Health Canada Santé Canada

Guide to the exceptional importation and sale of drugs in response to drug shortages (GUI-0148)

March 2, 2022

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 useof the public health care system.

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To obtain additional information, please contact:Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
Email: publications@hc-sc.gc.ca

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Introduction

Health Canada is responsible for helping people in Canada maintain and improve their health. This is done, in part, by helping to ensure that people in Canada have access to the drugs they need when they need them and that these drugs meet an acceptable level of safety.

Sections C.01.014.8 and C.10.004 to C.10.011 of the *Food and Drug Regulations* (FDR) create a framework for the exceptional importation and sale of foreign-authorized drugs. This framework was created to help prevent and mitigate drug shortages.

Drugs imported under this framework are labelled for a foreign market, but have been manufactured according to quality standards similar to those required in Canada. These drugs do not receive a Canadian notice of compliance. They are only permitted to be imported for sale during a limited period of time.

Exceptional importation was initially implemented through the following interim orders:

- Interim Order respecting drugs, medical devices and foods for a special dietary purpose in relation to COVID-19 (IO No. 1), effective March 18, 2020, to February 28, 2021
- Second Interim Order respecting drugs, medical devices and foods for a special dietary purpose in relation to COVID-19 (IO No. 2), effective March 1, 2021, to February 28, 2022

The provisions for the exceptional importation framework from IO No. 2, with some modifications, were made permanent through amendments to the FDR. The entry into force of these provisions was March 2, 2022, the day after IO No. 2 ceased to have effect.

Transitional provisions are included in the regulatory amendments for regulated parties that have imported drugs in accordance with IO No. 2 and must now come into compliance with the regulatory framework.

For more information on drug shortages and the roles of various parties in addressing shortage situations, consult the Drug Shortages in Canada page.

Purpose and scope

Purpose

This guidance document is meant to help drug establishment licence (DEL) holders involved in the exceptional importation and sale of drugs understand how to comply with the regulations. This document is intended to help you understand sections C.01.014.8 and C.10.004 to C.10.011 of the FDR by outlining:

- what is meant by exceptional importation and sale
- the circumstances where a foreign-authorized drug may be eligible for exceptional importation and sale in Canada
- the application process for the exceptional importation and sale of foreign-authorized drugs
- the regulatory requirements for the exceptional importation and sale of foreign-authorized drugs
- good manufacturing practices (GMP) requirements for the exceptional importation and sale of foreign-authorized drugs
- provisions for the transition from the IO No. 2 to FDR requirements

Scope

Inclusions

Sections C.01.014.8 and C.10.004 to C.10.011 of the FDR apply to the following drugs for human use that have a Canadian drug identification number (DIN):

- drugs that may be sold without a prescription, but are administered only under a practitioner's supervision
    - commonly referred to 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 (the Act)*
    - known as *radiopharmaceuticals and biological drugs*
    - 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.

Understanding the regulations

Exceptional Importation

Subject to sections C.01.014.8 and C.10.004 to C10.011 of the FDR, Health Canada may allow the exceptional importation and sale of a foreign-authorized drug by adding it to the List of Drugs for Exceptional Importation and Sale (the list). The list is incorporated by reference into the FDR and is updated as required. In order to have a foreign-authorized drug added to the list, the importer must hold an active DEL that meets the requirements laid out in the DEL information section.

Drugs on this list are known as designated drugs. They may be imported and sold to prevent or mitigate a drug shortage.

Examples of drugs that may be eligible for exceptional importation and sale (not an exhaustive list) include:

- a drug that is identical to a Canadian-authorized drug but has a foreign authorization, and consequently a foreign label (for example, a manufacturing site may make the same drug for many different markets)
- a drug that has been authorized by a regulatory authority in another country and Health Canada has reasonable grounds to believe the drug can be substituted for the Canadian-authorized drug in shortage or at risk of shortage
    - the drug must also be manufactured to similar quality standards to the Canadian-authorized drug

  For a drug to be considered eligible for exceptional importation and sale in order to prevent or address a drug shortage, Health Canada has established the following criterion through policy:
- there is an anticipated or actual critical shortage (Tier 3 or other critical shortage) of the Canadian-authorized version of the drug

Critical drug shortages are almost always national in scope and fall into one of 2 categories:

1. Tier 3 drug shortages: The Protocol for the Notification and Communication of Drug Shortages sets out a tiered classification system for drug shortages. Tier 3 shortages are drug shortages that are expected to have the most significant impact on the Canadian drug supply and health care system. Impact is largely determined based on low availability of alternative supplies, ingredients or therapies. Tier 3 drug shortages are determined by a Tier Assignment Committee (TAC), which is an ad hoc committee of federal and provincial/territorial governments, health care professionals and industry stakeholders. Drugs assessed by the TAC to be in a Tier 3 shortage are posted online in the List of Tier 3 Drug Shortages. All Tier 3 shortages are considered to be critical drug shortages.
2. Shortages with specific patient impacts: Other shortages not meeting the definition of a Tier 3 shortage may be considered to be critical if certain patient groups (for example, niche drugs that would affect a small number of patients) are likely to experience a serious impact.

Health Canada will consider proposals for adding a foreign-authorized drug to the List of Drugs for Exceptional Importation and Sale if the Canadian drug is considered to be in or at risk of a critical shortage.

The exceptional importation and sale framework is meant to complement other pathways that exist for accessing drugs under various special circumstances. Examples of such pathways are:

- the List of Drugs for an Urgent Public Health Need, as set out in Part C, Division 10 of the FDR: Access to drugs in exceptional circumstances and explained in Access to Drugs in Exceptional Circumstances
- the Special Access Program for Drugs, described in sections C.08.010 and C.08.011 of the FDR: Sale of new drug for emergency treatment

The following sections describe the process leading to the exceptional importation and sale and the importation and sale requirements.

Submitting a proposal and adding a drug to the List of Drugs for Exceptional Importation and Sale

Submitting a proposal

Regulatory requirements outlining when a drug may be added to the List of Drugs for Exceptional Importation and Sale are found in section C.10.005 of the FDR.

Health Canada has developed a process by which a DEL holder can submit a proposal to add a drug to the List of Drugs for Exceptional Importation and Sale. We will only consider proposals for foreign-authorized drugs that are considered appropriate substitutes for a drug in or at risk of a critical shortage.

Email the completed proposal form to drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca.

The details provided in the proposal form allow Health Canada to assess the foreign-authorized drug under consideration to determine if there are reasonable grounds to believe:

- the drug is an appropriate substitute for the Canadian drug in actual or anticipated shortage
- the DEL holder meets regulatory requirements for the applicable licensable activities to ensure safe use of the drug in Canada

This information, which will be reviewed on a case-by-case basis, includes:

- product-specific information
- DEL information

Product-specific information:

- product labelling (for example, conditions of use, approved indication in the country of authorization)
- product formulation
- clinical and quality information (for example, chemistry and manufacturing processes, and specifications of the drug substance and drug product)
- how this information may differ from a Canadian-authorized product

DEL information:

To have a drug added to the List of Drugs for Exceptional Importation and Sale:

- a company must hold an active DEL for the appropriate activity, category (for example, pharmaceutical or biologic) and dosage from (for example, tablet)
- the DEL's Foreign Building Annex must include the following:
    - all buildings involved in fabricating, packaging/labelling and/or testing the finished dosage form of the drug outside of Canada, including finished dosage form intermediates, for the applicable activity, category of drugs and dosage form
- the DEL's active pharmaceutical ingredient (API) Foreign Building Annex must include the following:
    - all buildings fabricating, packaging/labelling and/or testing APIs, including API intermediates, that are being imported by the Canadian building for the applicable activity, category of drugs and API form class
    - all buildings fabricating, packaging/labelling and/or testing APIs, including API intermediates, that are used in the fabrication of the finished drugs, that are being imported by the Canadian building for the applicable activity, category of drugs and API form class

For more information on the DEL application process and requirements, consult the:

- Guidance on drug establishment licences (GUI-0002) and
- Guidance on management of applications and performance for drug establishment licences (GUI-0127)

When amending a DEL Foreign Building Annex and API Foreign Building Annex, please consult the Guidance document on how to demonstrate foreign building compliance with drug GMP (GUI-0080) for more information.

To address a critical drug shortage, Health Canada may expedite the process to issue or amend a DEL in order to facilitate exceptional importation.

Health Canada will follow up with the DEL holder if any additional information is needed to evaluate a proposal. We will communicate the results of the evaluation of the proposal to the DEL holder. In the case where a decision is made to **not** add the foreign-authorized drug to the List of Drugs for Exceptional Importation and Sale, the DEL holder will be made aware of the reason(s) for the refusal. The DEL holder may address the issues for the initial refusal through the submission of a new proposal form.

