Guide to reporting medical device shortages and discontinuations

GUI-0137

April 29, 2022

Canada

Date issued:	April 29, 2022
Date implemented:	April 29, 2022
Replaces:	COVID-19 guidance for reporting medical device shortages, v2 GUI-0137 (March 17, 2021)

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This publication can be made available in alternative formats upon request.

Publication date: April 2022

Cat.: H139-38/2022E-PDF
ISBN: 978-0-660-42218-3
Pub.: 210701

Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations. In the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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Background

About this guidance document

This guidance document supports amendments to section 1 and the introduction of sections 62.21 to 62.26 of the *Medical Devices Regulations* (Regulations), which go into effect on March 2, 2022. These sections:

- require **manufacturers of Class I to IV medical devices** and **importers of Class I medical devices** to report shortages of devices (including their components, accessories and parts) that are on the *List of Medical Devices – Notification of Shortages*
- require **manufacturers** or designated **importers** to report if the manufacturer is discontinuing the sale of a specified medical device in Canada and the discontinuation may cause a shortage
- permit the Minister of Health to require a **manufacturer, importer or distributor** to provide information requested about a medical device shortage

A specified medical device is part of a category of medical devices that is set out in the *List of Medical Devices – Notification of Shortages*.

The guidance is to help manufacturers, importers and distributors meet their regulatory obligations. It outlines in general language their responsibilities for the mandatory reporting of medical device shortages and discontinuations, and mandatory information requests as set out in the legislation.

This document also provides information on how to voluntarily report a shortage of a medical device that is not on the List of Medical Devices - Notification of Shortages. Although Canada's role is focused on administering the requirements for mandatory shortage reporting, voluntary reports help us determine trends in the medical device supply chain and where there are areas of risk or concern.

Everyone has a role to play

Manufacturers and importers

Manufacturers and importers have a key role to play in preventing and reducing the impact of medical device shortages. They can control the volume of medical devices in the supply chain and can take steps to resolve a medical device shortage when one occurs. They are also in the best position to communicate to customers about the availability of their devices.

When a manufacturer experiences a shortage of a medical device it sells, we expect the manufacturer will take all necessary measures to resolve the shortage quickly. Manufacturers of specified medical devices must report a shortage of the device to Health Canada. We may require a manufacturer or importer to provide information about a shortage or potential shortage under certain conditions (refer to section 62.26 of the Regulations).

Manufacturers and importers may also voluntarily report shortages of other devices not on the *List of Medical Devices - Notification of Shortages* to support our work on shortage monitoring.

Distributors

Distributors are not required to report shortages of specified medical devices. They are, however, an integral part of the medical device supply chain and may also help to prevent or mitigate medical device shortages. Health Canada may require a distributor to provide information about a shortage or potential shortage under certain conditions (refer to section 62.26 of the Regulations).

Provincial/territorial governments

To prevent and/or reduce the impact of medical device shortages, provincial and territorial governments may:

- take measures to conserve their stock
- reallocate stock within regions or provinces/territories to where it is most needed and work together to share the existing supply
- identify and secure additional supplies of medical devices from other vendors or another provincial/territorial government
- identify and secure other compatible substitute medical devices
- voluntarily report shortages identified or anticipated at the provincial/territorial level to Health Canada to support our work on monitoring shortages

Group purchasing organizations

Group purchasing organizations also have an important role to play in preventing and mitigating medical device shortages. They may:

- engage stakeholders
- conduct market research
- ensure access to a diversity of suppliers
- negotiate with manufacturers on behalf of buyers

Health care authorities and health care professionals

Health care authorities and health care professionals also have an important role to play in preventing and mitigating medical device shortages. They may:

- conserve and reallocate stock in their area to meet their needs
- notify their applicable provincial or territorial departments about potential or actual shortages
- work with their procurement staff/organizations to secure substitute devices
- arrange suitable alternatives for patients
- voluntarily report shortages in a health care setting to Health Canada to support our work on monitoring shortages

International partners

Health Canada communicates with regulatory partners from around the world to share information on medical device shortages occurring in each other's jurisdictions. Sharing information keeps us up to date on emerging shortages and the status of medical device shortages globally. It also keeps us up to date on efforts to mitigate shortages, such as identifying possible substitute devices available outside Canada.

