Health Canada Santé Canada

Canada

Information Session

Regulations Amending the Medical Devices Regulations (Post-market Surveillance of Medical Devices)

Medical Devices Directorate
Health Products and Food Branch
Health Canada

February 2021

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline

- Changes to the *Medical Devices Regulations* (MDR) – Overview
- Coming into force
- Guidance documents – Overview
- Details of new regulations and associated guidance documents
  - Section 62.1 – Assessments Ordered Under Section 21.31 of the Act
  - Section 62.2 – Activities Ordered Under Section 21.32 of the Act
  - Sections 61.2 to 61.3 – Serious Risk of Injury to Human Health (Foreign Risk Notification)
  - Sections 25(1) and 39 – Issue-related analysis of safety and effectiveness
  - Sections 61.4 to 61.6 – Summary Report
- Applicability of regulations to devices authorized under the Interim Order on the importation and sale of medical devices for use against COVID-19

Changes to the *Medical Devices Regulations* (MDR) – Overview

Changes were made to the *Medical Devices Regulations* (MDR) to strengthen the lifecycle approach to the regulation of medical devices by increasing post-market surveillance authorities

Vanessa's Law Authorities under the Food and Drugs Act (the Act)

- Authority to compel manufacturers to conduct assessment
- Authority to compel manufacturers to compile information, conduct tests or studies, or monitor experience
- Requirement for manufacturers to notify Health Canada of foreign actions taken in response to serious risk of injury to human health

Monitoring and Surveillance Authorities

- Authority to request that manufacturers complete issue-related analysis
- Authority to require that manufacturers to conduct summary reporting & notify of changes to what is known about benefits and/or risks

Coming Into Force

Publication in CG II

December 23, 2020


Vol. 154, No. 26 Vol. 154, n° 26

Canada Gazette Part II

Gazette du Canada Partie II

OTTAWA, WEDNESDAY, DECEMBER 23, 2020
Statutory Instruments 2020
SOR/2020-257 to 280 and SI/2020-74 to 75 and 77 to 78
Pages 3554 to 4100

OTTAWA, LE MERCREDI 23 DÉCEMBRE 2020
Textes réglementaires 2020
DORS/2020-257 à 280 et TR/2020-74 à 75 et 77 à 78
Pages 3554 à 4100

Six months after publication in CG II

June 23, 2021

- Assessment
- Compile information, tests & studies, monitor experience
- Foreign risk notification
- Issue-related analysis

Twelve months after publication in CG II

December 23, 2021

- Summary report

Guidance Documents

- Amendments to the Food and Drugs Act: Guide to New Authorities (updated)
  - including power to require assessment and power to require tests, studies, etc.
    - https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/food-drugs-act-guide-new-authorities-2021.html

- Foreign risk notification for medical devices
  - https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/foreign-risk-notification-medical-devices-guidance.html

  - Incident reporting for medical devices (updated)
    - https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/incident-reporting-medical-devices-guidance-2021.html

- Summary reports and issue-related analyses of safety and effectiveness for medical devices
  - https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/medical-device-reports-analyses-guidance.html

MDR Section 62.1

Assessments Ordered Under Section 21.31 of the Act

Section 21.31 of the Act
Assessments

21.31 Subject to the regulations, **the Minister may order** the holder of a therapeutic product authorization to **conduct an assessment** of the therapeutic product to which the authorization relates and **provide** the Minister with **the results** of the assessment.

This power must be read in conjunction with its supporting regulations section **62.1** of the Medical Devices Regulations.

Section 62.1 of the MDR

Assessments Ordered Under Section 21.31 of the Act

- The Minister's power is subject to the following conditions:
  - the **person** to whom the order is made shall be the **holder of a medical device licence (i.e., class II-IV)**
  - reasonable grounds to believe that the **benefits — or the risks** to the health or safety of patients, users or other persons — **are significantly different** than they were when the licence was issued or amended

- The **Minister shall**, after examining the results of an assessment:
  - **provide** the holder of the medical device licence with the **results of the examination**
  - ensure that a **summary of the results of the examination**, together with a **description of any steps that the Minister has taken or may take** as a consequence of the examination, is **published** on the Government of Canada website

Section 62.1 of the MDR – Guidance

An Order under Section 21.32 is to be used:

- when new information available to the Minister indicates that the benefits or risks have changed since the previous authorization
- when an authorization holder is not willing to voluntarily conduct an assessment
- for the assessment of **existing information**

Before an order is issued, the Minister will:

- notify the authorization holder
- provide a reasonable opportunity to respond to the notification

An Order issued by the Minister should include, among other things:

- the rationale as to why the Minister now believes that the benefits or risks associated with the medical device are different
- the timeframe for responding to the Order and providing the Minister with the results
- the legal consequences for contravention of the Order

Section 62.1 of the MDR – Guidance (continued)

After examining the results of an assessment, the Minister must:

- provide the authorization holder with the results of the examination
- publish on the Government of Canada website a summary of the results of the examination along with a description of any actions that the Minister has taken or may take as a consequence of the examination

MDR Section 62.2

Activities Ordered Under Section 21.32 of the Act

Compile information, conduct tests or studies or monitor experience

Section 21.32 of the Act

Compile information, conduct tests or studies or monitor experience

21.32 Subject to the regulations, **the Minister may**, for the purpose of **obtaining additional information** about a therapeutic product's effects on health or safety, **order** the holder of a therapeutic product authorization to:

- **compile information**, **conduct tests or studies** or **monitor experience** in respect of the therapeutic product; and
- **provide** the Minister with **the information or the results** of the tests, studies or monitoring.

This power must be read in conjunction with its supporting regulations under section **62.2** of the Medical Devices Regulations

Section 62.2 of the MDR
Activities Ordered Under Section 21.32 of the Act

- The **person** to whom the order is made shall be **the holder of a medical device licence (i.e., class II-IV)**

- The **Minister shall** have reasonable grounds to believe that:
  - There are **significant uncertainties** relating to the benefits or adverse effects associated with the device
  - The licensee is **unable to provide the Minister with information that is sufficient** to manage those uncertainties, and
  - The applicable requirements of these Regulations, together with any terms and conditions that have been imposed on the medical device licence, **do not allow for sufficient information to be obtained** to manage those uncertainties

- The **Minister shall** take into account:
  - whether the activities that the licensee will be ordered to undertake are **feasible**, and
  - whether there are **less burdensome ways** of obtaining additional information about the device's effects on the health or safety of patients, users or other persons

Section 62.2 of the MDR – Guidance

An Order under Section 21.32 is to be used:

- when an authorization holder is not willing to voluntarily conduct the activities
- for those instances where a lack of knowledge could be detrimental to human health and safety
- To obtain **new information**

Before an order is issued, the Minister will:

- notify the authorization holder
- provide a reasonable opportunity to respond to the notification

An Order issued by the Minister should include, among other things:

- a description of the uncertainties and the activities intended to resolve them
- the timeframe for responding to the Order and providing the Minister with the results
- the legal consequences for contravention of the Order

The Order must be made publicly available (subsection 21.4(2) of the Food and Drugs Act)

Section 62.2 of the MDR – Guidance (continued)

After examining the compiled information, the results of a test or study, or the experience monitored, the Minister may:

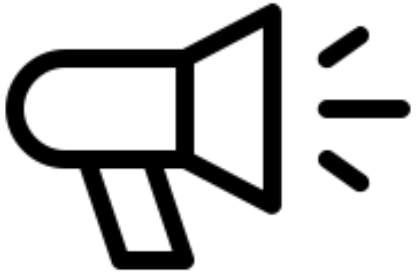
- take no further action
- amend terms and conditions on a medical device licence
- suspend a medical device licence
- order a label or packaging change under section 21.2 of the Food and Drugs Act
- issue an Order to recall the medical device under section 21.3 of the Food and Drugs Act

MDR Sections 61.2 to 61.3

Serious Risk of Injury to Human Health
Foreign risk notification

MDR Section 59 (modification)

Incident reporting by manufacturers and importers (Class II to IV)



Sections 61.2 to 61.3 of the MDR
Serious Risk of Injury to Human Health (Foreign Risk Notification)

- Applies to the holder of the following authorizations:
  - Medical device licence (i.e., Class II to IV)
  - Establishment licence to import Class II, III, or IV medical devices

- The importer of the device may submit on the manufacturer's behalf

- **List of Regulatory Agencies** for the Purposes of Section 61.2 of the Medical Devices Regulations:
  - published by the Government of Canada on its website
  - amended from time to time

- **Serious risk of injury to human health:** A hazard associated with the medical device that is relevant to the safety of the medical device and that, without risk mitigation, would likely:
  - be life-threatening
  - result in persistent or significant disability or incapacity
  - require inpatient hospitalization or prolonged hospitalization
  - result in a serious health consequence such as loss of function or debilitating chronic pain
  - result in death

Sections 61.2 to 61.3 of the MDR
Serious Risk of Injury to Human Health (Foreign Risk Notification)

Shall submit information in respect of any **serious risk of injury to human health** that the holder receives or becomes aware of and that is relevant to the safety of the device, regarding the following “notifiable actions”:

- **Risks that have been communicated** by:
  - by any regulatory agency that is set out in the “List of Regulatory Agencies”
  - any person who is authorized to manufacture or sell a medical device within the jurisdiction of such a regulatory agency

- **Changes that have been made to the labelling** of any medical device **and that have been communicated to or requested by** any regulatory agency that is set out in the “List of Regulatory Agencies”

- **Recalls**, **reassessments** and **suspensions or revocations of authorizations**, including licences, that have taken place within the jurisdiction of any regulatory agency that is set out in the “List of Regulatory Agencies”

Sections 61.2 to 61.3 of the MDR – Guidance

Intention of foreign risk notification (FRN)

- Improve the collection and assessment of new information concerning any serious risk of injury to human health related to the use of device that is authorized for sale in Canada
- Confirm that an appropriate response has been taken in Canada related to these risks

NOTE: This requirement replaces the requirement for manufacturers and importers of **Class II to IV devices** to report **an incident that occurs outside of Canada**, as required under the former section 59 of the Regulations

Sections 61.2 to 61.3 of the MDR – Guidance (continued)

- **What must be submitted (in English or French)**
  - foreign regulatory agency that took the notifiable action and/or the foreign jurisdiction in which the action was taken
  - the action taken

- **Additional information** should also be submitted, where applicable, related to the product and to the reasons for the action (e.g., the serious risk being mitigated and what is known about the root cause)

- **When to submit**
  - Within 72 hours of when the manufacturer or importer receives or becomes aware of a notifiable action

- **How to submit**
  - An electronic form is being developed and will be available on Canada.ca

MDR Sections 25(1) and 39 (Replacement)

Issue-related analysis of safety and effectiveness

Sections 25(1) and 39 of the MDR (replacement)
Issue-related analysis of safety and effectiveness

Section 25(1)

- If the Minister believes on reasonable grounds, after reviewing a report or information brought to his or her attention, that a **Class I** medical device may not meet the applicable requirements of sections 10 to 20, the Minister may request the manufacturer to submit, on or before the day specified in the request, **an analysis** or other information to enable him or her to determine whether the device meets those requirements.

Section 39

- If the Minister believes on reasonable grounds, after reviewing a report or information brought to his or her attention, that **a licensed medical device** may not meet the applicable requirements of sections 10 to 20, the Minister may request the manufacturer to submit, on or before the day specified in the request, samples — **or an analysis** or other information — to enable him or her to determine whether the device meets those requirements.

Sections 25(1) and 39 of the MDR – Guidance

- Health Canada may request, at any time, that an analysis be completed and submitted
  - Class I devices: the manufacturer is responsible
  - Class II to IV devices: the licence holder is responsible

- An analysis should be concise and fulfill the requirements set out in the request

- The request will specify the timeframe for submission
  - The default timeframe is 30 calendar days from the date of the request

- The analysis should be submitted by email in electronic-only format, in either English or French

Sections 25(1) and 39 of the MDR – Guidance (continued)

An issue-related analysis of safety and effectiveness should include, when relevant and available:

- Device complaints (section 57(1)(a)) and incident reports (section 59(1))
- Clinical data and other evidence
  - e.g., ongoing or completed post-market studies, scientific literature, etc.
- Exposure data or sales data
  - e.g., the number of units sold, estimated number of procedures/uses, etc.
- Device malfunction trends, quality issues and results from other analyses
  - e.g., root cause analysis
- Labelling
  - i.e., whether information needed to use the device safely and effectively is included
- A conclusion, including whether risk mitigation strategies are necessary

NOTE: Information specific to Canada is essential, as conditions of use in Canada may differ from other countries. In some cases, however, Canadian-specific information may be limited. Information about the use of the device outside Canada should be used when available and relevant.

MDR Sections 61.4 to 61.6

Summary Report

Sections 61.4 to 61.6 of the MDR
Summary Report

Class II medical devices:

- Summary report of the information that the licensee received or became aware of during the previous 24 months (biennial basis)

Class III or IV medical devices

- Summary report of the information that the licensee received or became aware of during the previous 12 months (annual basis)

The matters to be covered (class II to IV medical devices)

- adverse effects;
- problems referred to in paragraph 57(1)(a);
- incidents referred to in subsection 59(1); and
- serious risks of injury to human health that are relevant to the safety of the medical device and are referred to in subsection 61.2(2).

