Guide to reporting drug shortages and discontinuations

GUI-0120

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Canada

Guide to reporting drug shortages and discontinuations (GUI-0120)

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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.

Ce document est aussi disponible en français.

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About this document

1. Purpose

This guide is for people who hold a drug authorization issued by Health Canada, including either:

- drug identification number (DIN) holders (i.e. the person 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,
- manufacturers who were issued a Notice of Compliance (NOC) authorizing the sale of a drug listed in Schedule C to the *Food and Drugs Act* (the Act)

It will help you understand how to:

- report drug shortages and discontinuations
- notify Health Canada when twelve months have elapsed since you last sold the drug

These guidelines will help you comply with sections C.01.014.8 to C.01.014.12 of the *Food and Drug Regulations* (the Regulations).

Drug identification number (DIN) holders must also comply with the mandatory reporting of a discontinuation of the sale of a product that has a DIN assigned by Health Canada, pursuant to section C.01.014.7 of the Regulations. Refer to the guidance document *Cancellation of a Drug identification Number (DIN) and Notification of the Discontinuation of Sales* for more information.

The Regulations require the mandatory reporting of drug shortages and discontinuations through a third-party website (the reporting website). However, this guide does **not** tell you how to use the reporting website. For tutorials on how to report drug shortages and discontinuations using the reporting website, go to: drugshortagescanada.ca

The Multi-Stakeholder Steering Committee (MSSC) developed a number of tools to help stakeholders across the drug supply chain better prevent, manage and communicate the details of drug shortages. For example, the MSSC *Protocol for the Notification and Communication of Drug Shortages*

sets clear expectations for how and when key stakeholder groups (including provincial/territorial governments, the federal government, and manufacturers) communicate drug shortage information. The Protocol and other MSSC tools are available at: drugshortagescanada.ca.

2. Scope

Audience

This guide is for the following drug authorization holders:

- drug identification number (DIN) holders (i.e. the person to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for a drug)
- manufacturers who were issued a Notice of Compliance (NOC) authorizing the sale of a drug listed in Schedule C to the *Food and Drugs Act* (the Act)

Drugs

The guidance in this document applies to the following drugs for human use:

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

Drugs for veterinary use are excluded from the scope of this document.

About mandatory reporting

3. Policy objective

It is mandatory for drug authorization holders to report, on the reporting website, drug shortages and discontinuations. Early reporting of anticipated and active shortages and discontinuations provides timely, comprehensive and reliable information essential for drug manufacturers, provincial and territorial governments, drug supply stakeholders, health care professionals and patients to prevent or manage the adverse health effects of drug shortages and discontinuations, helping to protect the health and safety of Canadians.

4. Defining shortages and discontinuations

Sections C.01.001(1) and C.01.014.8 of the Regulations define terms that apply to drug shortages and to the discontinuation of the sale of drugs. The terms also apply to the requirement to notify Health Canada when 12 months have elapsed since the last sale of a drug. These include:

- drug authorization holder
- drug
- drug discontinuation
- drug shortage

The following pages explain how each term applies to mandatory reporting.

To learn when to report, who is responsible to report and what information needs to be reported, please refer to the Guidance section of this document.

C.01.001(1) and C.01.014.8

The following definitions apply to Part C of the Regulations:

authorization holder means, in respect of a drug,

(a) the person to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for the drug; and

(b) in the case of a drug that is listed in Schedule C to the Act, the manufacturer to whom a notice of compliance in respect of the drug was issued under section C.08.004 or C.08.004.01. (*titulaire de l'autorisation*)

discontinue means, in respect of the sale of a drug by the authorization holder for the drug, to permanently cease the sale of the drug. (*cesser*)

The following definitions apply in sections C.01.014.8 to C.01.014.12 of the Regulations:

drug means

(a) any of the following drugs for human use in respect of which a drug identification number was assigned under subsection C.01.014.2(1):

(i) drugs included in Schedule I, II, III, IV or V to the *Controlled Drugs and Substances Act*,

(ii) prescription drugs,

(iii) drugs that are listed in Schedule D to the Act, and

(iv) drugs that are permitted to be sold without a prescription but that are administered only under the supervision of a practitioner; or

(b) a drug that is listed in Schedule C to the Act. (*drogue*)

shortage means a situation in which an authorization holder for a drug is unable to meet demand for the drug. (*pénurie*)

Interpretation

Drug authorization holder

For drugs other than those listed in Schedule C to the Act, you are the authorization holder of a drug if you were issued the document that sets out the DIN assigned for the drug.