Health Canada

Health Canada administers various legislations, including the *Food and Drugs Act*, *Radiation Emitting Devices Act* and *Medical Devices Regulations*. The provisions for reporting medical device shortages and discontinuations can be found in the *Medical Devices Regulations*, effective March 2, 2022.

Health Canada does not control the supply of medical devices in Canada or have the authority to compel a manufacturer to supply a device. We work with stakeholders across the medical device supply chain to help determine the details and status of a shortage. We also coordinate and facilitate proactive information sharing.

Health Canada depends on early reporting of anticipated or actual shortages to help us identify national critical shortages. We work with stakeholders to ensure an adequate supply of medical devices in Canada for national critical shortages. We may use regulatory or communication tools and play a coordination role in managing these high risk shortages.

The Minister of Health can compel manufacturers, importers or distributors who import or sell a medical device to provide information within their control about a device shortage or potential shortage under certain conditions. The ability to do so is outlined in section 62.26 of the Regulations.

Information collected by Health Canada will be subject to applicable laws, including the *Privacy Act* and *Access to Information Act*.

Who must report

Mandatory shortage reporting

Manufacturers of Class I to IV devices and importers of Class I devices must report shortages to Health Canada for devices that belong to a category included on the List of Medical Devices - Notification of Shortages. This is specified in section 62.23 of the Regulations.

A manufacturer may permit any importer of a medical device to prepare and submit a shortage report on its behalf (refer to section 62.24). This is permitted only when the information that would have been reported by the manufacturer and importer is identical.

The manufacturer must complete the following form to permit an importer to report on their behalf:

- Authorization Form (FRM-0451) (PDF version)

Manufacturers can email the form to Health Canada at md.shortages.penurie.de.im@hc-sc.gc.ca.

Mandatory discontinuation reporting

Manufacturers or designated importers must report to Health Canada discontinuations that will lead to a shortage for devices on the List of Medical Devices - Notification of Shortages. This requirement is outlined in subsection 62.23(2) of the Regulations.

Voluntary shortage reporting

Manufacturers, importers, provinces/territories and other stakeholders may **voluntarily** report shortages of medical devices, even if they are not on the List of Medical Devices - Notification of Shortages, if:

- the shortage may cause a patient or user safety issue in Canada
- a compatible substitute medical device, component, accessory or part is not available in Canada or cannot be easily replaced
    - for example, due to capital equipment costs, regulatory requirements to update procedures, non-compatibility of surgical instruments or with other devices, extensive training required to use the replacement, or
- the shortage is national in scope

Voluntary shortage reporting provides Health Canada with information on the medical device supply chain. This information helps us determine trends in the supply chain and identify where there are areas of risk or concern for shortages.

If you are not sure whether to report a shortage of a device, you may contact us at md.shortages.penurie.de.im@hc-sc.gc.ca.

What must be reported

About mandatory reporting of medical device shortages

Section 1 of the Regulations defines a medical device shortage as a situation in which a manufacturer of a medical device is unable to meet the demand for a device in Canada.

Health Canada interprets the definition of 'shortage' for medical devices to include 2 types of shortages:

1. actual shortages, where the current supply can't meet current demand
2. anticipated shortages, where the future supply can't meet projected demand

Under section 62.22 of the Regulations, Health Canada may add categories of medical devices to the *List of Medical Devices – Notification of Shortages*. We may consider adding a category of medical devices to the list only if we have reasonable grounds to believe that a shortage presents or may present a risk of injury to human health. A device that belongs to a category of devices that is on this list is called a "specified medical device".

Under sections 62.23 to 62.25 of the Regulations, manufacturers of Class I to IV devices and importers of Class I devices are required to:

- report actual or anticipated shortages of a specified medical device
- update the status of a reported shortage if there is a change in the shortage information submitted
- report the end of a shortage
- report the discontinuation of a specified medical device sold in Canada if that discontinuation will lead to a shortage

In line with subsection 62.23(9), a manufacturer or importer does not need to report a shortage if they can confirm that the manufacturer can meet the demand with a substitute device that they also manufacture (including its components, accessories or parts).

