time after the licence has been issued. T&Cs may also be amended at any time.

The goal of imposing or amending T&Cs is to meet 1 or more of the following objectives:

- maintain the safety and effectiveness of the medical device
    - by ensuring the device continues to meet applicable safety and effectiveness requirements of sections 10 to 20 of the MDR
- optimize the benefits and manage the risks associated with the medical device
- identify changes and manage uncertainties related to the benefits and risks of the medical device

Before imposing or amending a T&C, the Minister will first consider whether:

- there are uncertainties relating to the benefits or risks associated with the medical device
- the requirements under the FDA are sufficient to meet the stated objectives

    - by considering, for example, if there are other legislative tools that can be used to meet the objectives instead of using T&Cs
- the proposed T&C may contribute to meeting the objectives
    - for example, by not knowingly requesting T&Cs that would not fulfill the stated objectives
- compliance with the proposed T&Cs is technically feasible
- there are less burdensome ways to meet the objectives of the proposed T&Cs

These considerations help to guide the Minister's decision to impose or amend T&Cs. The considerations are not conditions that must be met in order to impose or amend T&Cs.

Note about guidance documents in general

Guidance documents provide assistance to industry on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As always, we reserve the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of other applicable guidance documents.

About terms and conditions

Medical device licences may be issued with or without T&Cs.

During the pre-market stage of the medical device life cycle, the scientific review of applications is in proportion to the risk of the device. As required by subsection 36(1) of the MDR, the medical device **must** meet applicable safety and effectiveness requirements of sections 10 to 20 of the MDR before Health Canada will issue a medical device licence.

T&Cs may be imposed or amended at any time post-market. An example is when the Minister becomes aware of new risks or uncertainties about a device after the device has entered the market and where there is uncertainty about the safety, effectiveness, risks or benefits of that device.

Each T&C may also have a different timeline in which it must be fulfilled. There is no limit on the number of T&Cs that may be imposed on a licence or the number of amendments that can be made on existing T&Cs. The Minister takes a case-by-case approach to imposing T&Cs while also applying regulatory requirements consistently.

The following are examples of circumstances when T&Cs may be imposed or amended:

- uncertainties exist at the time of licensing that could impact safety and effectiveness, but cannot realistically be resolved during pre-market review
    - such as long-term clinical performance of the device
- new information about the device's performance in the real world suggests uncertainties with its safety or effectiveness

The following are **some** examples of what medical device manufacturers may be required, through T&Cs, to provide:

- stability study results
- real-time aging results
- new evidence from post-market studies
- performance data to confirm acceptable variations over time
- clinical data collected from underrepresented patient populations
    - to assess impacts based on sex or gender, for example
- future international market experience
    - sales and incident data in Canada or internationally to be submitted annually to verify that the safety profile of the device remains acceptable and similar to what it was at the time of licensing, for example
- clinical study results, for example:
    - long-term, ongoing follow-ups of clinical studies
    - final results of device-specific clinical studies in cases where strong interim data were used to support a medical device licence decision
- final results to confirm interim results, most often related to clinical evidence, stability studies or aging testing

Depending on the circumstances, these examples of T&C requirements may be applied upon licensing, after licensing or both.

Amending terms and conditions

Amending a T&C includes modifying or removing a T&C. Health Canada may modify a T&C, for example, when:

- further clarification is required to resolve an uncertainty
    - when the requested evidence has been provided but fails to completely address or resolve the uncertainty that was identified, for example
- the required data are not yet available and will be provided at a later point in time, necessitating a new T&C deadline
- new information about the device is provided by a third party, identified in the published literature or collected by Health Canada
- the information provided resolves the issue, resulting in the T&C being fulfilled and subsequently removed

In general, Health Canada initiates T&C amendments. However, a manufacturer may request an amendment to a T&C. When doing so, the manufacturer must provide us with the following:

- a strong rationale as to why they are requesting an amendment
    - for example, a study cannot be completed for scientific or technical reasons
- a detailed description of the proposed amendment

The Minister would consider the information provided by the manufacturer in making their decision.

Communicating with manufacturers

When imposing a new T&C or amending an existing T&C on a medical device licence, we will inform the manufacturer of the following in writing, as applicable:

- the issue that has been identified
- the proposed T&C, its objective and the timeframe for fulfilling the T&C
- the legal authority that supports the imposition of the proposed T&C
- the submission requirements to fulfill the proposed T&C, instructions on what to include in the response and how to submit the response
- the time period for making representations on the proposed T&C
- potential consequences of non-compliance with a T&C

In general, the manufacturer will have up to 10 calendar days to submit a response to the proposed T&C before the T&C comes into effect. During that 10-day period, manufacturers may voice their concerns or submit suggested modifications to the proposed T&C.

The Minister would consider the manufacturer's submission and issue a decision along with a rationale and the final T&Cs. For example, the manufacturer may submit an alternative approach that meets the T&C objective. We would respond with a decision as to whether we accept this approach and give a rationale explaining our decision. If the manufacturer does not express any concerns or make any submissions during the 10-day window, the proposed T&Cs would automatically come into effect and apply to the licence.

Note: Manufacturers may have less than 10 days to respond to T&Cs depending on the urgency of the situation. In emergency cases where the health and safety of Canadians may be severely compromised, Health Canada may provide no notice before we impose or amend a T&C. However, manufacturers can approach us after T&Cs have come into effect to discuss the T&Cs.

After T&Cs have been imposed on a medical device licence or amended, manufacturers may still reach out to us. Manufacturers are encouraged to reach out to us at any time if they have any questions or concerns about their medical device licence.

Enforcing terms and conditions

As required by section 21.7 of the FDA, medical device licence holders have an obligation to comply with T&Cs. All T&Cs are enforceable under the MDR and under the FDA.

Health Canada could consider pursuing compliance and enforcement measures against manufacturers that fail to comply with T&Cs. An example would be a failure to submit a stability study in the specified timeframe.

Non-compliance with T&Cs can lead to:

- licence suspension (section 40 of the MDR) or
- prosecution of the medical device licence holder (section 31.2 and, in some cases, section 31.4 of the FDA)

The licence holder may be liable to fines or even imprisonment.

For more information on compliance and enforcement measures in general, please refer to the following:

- Compliance and enforcement policy
- Guidance on medical device compliance and enforcement

Transparency

To increase transparency and communicate risks to people in Canada, Health Canada will begin to publish information about all T&Cs imposed on medical device licences. This includes new and amended T&Cs.

We will post information about T&Cs that have been imposed or amended on a medical device licence in both official languages. We will strive to update these summaries regularly.

The summaries will **not** include:

- confidential business information
- other information protected by law, such as:
    - personal information as defined in the *Privacy Act*
    - information that is protected by the *Canadian Charter of Rights and Freedoms*, section 8

Health Canada will also continue to communicate up-to-date information about medical devices, including the following sources of information:

- Medical Devices Active Licence Listing: contains product-specific information on all medical devices that are currently or have been licensed for sale in Canada
- Medical device incidents: contains product-specific information on medical device incidents reported in Canada