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# COVID-19 guidance for reporting medical device shortages

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Canada

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*Lignes directrices sur la déclaration des pénuries d'instruments médicaux dans le cadre de la pandémie de COVID 19*

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## Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and 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 the guidance document

This guidance document supports *Interim Order No. 2 Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19* (Interim Order No. 2).

The Minister of Health approved Interim Order No. 2 on March 1, 2021, to address the unprecedented demand and urgent need for medical devices to treat, diagnose and protect Canadians against COVID-19. This guidance covers sections 14 to 18 of the interim order. It remains in effect as long as the interim order is in effect.

Under Interim Order No. 2, manufacturers and importers must report medical device shortages to Health Canada for devices on the List of medical devices: Notification of shortages (specified medical devices).

A specified medical device is a device that is either:

- set out in the list of medical devices or
- part of a category of medical devices that is set out in that list

This guidance document includes new regulatory requirements for manufacturers, importers and distributors of COVID-19-related devices under Interim Order No. 2.

The guidance is intended to help manufacturers, importers and distributors meet their regulatory obligations. It outlines their responsibilities concerning the mandatory reporting of medical device shortages. Medical device shortages that were reported under the previous *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19* do not need to be reported again.

## About medical device shortages and reporting

A medical device shortage occurs when a manufacturer of a medical device is unable to meet Canadian market demand for the device or its components, accessories or parts. This does not apply to a situation in which the manufacturer is also the manufacturer of a substitute medical device, component, accessory or part and is able to meet demand for it in Canada.

There are 2 types of shortages:

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

Manufacturers and importers must:

- report a medical device shortage
- provide a shortage status update if there is a change in the shortage information submitted
- report an end of a medical device shortage

Section 18 of Interim Order No. 2 allows the Minister of Health to compel manufacturers, importers or distributors that import or sell medical devices in Canada to provide information within their control about a shortage or potential shortage when:

- there's a shortage of the device in Canada or the device is at risk of going into shortage
- 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
- the manufacturer, importer or distributor will not provide the information without a legal obligation to do so

When requested by Health Canada, manufacturers, importers and distributors must provide additional information about a shortage in an acceptable or electronic format within a specified time limit. We will only require that the information be submitted with less than 24 hours' notice if we have reasonable grounds to believe that there is a serious and imminent risk of injury to human health. The information that may be requested will not include personal information on a patient, user or other person whose health or safety may be adversely affected by the medical device being in shortage. Privacy considerations are defined in section 3 of the *Privacy Act*.

This guidance document also provides some guidance on how to voluntarily report a medical device shortage that does not fall under the interim order.

# 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 critical medical device it sells, we expect the manufacturer will take all necessary measures to resolve the shortage as quickly as possible.

## Distributors

Distributors may also be impacted by medical device shortages and have information about the availability of devices they sell. Although they are not required to report a medical device shortage, they may be contacted by Health Canada to provide information about a shortage or potential shortage under certain conditions. These are outlined in section 18 of the interim order.

## Provincial/territorial governments and health care authorities

Provincial and territorial governments and health care authorities also have an important role to play in preventing and mitigating critical medical device shortages. They can:

- conserve and reallocate stock within regions or provinces to where it is most needed and collaborate to share supply
- identify and secure additional supplies of medical devices from other vendors or another provincial or territorial government
- identify and secure other compatible, substitute medical devices

## Government of Canada

The federal government administers the *Food and Drugs Act*, *Radiation Emitting Devices Act* and *Medical Devices Regulations*.

We do not provide or 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 information sharing.

When it comes to medical device shortages, Health Canada depends on early reporting of anticipated or actual shortages to help us:

- prevent or manage impacts related to medical device shortages
- work with industry to identify mitigation strategies
- inform the procurement of medical devices for Canada

Depending on the situation, our options include:

- prioritizing the review and approval of regulatory applications received from manufacturers (for example, an application to authorize or import an acceptable compatible device)
- expediting the process for issuing Medical Device Establishment Licences (MDELs)
- permitting the importation and sale of medical devices that do not fully meet Canadian regulatory requirements, but are manufactured to comparable standards to help address device shortages
- working with international regulators to identify other manufacturers and to share needed safety and manufacturing information
- helping health care professionals and institutions get access to compatible substitute medical devices on an emergency basis (for example, the Special Access Program can be used to provide access to unlicensed alternative medical devices)

As part of the Government of Canada's response to COVID-19, the Public Health Agency of Canada is working with other government departments to procure bulk shipments to facilitate access to much-needed medical devices. These include ventilators, testing swabs, reagents, test kits and personal protective equipment.

# Who must report

Under section 15(1) of Interim Order No. 2, manufacturers and importers must report medical device shortages to Health Canada for devices that are on the List of medical devices: Notification of shortages.