For example, a manufacturer may be experiencing a shortage in accessories for laryngoscopes or ventilators. They are not required to report the shortage if they manufacture a compatible substitute device that is:

- fully interchangeable for the device in shortage
- authorized for sale in Canada and
- meets the Canadian market demand

When deciding on a substitute device, the manufacturer of Class I to IV medical devices and the importer of Class I medical devices should consider a number of factors, including:

- whether the substitute device, component, accessory or part is fully interchangeable with the specified device in shortage
- additional concerns regarding the use of a substitute device, such as:
    - whether the substitute device has the same intended use
    - whether the performance, safety or effectiveness of the device introduces new risks to the patient

Manufacturers or importers of medical devices that anticipate meeting projected demand within 30 calendar days of becoming aware of a shortage, such as in cases of back-orders, do not need to report.

Minister's power to require information about a shortage

Under section 62.26 of the Regulations, the Minister of Health may request manufacturers, importers or distributors of medical devices to provide information about a shortage. This authority will help assess factors, such as the level of risk posed by a shortage or potential shortage of the medical device. The information may be requested if the Minister has reasonable grounds to believe that:

- there's a shortage of the device in Canada or the device is at risk of going into shortage
- a shortage of the device presents or may present a risk of injury to human health
- the information is necessary to establish or assess:
    - the existence of a shortage or risk of shortage
    - the reasons for a shortage or risk of shortage
    - the effects or potential effects on human health of a shortage, or
    - measures that could be taken to prevent or alleviate a shortage; and
- the manufacturer, importer or distributor will not provide the information without a legal obligation to do so

Under this authority, the Minister will not require a person to create new information, such as conducting new analysis or studies.

The request can only be made for information that is in the person's control.

When responding to a mandatory information request, manufacturers, importers and distributors must provide additional information about a shortage that is specified by the Minister. The information must be submitted electronically by the deadline. The request will contain instructions for submitting the information, including the format for submitting that information.

Mandatory reporting of medical device shortages

Shortages of devices (including components, accessories and parts) that belong to a category specified on the List of Medical Devices - Notification of Shortages shall be reported (sections 62.21 to 62.23 of the Regulations). The list changes as medical device categories are added or removed based on shortage status, availability of substitute devices and risk and scope of potential shortages.

Health Canada gathers information about emerging and potential shortages from industry, other governments, health care institutions and professionals, international regulators and other stakeholders. We use this information and other data to decide which medical devices are to be added or removed from the list.

Using an established process for adding a category of device to the List of Medical Devices - Notification of Shortages, we consider several factors to determine if a shortage or potential shortage of a device presents or may present a risk of injury to human health.

Once we decide to add or remove a device from the list, we notify manufacturers and importers via a Medical Devices Compliance Program Bulletin. We also reach out to those manufacturers and importers that are directly impacted. We also encourage manufacturers and importers to review the list regularly.

To comply with mandatory reporting under section 62.23, manufacturers of Class I to IV devices and importers of Class I devices must file the following reports within these timelines:

- an initial shortage report **within 5 business days** after the day on which they become aware of an actual or anticipated shortage
- an updated shortage report with any new information **within 2 business days** after the day on which they become aware of a change to any of the information already submitted, such as:
    - the end date of the actual shortage
    - if an anticipated shortage was avoided
- an end of shortage report **within 2 business days** after the day on which the manufacturer is able to meet the demand for the medical device (or for its components, accessories or parts)
- a medical device discontinuation report **within 5 business days** after the day of making the decision to discontinue sale in Canada

For instructions on how to report, refer to the section on when and how to report.

Exemptions

Manufacturers and importers do not need to report a medical device shortage to Health Canada if they anticipate they can meet the demand for the device (or its components, accessories or parts) within **30 calendar days** after the day they anticipate or become aware of the shortage. This is outlined in subsection 62.23(7) of the Regulations. This includes devices that are on back-order for less than **30 calendar days**.

As well, a manufacturer of a Class I to IV device or importer of a Class I device does not need to report a medical device shortage if they:

- are also a manufacturer of another medical device that can be substituted for the device in shortage and
- are able to meet the demand for this substitute device

This is outlined in subsection 62.23(9) of the Regulations.

An acceptable substitute option must be authorized for sale in Canada.