For drugs listed in Schedule C to the Act, you are the authorization holder of a drug if you are the manufacturer to whom Health Canada has issued the NOC for that drug.

Drug

Section C.01.014.8 of the Regulations sets out the scope of drugs subject to the requirements for mandatory reporting of drug shortages and discontinuations to the reporting website, and

the requirement to notify Health Canada when 12 months have elapsed since the drug was last sold. These requirements only apply to the following drugs for human use:

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

Drug discontinuation

If you are a drug authorization holder, you are discontinuing the sale of your drug if you permanently stop selling it.

Drug shortage

Determining and meeting demand

You should interpret demand for your drug based on orders you receive from your Canadian clients. According to these guidelines, a shortage occurs when you cannot fill orders from your Canadian clients in their entirety and / or on time.

Shifting demand

A shortage is a situation in which you are unable to meet your Canadian clients' demand for your drug. Therefore, a shortage occurs when there are changes to either demand or supply of your drug and you can no longer meet demand.

Similarly, a shortage is resolved when either demand or supply of your drug changes, such that you can resume meeting demand.

Allocation – Managing demand

In order to manage demand and appropriately allocate your drug, you may take steps to identify your Canadian clients' needs (e.g. how much of your drug each client needs per month). If you can meet your Canadian clients' needs by distributing portions of an ordered amount on a scheduled basis rather than providing the ordered amount of your drug all at once, as described in Scenario 1 in the "Specific scenarios" section of this guide, such a strategy may allow you to meet demand.

However, if you anticipate that this strategy will only allow you to meet demand temporarily, as described in Scenario 2 in the "Specific scenarios" section of this guide, you must post a drug shortage report on the reporting website.

Emergency allocation – Rationing your drug

In this document, emergency allocation refers to a measure that goes beyond managing demand as described above. It refers to situations where you deem the supply of your drug to be insufficient to meet anticipated demand and you implement measures to ration your drug in a way where your Canadian clients' demand is only partially met. As described in Scenario 3 in the "Specific scenarios" section of this guide, if your drug is not already in shortage when you implement an emergency allocation strategy, a shortage begins on the day you implement it.

Guidance

5. Regulations

This section tells you when you must report:

- drug shortages
- drug discontinuations
- cases where you have not sold your drug for 12 months

The exact text from Part C, Division 1 of the Regulations is followed by Health Canada's interpretation (what you need to do to be compliant), where needed.

For more information on how to report drug shortages and discontinuations in a variety of situations, see the Specific scenarios section in this guide.

Reporting drug shortages

C.01.014.9

(1) If a shortage of a drug exists or is likely to occur, the authorization holder for the drug shall post the following information in English and French on a website that is operated by a party for that purpose with whom Her Majesty in right of Canada has entered into a contract to make that information available to the public:

(a) the authorization holder's name and their telephone number, email address, website address, postal address or any other information that enables communication with them;

(b) the drug identification number assigned for the drug under subsection C.01.014.2(1), if applicable;

(c) the drug's brand name and proper name or, if it does not have a proper name, its common name;

(d) the proper names of the drug's medicinal ingredients or, if they do not have proper names, their common names;

(e) the drug's therapeutic classification according to the Anatomical Therapeutic Chemical classification system (ATC), established by the World Health Organization Collaborating Centre for Drug Statistics Methodology — namely the level 3 description of, and level 4 code for, the drug;

(f) the drug's strength;

(g) the drug's dosage form;

(h) the quantity of the drug contained in its package;

(i) the drug's route of administration;

(j) the date when the shortage began or is anticipated to begin;

(k) the anticipated date when the authorization holder will be able to meet the demand for the drug, if the authorization holder can anticipate that date; and

(l) the actual or anticipated reason for the shortage.

