Health Canada Santé Canada

Guide on the requirements for providing information related to drug shortages(GUI-0146)

November 28, 2021

Canada

Date approved: November 8, 2021
Effective date: November 28, 2021

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Également disponible en français sous le titre: Guide sur les exigences relatives à la transmission d'informations sur les pénuries de médicaments (GUI-0146)

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Cat.: H139-31/2021E-PDF
ISBN: 978-0-660-40694-7
Pub.: 210402

Disclaimer: This document does not constitute legislation. In the event of any inconsistency or conflict between the legislation and this document, the legislation takes precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the legislation and the applicable administrative policies.

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Introduction

The Interim Order respecting drug shortages (safeguarding the drug supply) took effect on November 27, 2020. The interim order (IO) allowed Health Canada to compel a market authorization holder (MAH) or drug establishment licence (DEL) holder to provide information on an actual or anticipated drug shortage.

The provisions of that 1-year IO have been made permanent through amendments to the *Food and Drug Regulations* (FDR). These provisions, contained in sections C.01.014.8, C.10.004 and C.01.014.12 of the FDR, come into force on November 28, 2021. This date follows the day on which the IO ceases to have effect.

Health Canada is responsible for helping the people of Canada maintain and improve their health. This is done, in part, by our commitment and actions to help protect the Canadian drug supply, thus ensuring that people in Canada have access to the drugs they need when they need them.

Health Canada works with stakeholders across the drug supply chain to:

- determine the details and status of an actual or anticipated drug shortage
- coordinate information-sharing between parties
- identify mitigation strategies

Mitigation strategies include exploring access to international supply and facilitating efforts by companies, whenever possible and appropriate, to make additional supply available to Canadians.

For more information on drug shortages and the roles of various parties in addressing them, refer to the drug shortages in Canada page.

Purpose and scope

Purpose

This guidance document is meant to help regulated parties understand how to comply with the regulations. Italso provides guidance to Health Canada staff, so that the rules are enforced fairly, consistently and effectively.

This guidance document will help you understand sections C.01.014.8, C.10.004 and C.01.014.12 of the FDR by outlining:

- the circumstances where it is mandatory for MAHs or DEL holders to provide information to HealthCanada
- the manner in which Health Canada would require information to be provided

Scope

Inclusions

Sections C.01.014.8, C.10.004 and C.01.014.12 of the FDR applies to the following drugs for human use that have a Canadian drugidentification number:

- drugs that may be sold without a prescription, but are administered only under a practitioner's supervision
  - also known as 'ethical' drugs (for example, hemodialysis solutions, pre-filled syringes with epinephrine for severe allergic reactions, MRI contrast agents)
- drugs on the Prescription Drug List
- drugs listed in Schedules C and D of the *Food and Drugs Act*
- drugs listed in Schedules I, II, III, IV or V of the *Controlled Drugs and Substances Act*

Exclusions

Natural health products, over-the-counter drugs and drugs for veterinary use are excluded from the scope of these provisions.

Responsibilities of MAHs/DEL holders and Health Canada

Sections C.01.014.8, C.10.004 and C.01.014.12 of the FDR applies to MAHs and DEL holders. For more information on when DELs arerequired and how to obtain one, refer to the Guidance on drug establishment licences (GUI-0002).

Responsibilities of MAHs and DEL holders

MAHs and DEL holders are responsible for providing the needed information on an actual or anticipated drug shortage to Health Canada in the format and time limit indicated by Health Canada.

Responsibilities of Health Canada

Health Canada, determines the drugs for which information is needed in order to prevent or mitigate a drug shortage. Health Canada will provide MAHs and DEL holders with a reasonable amount of time to provide the information. As per laws governing the use of information, Health Canada will use the information only for the purpose for which it was collected.

We may take compliance and enforcement actions for failure to meet the requirements of these regulations. Consult our compliance and enforcement policy for health products (POL-0001).

The regulations

In the section below, the exact text from the FDR (section C.01.014.12) is provided first, followed by an interpretation.

Text on providing information

Regulatory text

The Minister may request that the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for a drug- or any person who holds an establishment licence in respect of a drug- provide the Minister with information that is in their control if the Minister has reasonable grounds to believe that:

(a) there is a shortage or risk of shortage of the drug;

(b) the information is necessary to establish or assess

  (i) the existence of a shortage or risk of shortage of the drug,

  (ii) the reason for a shortage or risk of shortage of the drug,

  (iii) the effects or potential effects on human health of a shortage of the drug, or

  (iv) measures that could be taken to prevent or alleviate a shortage of the drug; and

(c) the manufacturer or licensee will not provide the information without a legal obligation to do so.(section C.01.014.12 (1))

Interpretation

A person is an individual or an *organization* as defined in section 2 of the *Criminal Code*.

Health Canada will act on behalf of the Minister in assuming the responsibilities mentioned above.