Adding a drug to the List of Drugs for Exceptional Importation and Sale

Regulatory requirements for adding a drug to the List of Drugs for Exceptional Importation and Sale are found in section C.10.005 of the FDR. Further requirements related to the information required for the list are found in section C.10.006 of the FDR.

Once a proposal is accepted, Health Canada will notify the DEL holder in an email and place the designated drug on the List of Drugs for Exceptional Importation and Sale. Designated drugs may be imported once they have been added to this list and the DEL holder has met the notification requirements as outlined in the regulations.

Once imported, drugs may be sold until their expiry date, even if further importation is no longer permitted. Guidance on meeting other regulatory requirements before importing and/or selling these drugs is found in the following sections.

Designated drugs do not receive full market authorization in Canada and are not assigned a DIN (FDR, section C.10.008(1)(b)).

The following information is posted publicly on the List of Drugs for Exceptional Importation and Sale:

- the DEL holder's name ("Name of Licenced Importer" on the list)
- the brand name, medicinal ingredient(s), dosage form, strength, route(s) of administration, identifying code or number (if any) assigned in the country in which it is authorized for sale, a detailed description of its conditions of use and any other information as required
- the lot number(s) of the drug, if applicable ("Specified Batch Number" on the list)
- the name of the foreign regulatory authority that authorized the sale of the drug within its jurisdiction
- responsible regulatory authority in that country
- the date that the product was added to the list
- the date after which the importation will no longer be allowed
- the maximum quantity of the designated drug to be imported or the lot numbers that have been authorized for importation, if applicable
- information to support the drug's safe use (such as the DEL holder's contact information or link to the risk communications plan)

Health Canada may modify limitations on dates and importation quantities to address the changing circumstances of a shortage. We will notify DEL holders in advance of any changes.

Companies are encouraged to evaluate the quantities required to support the Canadian market before engaging in the exceptional importation of a drug so that an excess of product is not imported. Health Canada is not responsible for designated drugs that remain unsold in Canada.

Health Canada will remove a drug from the List of Drugs for Exceptional Importation and Sale if it is determined that incorrect or misleading information was provided in the proposal or any associated requests for information. We may also remove a drug from the list based on a risk assessment, which may result in a stop sale, recall or other post-market actions. We will notify affected DEL holders as early as possible.

The List of Drugs for Exceptional Importation and Sale indicates the most recent date that the list was updated. Health Canada will work with and/or notify the affected DEL holder(s) when a change is being made. All other DEL holders may consult the list regularly to monitor the status of the various drugs on the list.

Notification requirements before importing and selling a designated drug

Regulatory provisions for notification requirements are found in section C.10.006 (1)(a) of the FDR.

DEL holders must notify Health Canada at least 3 business days before they import a designated drug. This is necessary to help avoid unnecessary processing delays at the border.

Please email your notification to drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca. Include the following information in the notification:

- DEL holder's name and contact information
- name and contact information of each fabricator, packager/labeler and tester and the address of each building in which the drug is fabricated, packaged/labelled or tested
- brand name of the drug to be imported
- medicinal ingredient(s)
- dosage form
- strength
- route of administration
- expiry date(s) of drug to be imported
- identifying code assigned in the country in which it is authorized for sale, if any
- detailed description of the conditions of use
- intended port of entry into Canada
- estimated date of arrival into Canada
- total quantity of drug to be imported on this date

DEL holders must communicate any changes to this information between the initial notification and importation dates. Changes must be communicated using drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca.

Health Canada advises DEL holders to include the customs identification number in the notification. If a DEL holder does not know the customs identification number at the time of import notification, this should not delay the submission of the import notification. You should clearly indicate if this is the case and that you will provide the number when it is available. Email us at drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca.

Information to support the safe use of the drug

Regulatory provisions for the detailed description of conditions of use of the drug are found in section C.10.011 of the FDR.

DEL holders can import a drug once it has been added to the List of Drugs for Exceptional Importation and Sale. However, the drug product cannot be sold until information is available on the conditions to support the safe use of the drug. Health Canada refers to this information as the risk communication.

Health Canada will discuss the requirements for the risk communication plan with DEL holders during the proposal review process. In most cases, companies are expected to generate letters to health care professionals informing them about the safe use of the designated drug. The letters should also contain information comparing the Canadian-authorized product to the foreign-authorized product.