A shortage (back-order) of more than 30 days

Manufacturers of Class I to IV devices and importers of Class I devices may anticipate that the manufacturer can meet the demand for a device pursuant to subsection 62.23(7). They may then conclude later that they cannot meet the demand within a **30-day calendar** period. In this case, they must report a medical device shortage.

This is outlined in subsection 62.23(8) of the Regulations. For example, a back-order becomes a shortage and must be reported if it cannot be resolved within **30 calendar days**. A manufacturer and importer must report such a shortage within **5 business days** from when they learn that the duration of it will exceed **30 calendar days**.

When medical device shortages do not need to be reported

A manufacturer or importer does not need to report a medical device shortage under a number of situations. These situations include:

- a manufacturer or importer who had previously reported a shortage under one of the interim orders
    - Interim Order No. 1 - Interim order respecting drugs, medical devices and foods for a special dietary purpose in relation to COVID-19
    - Interim Order No. 2 - Second interim order respecting drugs, medical devices and foods for a special dietary purpose in relation to COVID-19
- an actual or an anticipated shortage of a Class I medical device that's not authorized for sale or import in Canada by a medical device establishment licence (MDEL) holder
- an actual or an anticipated shortage of a Class II, III and IV medical device that's not licensed for sale in Canada
- an actual or an anticipated shortage of a medical device that has not entered the Canadian market (not yet sold in Canada)
- a manufacturer or importer who has never sold or imported medical devices in Canada and is having problems obtaining supply (a new supplier)
- a manufacturer or importer who has previously sold medical devices is not actively selling in Canada and does not have any orders in Canada
- disruptions in manufacturing that don't cause a shortage

Documented procedures for mandatory shortage reporting

Health Canada recommends that manufacturers and importers develop a process for reporting medical device shortages to us as part of their internal quality management system. When developing internal written procedures for reporting medical device shortages, we suggest that manufacturers and importers consider:

- Health Canada shortage reporting requirements
- which department is responsible for reporting shortages to us
- timeline requirements for initial shortage reports, updates, avoided shortages, shortage closures and device discontinuations
- a procedure for checking the List of Medical Devices - Notification of Shortages regularly to ensure you are reporting all mandatory medical device shortages
- subscribing to our Medical Devices Compliance Program Bulletin to ensure your company is up to date on the latest developments on shortage reporting
- risk mitigation steps to be taken to address medical device shortages in your organization

When and how to report

When to report

The following shortage scenarios illustrate a few examples of how to report shortages and discontinuations in a variety of situations and describe manufacturer and importer reporting obligations. Medical device shortage and discontinuation reporting is not limited to the scenarios below. These scenarios are intended as examples only for the purpose of this guidance document.

Scenario 1: A manufacturer also manufactures a substitute medical device, component, accessory or part that can be substituted for the device in shortage and is able to meet the demand for it in Canada

No shortage report is required (subsection 62.23(9)).

Scenario 2: A back-order of less than 30 calendar days

Examples:

- A manufacturer/importer is unable to meet the demand for a specified medical device and anticipates being able to meet demand in 14 days. After 14 days, the manufacturer is once again able to meet demand.
- A manufacturer/importer is unable to meet the demand for a specified medical device and anticipates being able to meet demand in 14 days. This timeline is extended by 10 days. After 24 days, the manufacturer is once again able to meet demand.
- A manufacturer/importer's typical delivery time for a specified medical device is 40 days and the delivery time increases by an additional 25 days.

No shortage report is required (subsection 62.23(7)).

Scenario 3: A back-order of more than 30 calendar days

Examples:

- A manufacturer/importer is having issues with sterilizing a specified medical device and anticipates that it will take 45 days to sterilize the device to meet demand.
- A manufacturer/importer's typical delivery time for a specified medical device is 40 days and the delivery time increases by an additional 35 days.

A shortage report must be submitted:

- within **5 business days** from the day the manufacturer/importer is informed that the back-order will be more than **30 calendar days** and
- when the manufacturer responsible for reporting the shortage has no identified substitute device available in Canada (subsection 62.23(8))

Scenario 4: An initial back-order of less than 30 calendar days is extended to more than 30 calendar days

Example:

- A manufacturer/importer is unable to meet the demand for a specified medical device and anticipates being able to meet demand in 14 days. This timeline is extended to 40 days.