Three conditions must be met for Health Canada to require you to provide information on an actual or anticipated drug shortage. Health Canada must have reasonable grounds to believe that:

1) there's a shortage of the drug or the drug is at risk of going into shortage
2) the information is necessary to establish or assess one or more of the following:
   - the existence of a drug shortage or risk of shortage for the drug
   - the reasons for a drug shortage or risk of shortage for the drug
   - the effects or potential effects on human health of a shortage of the drug
   - measures that could be taken to prevent or alleviate a shortage of the drug
3) the MAH or DEL holder will not provide the information without a legal obligation to do so

Health Canada considers a number of factors when determining whether to collect information on a drug and when assessing the type of information to be provided. These include:

- mandatory drug shortage reports
- environmental scans
- inspection reports or reports covering other quality issues
- information from within the federal government or from external sources such as patients, healthcare professionals, provincial and territorial partners, and international regulatory agencies
- media reports
- consultations with clinicians
- academic literature
- past experience or knowledge

Note: Health Canada will continue to work with companies, provinces and territories and stakeholders from across the drug supply chain to address actual or anticipated shortages. Sharing information voluntarily helps mitigate shortages.

This regulatory power will only be used where the criteria for requiring the information have been met and the information is notvoluntarily provided by the MAH/DEL holder.

Types of information that must be provided

Health Canada can only use the authority under these regulations to obtain from an MAH or a person who holds a DEL information that is within their control.

Process for providing information

Health Canada will provide the MAH or DEL holder with a set of instructions for providing the information. The MAH or DEL holder will also receive a written reason for why this information is required. This allows for more transparent decision-making.

A request for required information will include:

- the name of the MAH or DEL holder
- the regulatory authority being relied upon
- the drug(s) in question
- a description of the information in the person's control that the Minister has reasonable grounds tobelieve is necessary to determine if:
    - the product is at risk of a drug shortage and
    - the drug shortage presents a risk to human health or the information could help prevent oralleviate the drug shortage
- the timeframe for providing the information
- the format for submitting the information

The information must be submitted by the deadline in the format specified.Health Canada may follow up with more questions should the need arise.

Contact us

For questions about drug shortage and discontinuation regulations, contact us at Drug.shortages-Penurie.de.medicament@hc-sc.gc.ca.

Definitions

Actual shortage: a manufacturer's current supply cannot meet current demand in Canada *(pénurie réelle)* (refer to "Shortage")

Anticipated shortage: a manufacturer's future supply cannot meet projected demand in Canada *(pénurie anticipée)* (refer to "Shortage")

Drug: any of the following drugs for human use:

(a) drugs included in Schedule I, II, III, IV or V to the *Controlled Drugs and Substances Act*;
(b) prescription drugs;
(c) drugs that are listed in Schedule C or D to the Act; and
(d) drugs that are permitted to be sold without a prescription but that are to be administered only underthe supervision of a practitioner. (*drogue*) (FDR, C.10.004 (1))

For clarity, prescription drugs are found on the Prescription Drug List

Drug establishment licence (DEL): a licence issued to a person in Canada pursuant to Division 1A of the FDR to conduct licensable activities in a building which has been inspected and assessed as being in compliance with the requirements of Divisions 2 to 4 of the *Food and Drug Regulations* *(Licence d'établissement de produits pharmaceutiques (LEPP))*

Drug identification number (DIN): an 8-digit numerical code assigned by Health Canada to each drug product marketed under the *Food and Drugs Act* and Regulations

A DIN uniquely identifies the following product characteristics: manufacturer, brand name, medicinal ingredient(s), strength of medicinal ingredients(s), pharmaceutical form, route of administration (*numéro d'identification d'un médicament*)

Establishment licence: Refer to Drug Establishment Licence above

Manufacturer: a person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word, or mark controlled by them, sells a food ordrug (*fabricant*) (FDR, A.01.010)

Market authorization holder (MAH): the legal entity that holds the notice of compliance, the drug identification number (DIN), the medical device licence, the product licence or that has received authorization to import and sell a drug for the purpose of a clinical trial (détenteurs d'une autorisation de mise sur le marché (DAMM))

Person: an individual or an *organization* as defined in section 2 of the *Criminal Code* (*personne*) (FDA, section 2)

Shortage: in respect of a drug, a situation in which the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for the drug is unable to meet the demand for the drug in Canada (*pénurie*) (FDR, C.01.014.8 (2))

References

Legislation and regulations

- *Controlled Drugs and Substances Act*
- *Criminal Code*
- *Food and Drugs Act*
- *Food and Drug Regulations*
- *Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply)*
- *Regulations Amending Certain Regulations Concerning Drugs and Medical Devices (Shortages): SOR/2021-199*

Policies and Guides

- Compliance and enforcement policy for health products (POL-0001)
- Guidance on drug establishment licences (GUI-0002)

Web pages/Associated documents

- Canada Gazette, Part I, Volume 154, Number 50: Government Notices
- Drug shortages homepage for mandatory drug shortage reports
- Prescription Drug List
- Drug Shortages in Canada

Contacts

- Health Canada Drug Shortages Division
  Drug.shortages-Penurie.de.medicament@hc-sc.gc.ca

Related links

Legislation and regulations

- Notice: Regulations amending certain regulations concerning drugs and medical devices (shortages)

Guidance on drug shortages

- Guide to the exceptional importation and sale of drugs in response to drug shortages (GUI-0148)
- Guide to distributing drugs intended for the Canadian market for consumption or use outside Canada (GUI-0145)
- Guide to reporting drug shortages and discontinuations (GUI-0120)