Before a designated drug can be sold in Canada, risk communications to support its safe use must be finalized and available in both English and French.

A company's risk communication plan should include the following information:

- the audience for risk communications
- the method of dissemination
- a statement that Health Canada has permitted the exceptional, temporary importation and sale of the foreign-authorized product
- information to support the safe use of the designated drug, such as:
    - name of the foreign product and why it is being imported at this time
    - differences between the foreign and Canadian products that are relevant to users
    - specific recommendations for the foreign product, if any, that are identified in Health Canada's assessment, including a statement that clearly tells health care professionals about the appropriate use of the foreign product
    - where to find information about the foreign and Canadian-authorized products online
    - how to report adverse reactions
    - English and/or French translation of the foreign product label(s), if original label does not include both official languages
- a clear image of the foreign product label(s) and the final foreign product in its primary packaging to help identify the product
- additional information specified by Health Canada

For additional information about risk communication requirements, refer to the risk communication plans page.

Good manufacturing practice (GMP) requirements for selling designated drugs

Regulatory GMP requirements for selling designated drugs are found in sections C.10.008(1)(b), C.10.009 and C.10.010 of the FDR. Designated drugs must meet all GMP requirements in the FDR (Part C, Division 2 on good manufacturing practices) with the exception of the following:

Finished product testing requirements:

The requirements in section C.02.019 of the FDR have been modified for designated drugs to:

- remove the requirements for periodic complete confirmatory testing of imported designated drugs
- require visual examination to be used for identity testing of drugs imported from jurisdictions with which Canada does not have a mutual recognition agreement (non-MRA jurisdictions) if the useful life of the drug is more than 30 days
    - for a list of jurisdictions that have MRAs with Canada, visit Updates on mutual recognition agreements
    - identity testing must include a review of:
        - product labelling
        - dosage form
        - physical measurements (for example, dimensions, volume), if applicable
- clarify that the term "specifications" refers to the relevant specifications for the designated drug in the foreign jurisdiction where it was authorized

Record-keeping requirements:

The records specified in section C.02.020 (1) paragraphs a, b and d of the FDR are required to be maintained but need not be maintained on the DEL holder's premises in Canada. However, this information must be provided electronically in a format specified by or acceptable to Health Canada when requested by Health Canada.

These records include:

- validation reports
- executed batch records
- stability documentation
- master production documents

Other regulatory requirements and exemptions under the exceptional importation framework

Other regulatory requirements and exemptions under the exceptional importation framework are found in sections C.10.007 to C.10.009 of the FDR.

Designated drugs are **exempt** from the following FDR provisions:

- the prohibition on importing drugs in Canada for sale, if the sale of the drug would violate the Act or the FDR (A.01.040)
- the provision allowing for the opportunity to re-label a drug to make an imported drug sellable in Canada (A.01.044)
- the requirement to have a person in Canada who is responsible for the sale of the drug, prior to importing a drug in dosage form for sale (C.01.004.1(1))
- the prohibition on selling drugs in dosage form imported into Canada unless the following is provided on the label:
    - the importer's name
    - the principal business address in Canada of the person responsible for the drugs' sale (C.01.004.1(2))
- requirements for labels to be in both official languages (A.01.015)
- requirements for label format, prominence of information and plain language (A.01.017)
- the sampling provision that calls for duplicate analysis or examination (A.01.051)

DEL holders should note the **requirements that remain in effect**, including:

- obligation to report all adverse drug reactions and issue-related summary reports (C.01.016, C.01.017, C.01.019, C.01.020)
- obligation for hospitals or other health care institutions to report serious adverse drug reactions (C.01.020.1)
- existing requirements and controls for prescription drugs (C.01.040.3 to C.01.049)
- obligation for importers of the drug for sale who commence a recall to report certain information (C.01.051)
- all DEL requirements in Division 1A of the FDR, including listing foreign buildings on their licence (see the DEL information section)
- all GMP requirements in Division 2 of the FDR, except for those specifically described in the GMP requirements section

Note: All other applicable FDR provisions remain in effect. Examples include the following:

- security packaging when the drug is intended for sale to the general public (A.01.065)
- provisions relating to advertising (A.01.067) and sale (A.01.068)

Removing drugs from the List of Drugs for Exceptional Importation and Sale

Critical drug shortages are considered resolved when the Canadian-authorized drug is available in sufficient quantities to meet demand. For Tier 3 shortages, decisions to remove a drug from the List of Tier 3 Drug Shortages are made by the TAC, including the same representatives who determined that the drug was in a Tier 3 shortage.