A shortage report must be submitted:

- within **5 business days** from the day the manufacturer/importer is aware that the back-order will cause a shortage longer than **30 calendar days** (subsection 62.23(8)) and
- when the manufacturer responsible for reporting the shortage has no identified substitute device available in Canada (subsection 62.23(9))

Scenario 5: A manufacturer/importer discovers a medical device is in shortage and hasn't anticipated the shortage

A shortage report must be submitted:

- within **5 business days** from the day the shortage is identified and when the manufacturer responsible for reporting the shortage has no identified substitute device available in Canada (subsections 62.23(4) and (9))

Scenario 6: A manufacturer/importer becomes aware that a medical device for which it had already reported an anticipated shortage is now in shortage

A shortage report update must be submitted:

- within **2 business days** from becoming aware of the shortage (must indicate the date the shortage began) (subsection 62.23(5))

Scenario 7: The information a manufacturer/importer submitted to Heath Canada about a medical device shortage has changed

Example:

- A manufacturer/importer reported a shortage and learned the end date for the shortage has changed from the original date provided to Health Canada.

A shortage report update must be submitted within **2 business days** of becoming aware of the change (subsection 62.23(5))

Scenario 8: The shortage for a medical device has ended

Example:

- A manufacturer/importer is once again able to meet the demand for a device in shortage.

An end-of-shortage report must be submitted:

- within **2 business days** from the day the manufacturer is again able to meet the demand for the medical device
    - include this date in the report as the end date for the shortage (subsection 62.23(6))

Scenario 9: The shortage of a medical device has been avoided

Example:

- A manufacturer/importer has reported an anticipated shortage to Health Canada. However, they find a compatible substitute device before the anticipated start date of the shortage.

A manufacturer/importer must report that a shortage has been avoided if they reported an anticipated shortage to us and have found a solution to avoid the shortage before the start date of an anticipated shortage

The end-of-shortage report, including the rationale for why the shortage has been avoided, must be submitted:

- within **2 business days** of becoming aware of the change (subsection 62.23(5))

Scenario 10: Reporting the discontinuation of the sale of a medical device listed on the *List of Medical Devices - Notification of Shortages*

A manufacturer or designated importer must report that the manufacturer is discontinuing the sale of a specified medical device in Canada if the discontinuation may cause a shortage (subsection 62.23(2)).

The report needs to be submitted:

- within **5 business days** after the day on which the manufacturer or importer anticipates a shortage due to the decision to discontinue sale (subsection 62.23(4)(b))

How to report

To report a shortage

To report a shortage, complete the following electronic reporting form and choose the 'Initial' option under the 'Type of Report(s)' section at the start of the form.

- Report a shortage

At a minimum, the following information is required when submitting a medical device shortage report, update report or final report to Health Canada:

- name and contact information for the manufacturer of Class I to IV devices and/or the importer of Class I devices
- medical device licence (MDL) number for Class II, III or IV devices
    - authorization identification number for a device authorized for importation or sale under another interim order made under section 30.1 of the *Food and Drugs Act*
- device identifier
    - includes the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or device group family

- name of the device and of any component, accessory or part of the affected device, including the model name (if applicable) in both English and French, as it appears on the device label
- description of the medical device, its packaging and an indication of whether it is a single-use device
- date when the shortage began or is anticipated to begin (start date of shortage)
- date when the manufacturer anticipates meeting the demand for the medical device (estimated end date of shortage), if known
- description of the reason for the shortage
- description of the information that the manufacturer of a Class I to IV device or an importer of a Class I device relied upon to determine that a shortage exists or is likely to occur, such as:
    - details on the reason for the manufacturing disruption of the affected medical device
    - information on a compatible substitute device
    - details on how long your Canadian inventory will last, given the current and anticipated demand
    - details on the current Canadian demand for the medical device
    - details on your total manufacturing capacity for the specified device and how many units of the device your company is shipping to Canada per week/month/year
    - information (if known) on any compatible substitute devices manufactured by other companies

One shortage reporting form may be used for multiple shortage reports as long as the devices being reported are from the same manufacturer. The form contains separate sections for reporting up to 10 device shortages. You must provide the information listed above for each additional device.

To report a shortage status update or provide additional information

Choose the 'Update' option under the 'Type of Report(s)' section at the start of the reporting form. Include your Health Canada-issued shortage report number, if known.