To avoid duplicate reporting, under section 16, a manufacturer may designate an importer of a medical device to prepare and submit a shortage report on its behalf. This is permitted only when the information that would have been reported by the manufacturer and importer is identical.

To delegate an importer, the manufacturer must submit a delegation of mandatory shortage reporting for medical devices authorization using the following form.

- Authorization Form (FRM-0451)

Email the form to Health Canada at hc.meddev-matmed.sc@canada.ca.

# What must be reported

For mandatory reporting under sections 15(2) to 15(4) of Interim Order No. 2, manufacturers and importers must file the following reports within the specified 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)

Manufacturers and importers do not need to report a medical device shortage to Health Canada if the manufacturer anticipates to meet the demand for the device or for its components, accessories or parts within 30 days after the day they anticipate or become aware of the shortage. (See section 15(5) of Interim Order No. 2.) This includes devices that are on back-order for less than 30 days.

Manufacturers and importers must report a medical device shortage if they determine they are unable to meet the demand for the device within a 30-day period. (See section 15(6).) For example, a back-order becomes a shortage and must be reported to Health Canada if it cannot be resolved within 30 days. A shortage report must be reported within 5 business days from when the manufacturer or importer become aware that a shortage or back-order situation will exceed 30 days.

Situations in which medical device shortages do **not** need to be reported include:

- an actual or an anticipated shortage for Class II, III and IV medical devices that are not licensed for sale in Canada
- an actual or an anticipated shortage for Class I medical devices that are not authorized for sale or import by a Medical Device Establishment Licence (MDEL) holder
- an actual or an anticipated shortage for medical devices that are not currently being sold in Canada
- a manufacturer or importer has a device in back-order that is not expected to go beyond 30 days

- a manufacturer is also the manufacturer of a substitute medical device and is able to meet demand for it in Canada
- a manufacturer or importer has never sold or imported medical devices in Canada and is having problems obtaining supply
- a manufacturer or importer is not actively selling in Canada and doesn't have any orders in Canada
- disruptions in manufacturing that are leading to a "longer lead time" but the disruptions do not result in a shortage
    - "longer lead time" is the prolonged typical turnaround time it takes a manufacturer to deliver a device to a customer
- a medical device has been discontinued
    - the manufacturer has stopped selling the device in Canada

Manufacturers, importers and other stakeholders are also encouraged to **voluntarily report** shortages of medical devices not included on the list of specified medical devices when:

- the shortage may cause a patient or user safety issue in Canada
- a compatible substitute medical device, component, accessory or part isn't available in Canada or can't be easily replaced
    - for example, due to capital equipment costs, regulatory requirements to validate procedures, lack of compatibility of surgical instruments or with other devices, extensive training

This information helps us determine whether we should add a certain medical device to the list of specified medical devices for mandatory reporting.

If you are not sure whether to report a shortage of a device, please contact the Medical Devices and Clinical Compliance Directorate at hc.meddev-matmed.sc@canada.ca.

# When and how to report

## When to report

The following 10 scenarios will help manufacturers and importers understand the timelines for reporting or updating shortage reports.

### Scenario 1: A back-order of less than 30 days

- No shortage report is required.

### Scenario 2: A back-order of more than 30 days

- A shortage report must be submitted within 5 business days from the day the manufacturer/importer is aware that a shortage is likely to occur and when the manufacturer responsible for reporting the shortage has no identified substitute device available in Canada.

### Scenario 3: An initial back-order of less than 30 days is then extended to more than 30 days

- A shortage report must be submitted within 5 business days from the day the manufacturer/importer is aware that the back-order has been extended beyond 30 days and when the manufacturer responsible for reporting the shortage has no identified substitute device available in Canada.

### Scenario 4: The manufacturer/importer's typical lead time is more than 30 days

- No shortage report is required.

### Scenario 5: The typical lead time is more than 30 days and has been extended (back-ordered) by less than 30 days

- No shortage report is required.

### Scenario 6: The manufacturer/importer's typical lead time is more than 30 days and has been extended (back-ordered) by 30 days or more

- A shortage report must be submitted within 5 business days from the day the manufacturer/importer is aware that the back-order has been extended beyond 30 days and when the manufacturer responsible for reporting the shortage has no identified substitute device available in Canada.

### Scenario 7: The 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.

### Scenario 8: The 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) and when the manufacturer responsible for reporting the shortage has no identified substitute device available in Canada.

### Scenario 9: The information the manufacturer/importer submitted to Heath Canada about a medical device shortage has changed

- A shortage report update must be submitted within 2 business days of becoming aware of the change.

### Scenario 10: The shortage for a medical device has ended

- An end-of-shortage report must be submitted within 2 business days from the day the manufacturer/importer is aware that the shortage has ended (include this date in the report as the end date for the shortage).

