Health Canada Santé Canada

Guide to distributing drugs intended for the Canadian market for consumption or use outside Canada (GUI-0145)

November 28, 2021

Canada

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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 la distribution des médicaments destinés au marché canadien pour consommation ou usage à l'extérieur du Canada (GUI-0145)

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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) prohibited a drug establishment licence (DEL) holder from distributing drugs intended for the Canadian market for consumption or use outside Canada if they had reasonable grounds to believe the distribution would cause or exacerbate a drug shortage.

The provisions of that 1-year IO have been made permanent through amendments to the *Food and Drug Regulations*. These provisions, contained in sections C.01.014.8, C.10.004 and C.01.014.13 to C.01.014.14 of the *Food and Drug Regulations* (FDR), come into force on November 28, 2021. This date follows the day on which the IO ceases to have effect.

DEL holders who distributed drugs for consumption or use outside of Canada between November 27, 2020, and November 27, 2021, must keep records of the assessment to show that there were reasonable grounds to believe that the distribution would not cause or exacerbate a shortage. DEL holders must do so until at least 1 year after the latest expiry date of the drug distributed.

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 expects stakeholders across the drug supply chain to make business decisions that keep in mind the stability of the Canadian drug supply. For more information on drug shortages and the various roles and responsibilities in addressing them, refer to drug shortages in Canada.

Purpose and scope

Purpose

This guidance document sets out Health Canada's interpretation of the requirements in sections C.01.014.8, C.10.004 and C.01.014.13 to C.01.014.14 of the FDR. These sections prohibit the holder of a DEL from distributing drugs intended for the Canadian market for consumption or use outside Canada unless the licensee has reasonable grounds to believe that doing so would not cause or worsen a drug shortage. The sections were implemented to safeguard the Canadian drug supply and help ensure that the people of Canada have continuous access to the drugs they need to maintain their health.

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

This guidance document will outline:

- when a DEL holder is allowed to distribute drugs intended for the Canadian market for consumption or use outside Canada in the context of drug shortages
- the type of analysis a DEL holder should perform in determining whether such distributions are allowed
- the types of records a DEL holder must keep when distributing drugs meant for the Canadian market for consumption or use in other countries

Scope

Inclusions

Sections C.01.014.8, C.10.004 and C.01.014.13 to C.01.014.14 of the FDR apply to distribution by a DEL holder of the following drugs intended for the Canadian market for human consumption or use outside Canada:

- drugs that may be sold without a prescription, but are administered only under a practitioner's supervision
- 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.

Sections C.01.014.8, C.10.004 and C.01.014.13 to C.01.014.14 of the FDR do not apply to:

- sales made by a person who is not required to hold a DEL (for example, pharmacies selling drugs at the retail level)
- exports of drugs that are imported for the sole purpose of export (transhipment)
- exports of drugs that are manufactured in Canada for the sole purpose of export

Responsibilities of MAHs/DEL holders and Health Canada

Sections C.01.014.8, C.10.004 and C.01.014.13 to C.01.014.14 of the FDR apply to DEL holders. For more information on when DELs are required and how to obtain one, consult the Guidance on drug establishment licences (GUI-0002).

Responsibilities of DEL holders

DEL holders are responsible for the following:

- ensuring they have reasonable grounds to believe that the decision to distribute drugs intended for the Canadian market for consumption or use outside Canada does not cause or worsen a shortage
- maintaining a record of their decision to distribute all drugs intended for the Canadian market for consumption or use outside Canada that are subject to C.01.014.8, C.10.004 and C.01.014.13 to C.01.014.14 of the FDR (products with a drug identification number (DIN)) for a minimum of 1 year after the latest expiry date for those drugs

Note: Any changes to the status of the DEL (for example, DEL cancelled or not renewed) would not change the person's responsibilities for maintaining the records until 1 year after the latest expiry of the drugs.

Responsibilities of Health Canada

Health Canada is responsible for compliance monitoring and enforcement activities related to health products in order to verify that regulatory requirements are being met.

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

The regulations

For each section below, the exact text from the FDR is provided first. This is followed by Health Canada's interpretation.

The prohibition

Regulatory text

No person who holds an establishment licence shall distribute a drug for consumption or use outside Canada unless the licensee has reasonable grounds to believe that the distribution will not cause or exacerbate a shortage of the drug. (section C.01.014.13)

Interpretation

These regulations apply to any distribution of in-scope drugs by DEL holders. A Canadian drug is defined above, is approved by Health Canada (assigned a DIN) and labelled with a Canadian label. Such drugs are considered to be intended for the Canadian market.

Before distributing a drug intended for the Canadian market for consumption or use outside Canada, DEL holders must evaluate the impact that the distribution would have on Canada's drug supply. Distribution in the context of this prohibition includes the act of shipping, selling and/or delivering a drug. This includes the export of drugs meant for the Canadian market for consumption or use in other countries.

DEL holder responsibility

You must evaluate the potential impact on the Canadian drug supply if you are considering distributing a drug intended for the Canadian market for consumption or use in another country. You should base your analysis on information available to you at the time of export/distribution. This analysis, which includes publicly available information and your organization's business intelligence, must be documented.

Examples of factors to consider in your assessment of drug shortage risks are included in Table 1 (not an exhaustive list). Other factors may need to be considered based on the specific situation of the drug being evaluated for potential distribution.