- Report a shortage

To report an avoided shortage

The manufacturer of a Class I to IV device and an importer of a Class I device must report the shortage has been avoided if they:

- reported an anticipated shortage to us and
- are able to resolve or avoid the shortage before the date of their anticipated shortage
- This report must be submitted to Health Canada within **2 business days** of becoming aware of the change.

In these cases, complete the following form and indicate the rationale for why the shortage has been avoided under the 'Rationale for why the shortage has ended' section:

- Report the end of a shortage

To report the end of a shortage, complete the following form:

- Report the end of a shortage

A shortage may be considered resolved when:

- a manufacturer can once again meet current demand for the medical device and
- there are no anticipated shortages of the same medical device or
- a manufacturer reporting the shortage has an acceptable substitute option manufactured by them

To report a discontinuation, complete the following form:

- Report a discontinuation

A manufacturer or designated importer must report a discontinuation of a specified medical device to Health Canada if:

- they decide to discontinue sale of the device in Canada and
- discontinuation is likely to result in a shortage

At a minimum, the following information is required when submitting a medical device discontinuation report or update report to Health Canada:

- name and contact information of the manufacturer and/or the importer
- medical device licence (MDL) number in the case of Class II, III or IV devices

    - authorization identification number for a device authorized for importation or sale under another interim order made under section 30.1 of the *Food and Drugs Act*
- device identifier
    - includes the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or device group family
- name of the device and of any component, accessory or part of the affected device, including the model name (if applicable), in both English and French
- description of the medical device, its packaging and an indication of whether it's a single-use device
- date on which the shortage caused by the decision to discontinue sale began or is anticipated to begin
- reason for discontinuation

This does not affect the obligation of an MDL holder to report a discontinuation under section 43(3) of the Regulations. This section states that if the MDL holder discontinues the sale of the medical device in Canada, the licensee shall inform the Minister **within 30 days** after the device has been discontinued. The licence will be cancelled at the time that the Minister is informed.

If an actual or anticipated shortage of the reported discontinued medical device occurs before the reported discontinuation date, the manufacturer of a Class I to IV device and importer of a Class I device must report this as a shortage.

If you are not sure whether to notify us about a shortage or discontinuation of a particular device, email us at md.shortages.penurie.de.im@hc-sc.gc.ca.

Compliance and enforcement

Health Canada undertakes compliance and enforcement activities in accordance with the Compliance and enforcement policy for health products (POL-0001). This policy describes our national compliance and enforcement approach for all health products regulated under the *Food and Drugs Act* and its Regulations. Compliance and enforcement actions are based on the risk posed to the health and safety of people living in Canada and the seriousness of the non-compliance.

What happens to your report

Manufacturers and importers are responsible for sending medical device shortage and discontinuation reports to Health Canada. We will review this information to determine if the reported shortage meets the statutory definition of a shortage and similarly, if a reported discontinuation meets the definition of a discontinuation.

We will post certain information about confirmed medical device shortages and discontinuations on the List of shortages and discontinuations (section 62.25).

This information is used to:

- alert health care facilities and other manufacturers of supply gaps
- help health care providers and patients make timely and informed choices about their health
- help minimize the impact of a shortage on patient care

Each device posted on the List of shortages and discontinuations is linked to a detailed report. The reports contain the following information:

- type and status of the shortage/discontinuation (actual, anticipated, resolved, avoided, discontinued, to be discontinued)
- name of medical device in English and French, as well as any component, accessory or part, including the model name
- other names (for example, trade name)
- anticipated or actual start date of shortage/discontinuation
- estimated end date of shortage
- reason for the shortage/discontinuation
- names of importers listed who have reported the shortage/discontinuation separately from the manufacturer or are reporting on behalf of the manufacturer in a delegated capacity
- description of the device
    - package description (for example, packaging formats, sizes, quantities)
    - single-use product
- class of medical device (I, II, III or IV)
- device identifiers (for example, catalogue number, part number, model number or unique device identifier)

- medical device licence (MDL) number for the applicable Class II, III and IV device
    - authorization identification number for devices authorized for importation or sale under an interim order made under section 30.1 of the *Food and Drugs Act*, if applicable
- manufacturer's name and mailing address

Additional information used to confirm the existence of a shortage is not posted on the report online.