Once a critical drug shortage is resolved, Health Canada may amend:

- the end date for importing the designated drug on the List of Drugs for Exceptional Importation and Sale and/or
- the maximum quantity or lot numbers that are allowed to be imported

This is done so that no further inventory is imported. However, the drug will remain on this list for a time to allow the remaining inventory in Canada to be sold until its expiry date.

Once a shortage has been resolved, Health Canada will remove the following from the list:

- designated drugs for which there have been no imported shipments
- drugs for which all imported inventory has been sold
- drugs that have expired

Health Canada will notify DEL holders when the process to remove a designated drug from the List of Drugs for Exceptional Importation and Sale has begun. We may ask for information from the DEL holder to help determine when the drug should be removed from the list.

A drug that has been removed from the List of Drugs for Exceptional Importation and Sale can no longer be imported or sold.

Coming into force and transition from interim order provisions

Coming into force of the Regulations

The amendments to the FDR come into force on March 2, 2022.

Transitional provisions

On March 2, 2022, all active products that were added to the List of Drugs for Exceptional Importation and Sale under IO No. 2, and whose Canadian substitute is still in or at risk of a critical shortage, will be transitioned to the new list and covered under the new regulations. Transitional provisions are outlined in sections 10 to 15 in the amendments to the FDR.

These drugs will be subject to the FDR requirements and guidance stipulated in this document.

Health Canada will work with DEL holders for existing products on the List of Drugs for Exceptional Importation and Sale to assign an end of importation date and, if applicable, maximum quantities for importation and sale. This information will be added to the list.

Contact us

For more information about drug shortages in Canada, please visit our drug shortages page.

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

For questions about submitting a proposal or adding a drug to the List of Drugs for Exceptional Importation and Sale, email us at drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca.

At least 3 days before importing designated drugs, submit notifications to drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca.

For questions on the DEL application requirements, email us at del.questions-leppp@hc-sc.gc.ca.

For questions on the Domestic GMP requirements, email us at drug.gmp.questions-bpf.medicaments@hc-sc.gc.ca.

For questions on the Foreign GMP requirements, email us at foreign.site-etranger@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")

Business day: a day other than a:

- a Saturday or
- a Sunday or other holiday

(jour ouvrable) (*FDR*, C10.006 (2))

Critical drug shortages: shortages that will have the most impact on the health of people in Canada
Critical drug shortages are almost always national in scope and fall into 2 classes:

1. Tier 3 drug shortages: The Protocol for the Notification and Communication of Drug Shortages sets out a tiered classification system for drug shortages:
   - Tier 1: anticipated shortages, of which a manufacturer or importer expects that future supply may not meet projected demand for the drug
   - Tier 2: actual drug shortages
   - Tier 3: actual drug shortages with the greatest potential impact on the Canadian drug supply and health care systems by virtue of availability of alternative supplies, ingredients or therapies
   - Tier 3 shortages are determined on a case-by-case basis by a specially convened Tier Assignment Committee (TAC), which includes representatives from federal and provincial/territorial governments and health care professionals. Drugs assessed by TAC to be in Tier 3 shortage are posted online in the List of Tier 3 Drug Shortages. All Tier 3 shortages are considered critical drug shortages.

2. Shortages with specific patient impacts: Other shortages may also be considered to be critical even if they do not meet the definition of a Tier 3 shortage if it is determined that such shortages will impact the health of specific groups of patients. For example, a shortage of a niche drug that would impact a small number of patients would be considered to be critical without necessarily meeting the definition of a Tier 3 shortage.
   Shortages with specific patient impacts are determined by Health Canada. Health Canada looks at the on-label use of the drug to determine if it would impact the health of people in Canada if not available to those who need it.