Table 1: Examples of factors to consider in an assessment of drug shortage risks

Consideration	Context
Is the drug listed as a Tier 3 drug shortage?	Tier 3 drug shortages have the greatest potential impact on Canada's drug supply and health care system. It would be difficult to show reasonable grounds to believe that distributing a drug in a Tier 3 drug shortage for consumption or use outside Canada would not cause a shortage, as there are established shortage concerns for the drug.
Are there any actual or anticipated drug shortages or discontinuations of the drug reported on the mandatory drug shortage reporting webpage?	Further analysis will be required if there are actual or anticipated shortages of a drug to determine, to the best of your knowledge, if the reported drug shortages are likely to cause availability issues for people in Canada that can't be addressed by other suppliers.
Will the distribution of the drug for use outside Canada impact your ability to meet your Canadian customers' requirements?	If yes, it would be difficult to show reasonable grounds to believe that distributing the drug for use outside Canada would not cause a shortage.
Is the quantity of drug under consideration for distribution for use outside Canada significant compared to: • your historic sales • your current inventory • overall national sales	Careful consideration will be required if the potential quantity of drugs to be exported is substantial. Companies will need to clearly demonstrate that the exports will not cause or worsen a drug shortage in Canada. This includes an examination of their known market share.
Is this a sole-source drug or a drug with a limited number of market authorization holders?	Drug shortages of sole-sourced drugs or drugs produced by companies with dominant market shares are a concern. Sole-sourced drugs and drugs with a small number of suppliers (or a dominant supplier in terms of market share) are considered to be at a higher risk of drug shortage.

Consideration	Context
Do you expect any demand changes for the drug?	Demand changes can be caused by a variety of factors, such as: • drug shortages reported by other manufacturers • shortages of alternative drugs and environmental factors (for example, the COVID-19 pandemic caused major changes in drug demand) Assessments of demand projections should be included in your analysis.
Is there a shortage of the drug in other markets?	Assess the global supply situation to determine if there is a risk of a shortage of this drug in Canada.
Are you aware of any other issues that may impact supply of this drug in Canada (for example, supply chain issues, shipping delays, material shortages, environmental/natural disasters such as floods or fires)?	Further assessment is required to ensure that issues which may result in a shortage of the drug in Canada are considered. There may be context specific to the drug in question that is relevant to your decision-making.

The table above is not an exhaustive list of examples of factors to consider when determining whether there are reasonable grounds to believe that drugs meant for the Canadian market can be distributed for consumption or use outside of Canada without causing or worsening a shortage.

Potential decisions to make:

- **Distribution prohibited:** if you have reasonable grounds to believe that the distribution of a drug meant for the Canadian market for consumption or use outside Canada would cause a drug shortage or exacerbate an existing drug shortage
- **Distribution permitted:** if you have no reasonable grounds to believe that the distribution would result in a drug shortage or make an existing drug shortage worse, distribution is permitted, and you maintain records of the rationale for this determination (refer to section entitled "Requirements for making and retaining records")

Requirements for making and retaining records

Regulatory text

If a person who holds an establishment licence distributes a drug for consumption or use outside Canada, the licensee shall immediately create a detailed record of the information that they relied on to determine that the distribution of the drug is not prohibited by section C.01.014.13. (section C.01.014.14 (1))

The licensee shall retain the record for at least one year after the latest expiration date of the drug that they distributed. (section C.01.014.14 (2)).

Interpretation

Before distribution, you must conduct a thorough analysis of the potential distribution of drugs intended for the Canadian market for consumption or use outside Canada. A non-exhaustive list of examples of factors to consider are described in Table 1. This is done to help determine if there are reasonable grounds to believe distributing the drug would cause or worsen a drug shortage. You must keep documentation of this analysis, which should clearly justify your conclusions about shortage concerns, including the sources of information and the date(s) they were accessed.

You must maintain these records until 1 year after the latest expiration date of the distributed drugs.

As part of regulatory compliance verification activities, Health Canada may require your assessment if you distributed for consumption or use outside Canada any Canadian drugs that are subject to C.01.014.13 to C.01.014.14 of the FDR.

Under section C.01.014.12 of the FDR, we may require you to provide information on a drug shortage. For more information about this provision, refer to the Guidance on requirements for providing information related to drug shortages (GUI-0146).

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 under the 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)

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

Tier 3 shortage: drug shortages that are deemed the most critical national shortages determined by a specially convened Tier Assignment Committee on a case-by-case basis (les pénuries de niveau 3)

Transhipment: after goods have been unloaded or in any way removed from the means of transportation by which they came into Canada, their loading, placing on board or within or upon the same or any other means of transportation (*transbordement*) (*Transhipment Regulations Part II, Section 3*)

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)*
- *Transhipment Regulations, Part II, Section 3*
- *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

- Drug shortages homepage for mandatory drug shortage reports
- Drug Shortages in Canada
- List of Tier 3 drug shortages
- Prescription Drug List

Contacts

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

Related links

Legislation and regulations

- Canada Gazette, Part II, volume 155, number 18
- 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 on the requirements for providing information related to drug shortages (GUI-0146)
- Guide to reporting drug shortages and discontinuations (GUI-0120)

Web pages/Associated documents

- Canada Gazette, Part I, Volume 154, Number 50: Government Notices