Health Canada actively monitors the status of reported shortages and discontinuations and regularly updates the List of shortages and discontinuations as information is received from the manufacturer or importer.

However, the detailed reports that are linked from this list, which include specific information related to the device that is in shortage or discontinued, will not be updated.

Definitions and instructions

Definitions

Medical device: a device within the meaning of the *Food and Drugs Act*, but does not include any device intended for use in relation to animals

List of Medical Devices - Notification of Shortages: the List of Medical Devices – Notification of Shortages that is published by the Government of Canada on its website, as amended from time to time

Specified medical device: a medical device that belongs to a category of medical devices that is set out in the *List of Medical Devices - Notification of Shortages*

Shortage: for a medical device, a situation in which the manufacturer of the device is unable to meet the demand for the device in Canada

Actual shortage: a manufacturer's current supply cannot meet current demand in Canada

Anticipated shortage: a manufacturer's future supply cannot meet projected demand in Canada

Avoided shortage: an anticipated shortage that will no longer occur

Resolved shortage: an actual shortage where:

- a manufacturer has found an acceptable substitute option
- a manufacturer can once again meet current demand for the medical device and
- there are no anticipated shortages of the same medical device in the near future

Authorization identification number: number assigned to devices authorized for importation or sale under an interim order made under section 30.1 of the *Food and Drugs Act*

Discontinuation of a medical device: a manufacturer decides to discontinue the sale of a specified medical device in Canada and the discontinuation will lead to a shortage

Health care professional: a person who is entitled under the laws of a province or territory to provide health services in the province or territory

Manufacturer: a person who:

- sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf

Importer: a person in Canada, other than the manufacturer of a device, who is responsible for bringing the medical device into Canada for sale

Distributor: a person:

- other than a manufacturer, an importer or a retailer who sells a medical device in Canada for the purpose of resale or use, other than for personal use
- outside of Canada who sells medical devices into Canada

Instructions

Below are instructions on completing the medical device shortage reporting form.

Shortage report number(s): A shortage report number will be provided when Health Canada follows up on an initial shortage report. This field only needs to be completed when an 'Update' report is submitted.

Name of medical device: Provide the name as it appears on the device label, if available. The medical device, component, accessory or part name may or may not be the same as the device name or licence name.

Device identifier(s): Provide the device identifier (for example, serial number, catalogue number, part number, model number, unique device identifier) as it appears on the device label, if available. If necessary, please consult the Medical Devices Active Licence Listing (MDALL), a reference tool for licensed medical devices in Canada.

You may also consult other listing tables for devices authorized by Health Canada for importation or sale under an interim order made under section 30.1 of the *Food and Drugs Act*, including the:

- List of authorized medical devices other than testing devices
- List of medical devices for exceptional importation and sale

Reason for shortage: Common reasons for why a shortage can occur and are part of the drop-down menu in the 'Electronic reporting form – Reason for shortage' section include:

- **Disruptions in manufacturing:** the circumstances that impede the actual manufacturing of a device, such as:
    - change in ownership
    - equipment breakdown
    - inability to source components or parts
    - natural disasters and pandemics
    - insufficient employees available
- **Device was subject to recall:** the action taken by the manufacturer, importer or distributor of the device to:
    - recall or correct the device or
    - notify its owners and users of its defectiveness or potential defectiveness
- **Delay in shipping of a medical device:** a situation in which a shortage results from the delays in getting a device shipped, such as:
    - increased shipping volumes
    - shortage of shipping containers
    - blocked transportation routes (for example, rail lines)
    - strikes (for example, major shipping company)
- **Increase in demand for the medical device:** the inability of a manufacturer to produce a sufficient quantity of devices to fulfill their customer orders
- **Licensing issue:** the suspension or cancellation of an existing medical device licence (MDL) or medical device establishment licence (MDEL) due to a:
    - compliance issue
    - licence that has not been renewed during the annual renewal process or
    - MDL requiring an amendment application
- **Export restrictions:** restrictions imposed by foreign governments that limit the number of devices allowed for export to other countries
- **Discontinuation:** a manufacturer decides to discontinue the sale of a medical device in Canada

Reporter comments: This information may be posted online. Examples of information to include:

- description of alternative devices
- 1-800 support numbers
- website for additional information