Designated drugs: a drug that is set out in the List of Drugs for Exceptional Importation and Sale (*drogue désignée*) (FDR, C10.004 (1))

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:

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

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 that 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, product 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

Expiration date: in the case of a drug in dosage form, the earlier of the following dates, expressed at minimum as a year and month:

- the date up to and including which the drug maintains its labelled potency, purity and physical characteristics and
- the date after which the manufacturer recommends that the drug not be used

(*date limite d'utilisation*) (C.01.001 (1))

Fabricate: to prepare and preserve a drug for the purposes of sale (manufacturer) (*FDR*, C.01A.001(1))

Foreign regulatory authority: a government agency or other entity outside Canada that has a legal right to control the manufacturing, use or sale of drugs within its jurisdiction (autorité réglementaire étrangère) (FDR, C10.001(1) and C10.004(1))

Incorporation by reference: a term used to describe a mechanism, which allows a document or list that is not in the text of the regulations, in whole or in part, to be made a part of the regulations. Health Canada uses incorporation by reference to achieve policy and regulatory objectives.
Incorporation by reference enables Health Canada to leverage existing documents and maintain agile regulatory frameworks that can more quickly adapt to changes in science or technology, or in response to an emerging health or safety risk. Incorporation by reference can also contribute to items such as regulatory alignment with the provinces and territories and to international cooperation on matters of trade, without compromising health and safety (*incorporation par renvoi*) (Health Canada Incorporation by Reference Policy)

List of drugs for exceptional importation and sale: published and updated by the Government of Canada on its website (FDR, C10.004 (1)). A drug included on this list is permitted to be imported and sold for the duration and in the quantities specified (if applicable). This list is incorporated by reference in the FDR. (*Liste des drogues destinées aux importations et aux ventes exceptionnelles*)

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 or drug (*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*))

MRA country: a country that is a participant in a mutual recognition agreement with Canada (pays participant) (FDR, C.01A.001(1))

For clarity, this term can also be taken to mean jurisdictions other than countries (for example, the European Union), with which Canada has an MRA

Package/label: to put a drug in its immediate container or to affix the inner or outer label to the drug (emballer-étiqueter) (FDR, C.01A.001(1))

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))

Tier 3 drug shortage: refer to critical drug shortages above (*les pénuries de niveau 3*)

Tier 3 list: a list published online and maintained by Health Canada that lists the molecules/drugs whose finished dosage form(s) are in shortage on the Canadian market. The molecules/drugs have been determined to meet the definition of a Tier 3 shortage by a Tier Assignment Committee *(Liste des pénuries de niveau 3)*

Tier Assignment Committee (TAC): an ad hoc committee of federal and provincial/territorial governments, health care professionals and industry stakeholders that makes recommendations on the tier assignment of a drug shortage *(Comité d'attribution de niveaux* (CAN))

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 and related links

Legislation and regulations

- *Controlled Drugs and Substances Act*
- *Criminal Code*
- *Food and Drugs Act*
- *Food and Drug Regulations*
- *Interim Order respecting drugs, medical devices and foods for a special dietary purpose in relation to COVID-19 (IO No. 1)*
- *Second Interim Order respecting drugs, medical devices and foods for a special dietary purpose in relation to COVID-19 (IO No. 2)*
- *Notice: Regulations amending certain regulations concerning drugs and medical devices (shortages)*
- *Part C, Division 2 of the FDR: Good manufacturing practices*
- *Part C, Division 10 of the FDR: Access to drugs in exceptional circumstances*
- *Regulations Amending Certain Regulations Concerning Drugs and Medical Devices (Shortages): SOR/2021-199*
- *Sections C.08.010 and C.08.011 of the FDR: Sale of new drug for emergency treatment*
- *Special access program for drugs*

Policies and Guides

- Compliance and enforcement policy for health products (POL-0001)
- Good manufacturing practices guide for drug products (GUI-0001)
- Guidance document – Certificates of supplementary protection
- Guidance on drug establishment licences (GUI-0002)
- Guidance: How to demonstrate foreign building compliance with drug GMP (GUI-0080)
- Guidance on management of applications and performance for drug establishment licences (GUI-0127)
- Guide to reporting drug shortages and discontinuations (GUI-0120)
- Guide to distributing drugs intended for the Canadian market for consumption or use outside Canada (GUI-0145)
- Guide on the requirements for providing information related to drug shortages (GUI-0146)
- Health Canada Incorporation by Reference Policy
- Protocol for the Notification and Communication of Drug Shortages

Web pages/Associated documents

- Access to Drugs in Exceptional Circumstances
- Canada Gazette, Part I, Volume 154, Number 50: Government Notices
- Mandatory drug shortage reporting
- Drug Shortages in Canada
- Prescription Drug List
- List of Drugs for Exceptional Importation and Sale
- List of Drugs for an Urgent Public Health Need
- List of Tier 3 Drug Shortages
- Proposal for adding a foreign-authorized drug on the List of Drugs for Exceptional Importation and Sale
- Risk communication plans
- Updates: Mutual recognition agreements