## How to report

Manufacturers and importers must report actual or anticipated shortages for specified medical devices that are on the List of medical devices: Notification of shortages. These include devices authorized for importation or sale under another interim order made under section 30.1 of the *Food and Drugs Act*.

Health Canada updates the List of medical devices: Notification of shortages regularly. Manufacturers and importers are responsible for reviewing this list to ensure that they are submitting mandatory shortage reports for the required medical devices. Health Canada will not notify companies each time this list is updated.

To report an actual or an anticipated 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:

- Electronic reporting form for a medical device shortage

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.

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

- name and contact information for the manufacturer or the importer
- Medical Device Licence (MDL) number in the case of Class II, III or IV devices
- authorization identification number in the case of 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 is a single-use device
- date on which the shortage began or is anticipated to begin
- date on which the manufacturer anticipates meeting the demand for the medical device, if known

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.

The following information must be provided for each additional device:

- medical device licence number in the case of Class II, III or IV devices
- authorization identification number in the case of 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
- date on which the shortage began or is anticipated to begin
- date on which the manufacturer anticipates meeting the demand for the medical device, if known

A shortage is 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 in the near future or
- an acceptable substitute option has been found by the manufacturer reporting the shortage

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

- Report the end of a medical device shortage form

A manufacturer or importer may submit multiple end of shortage reports on a single reporting form as long as the devices being reported are from the same manufacturer.

If you are not sure whether to notify us about a shortage of a particular device, email us at hc.meddev-matmed.sc@canada.ca.

Once we receive a report that a shortage has ended, we will update the list of shortages to reflect this new information.

# What happens to your report

Once Health Canada receives a medical device shortage report, we follow up with the manufacturer to ask additional questions about the company's supply and demand. We also confirm whether the:

- report meets the definition of a shortage
- manufacturer has an acceptable substitute option available in Canada

Interim Order No. 2 allows the Minister of Health to compel manufacturers, importers or distributors who import or sell a medical device to provide information within their control about a shortage or potential shortage of the device under certain conditions.

The information that may be requested does not include personal information on a patient, user or any other person whose health or safety may be adversely affected by the medical device being in shortage. (See section 18(3) of Interim Order No. 2.) Requested information is treated as confidential business information and is not shared with any external stakeholders without prior consultation with the company.

We use this information to:

- work with the manufacturer to identify mitigation strategies and
- help inform the procurement of medical devices for Canada

An acceptable substitute option must be available in a sufficient quantity and quality. A suitable option is:

- a Class I device that is sold or imported by an authorized Medical Device Establishment Licence (MDEL) holder or
- a Class II to IV device that is licensed by Health Canada or
- any device that is authorized for sale or import under another interim order made under section 30.1 of the *Food and Drugs Act*

We will post information about the shortage on the list of shortages if we determine that the:

- shortage report meets the definition of a shortage and
- reporting manufacturer does not have an acceptable substitute option available for sale in Canada

This information:

- alerts health care facilities and other manufacturers of the supply gaps
- helps health care providers and patients make timely and informed choices about their health
- helps to minimize the impact on patient care

Each device on the list of medical device shortages is linked to a detailed report. The reports contain the following information:

- type and status of the shortage (actual, anticipated, resolved, avoided)
- name of medical device, as well as any component, accessory or part that is in shortage, including the model name
- other names (for example, trade name)
- anticipated or actual start date of shortage
- estimated end date of shortage
- reason for shortage
- names of importers listed who have reported the shortage 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 number (for Class II, III and IV), if applicable
- 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

# Definitions and interpretation

## 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

**Substitute device**, such as:

- Class I device that's authorized for sale or import by a Medical Device Establishment Licence (MDEL) holder
- Class II to IV device that's licensed by Health Canada
- any device that is authorized for sale or import under another interim order made under section 30.1 of the *Food and Drugs Act*

**List of medical devices: Notification of shortages:** Canada's List of medical devices: Notification of shortages is amended from time to time

**Specified medical device:** a medical device that is:

- set out in the List of medical devices: Notification of shortages or
- is part of a category of medical devices that is set out in that list

**Shortage:** a situation in which the manufacturer of a medical device is unable to meet the Canadian market demand for the device or for its components, accessories or parts

Does not include a situation in which the manufacturer is also the manufacturer of a substitute medical device, component, accessory or part and is able to meet demand for it

**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:

- an acceptable substitute option has been found
- 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*

**Back-order:** device is temporarily unavailable and the manufacturer is unable to fulfill customer orders

A back-order is considered to become a shortage if it cannot be resolved within 30 days and there is no identified substitute device available in Canada

**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 the medical device being brought into Canada for sale

**Lead time:** typical time from when a customer makes a medical device purchase order to when a manufacturer is able to deliver it to a customer

## Interpretation

Electronic Reporting Form - Reason for Shortage section:

- **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 due to lockdown or social distancing
- **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
    - 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 limits the number of devices allowed for export to other countries