Sections 61.4 to 61.6 of the MDR
Summary Report

The summary report shall:

- contain a concise critical analysis of the matters to be covered

- The licensee shall determine **whether what is known about the benefits and risks associated with the device has changed** in one or more of the ways described below:
  - any of the benefits could be less;
  - in respect of any of the risks;
    - the risk is more likely to occur, or
    - if the risk occurs, the consequences for the health or safety of patients, users or other persons could be more serious; and
  - a new risk has been identified

- If, in preparing the summary report, the licensee concludes that what is known about the benefits and risks associated with the medical device **has changed**, they shall **notify the Minister, in writing, within 72 hours** after having reached the conclusion, unless that has already been done.

Sections 61.4 to 61.6 of the MDR
Summary Report

The holder of a medical device licence shall maintain records of the summary reports and the information on the basis of which those reports were prepared (for 7 years)

The Minister may request that the holder of a medical device licence submit:

- summary reports
- information on the basis of which summary reports were prepared

Sections 61.4 to 61.6 of the MDR – Guidance

The information in a summary report is expected to form part of ongoing post-market monitoring by medical device licence holders

The timing, frequency and type of scanning should depend on a number of factors, such as:

- the risk profile of the device, with details of the risks and benefits
- any known or specific issues that have arisen
- the scheduling of the summary report

- The reporting period is **not tied to the anniversary date** of a medical device licence

- Licence holders:
  - are required to prepare summary reports for as long as their device is licensed in Canada
  - may choose the reporting period for the report as long as the report falls within the required reporting timeframe
  - may choose to use the same timeline for both the Canadian summary report and similar reports created to meet the requirements of international jurisdictions

Sections 61.4 to 61.6 of the MDR – Guidance (continued)

- A summary report is required for each medical device licence

- It may be reasonable to combine certain devices when preparing a summary report, even if they're not included in the same licence
  - Devices could be grouped in a manner that has been specified in jurisdictions outside Canada to meet similar periodic reporting requirements
  - A decision to group devices or combine data should not prevent the identification of issues that would have been detected without the grouping

- **Different formats are acceptable** for a summary report, including those from other jurisdictions, as long as the report includes the required information outlined in sections 61.4(1) to 61.4(5) of the Regulations

Sections 61.4 to 61.6 of the MDR – Guidance (continued)

- The summary report should add to the cumulative knowledge about the safety and effectiveness of a device from real-world use

- Information in a summary report may vary from report to report

- A report should generally contain the following sections:
  - introduction or cover page
  - summary of changes to the device or licence
  - analysis
  - conclusion

- If you determined that there was no change to the benefits and risks of your medical device since the previous reporting period, do **not** submit the summary report to Health Canada

Sections 61.4 to 61.6 of the MDR – Guidance (continued)

If it is concluded that there has been a change to what is known about the benefits and/or risks of a device, Health Canada must be notified within 72 hours

Methods to notify Health Canada include:

- submission of an **application for a medical device licence amendment**, such that the amendment addresses the change
- notification of a **recall** of the impacted device(s), such that the recall addresses the change, or
- submission of the **summary report**

- The licence holder may have identified a change, implemented preventive or corrective actions and notified Health Canada during the reporting period (**before completing the summary report**)
- In this case, it should be documented in the summary report that:
  - any necessary actions were already taken
  - Health Canada has already been notified (e.g., recall notification)
- Unless requested, do **not** submit the summary report to Health Canada in this situation

Applicability of regulations to devices authorized under the Interim Order on the importation and sale of medical devices for use against COVID-19

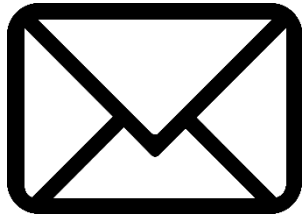
- On March 18, 2020, the Minister of Health signed a one year Interim Order (IO) to expedite the review and authorization of medical devices used in COVID-19

- A second IO is expected to be introduced before the expiry of the first IO to extend the effects of the current IO and keep devices on the market during the pandemic

- The second IO will be succeeded by a transition period, from Fall 2021 to Fall 2023

- At the end of this period, IO authorized devices will be regulated under the MDR, either through a medical device licence (Class II, III and IV devices) or through a Medical Device Establishment Licence (MDEL) (Class I devices)
  - For Class II, III and IV, once they hold medical device licences under the MDR, they will be subject to the new post-market surveillance regulations as described in the previous slides
  - For Class I devices, once they are marketed under a valid MDEL, they will be subject to the revised s. 25(1) (slides 22 to 24)

Questions, comments, or need support?



Medical Devices Directorate:
hc.meddevices-instrumentsmed.sc@canada.ca

Incident reporting: hc.canada.vigilance.sc@canada.ca