(2) The authorization holder shall post the information

(a) if they anticipate that a shortage will begin in more than six months, at least six months before the day on which they anticipate it to begin;

(b) if they anticipate that a shortage will begin in six months or less,

within five days after the day on which they anticipate it; or

(c) if they did not anticipate the shortage, within five days after the day on which they become aware of it.

(3) If any of the information that was posted by an authorization holder changes, they shall update that information on the website within two days after the day on which they make or become aware of the change.

(4) Within two days after the day on which the authorization holder is able to meet the demand for the drug, they shall post information on the website to that effect.

Interpretation

1) If you are the authorization holder for a drug, you must report a shortage when:

- you have reason to believe that a shortage is likely to occur
- you are aware that a shortage is occurring

2) You must report drug shortages by posting all mandatory information on the reporting website at: drugshortagescanada.ca (French language website is penuriesdemedicamentscanada.ca). Designated representatives may report drug shortages on behalf of the authorization holder.

3) You must post all information required by subsection C.01.014.9(1) of the Regulations. The drug authorization holder's name and drug identification number (DIN), where applicable — along with all other information required under paragraphs C.01.014.9(1)(c) to C.01.014.9(1)(g) and C.01.014.9(1)(i)—must be consistent with information in Health Canada's Drug Product Database. Mandatory fields will be identified on the website.

   Note: English ATC codes and descriptions can be found on the WHO Collaborating Centre for Drug Statistics Methodology at the Norwegian Institute for Public Health's website at https://www.whocc.no/atc_ddd_index/.

4) You must post a method to contact your company. This method could be a telephone number, an email address, a website address, a postal address or any other information that can be used to communicate with your company.

5) You must post the date when the shortage began or is expected to begin. This is the day you can no longer meet demand.

   For anticipated shortages, determine the date when you expect the shortage to begin. If

circumstances change, update this date. When the shortage begins, you have to enter the date when the shortage actually began.

6) You must post the date you anticipate the shortage will be resolved. Your drug shortage is considered resolved when you can resume meeting demand for your drug. This is the day when you are able to fill your Canadian clients' orders in their entirety and on time. If you cannot determine this date (e.g. when the cause of the shortage is out of your control), use "unknown." If circumstances change or you get new information, update this date accordingly. Additionally, when you use "unknown," you are expected to update your shortage report at least every three months to confirm your situation has not changed.

7) If any of the information you have posted about your drug shortage changes, you must update your report on the reporting website. This requirement applies to all information you post, including additional information that you provide voluntarily (i.e. information not required by the Regulations).

8) When the shortage for your drug is resolved, you must indicate the date on which you resumed meeting demand.

9) If circumstances change and an anticipated drug shortage will no longer occur, you must update your shortage report to indicate that the shortage was avoided.

10) When your drug is in shortage and you decide to discontinue its sale, you must post a drug discontinuation report and update your drug shortage report to indicate that you no longer intend to meet demand. When the drug is discontinued, you must update the reason for the shortage to indicate that the shortage is due to the drug discontinuation. For further details, see Scenario 4 and Scenario 5 in the "Specific scenarios" section of this guide.

11) When reporting drug shortages, you may provide and update voluntary information in addition to the mandatory information listed above. When providing voluntary information, it is strongly recommended that you provide the information in both English and French.

Reporting drug discontinuations

C.01.014.10

(1) If an authorization holder for a drug decides to discontinue the sale of the drug, they shall post the following information in English and French on the website referred to in subsection C.01.014.9(1):

(a) the authorization holder's name and their telephone number, email address, website address, postal address or any other information

that enables communication with them;

(b) the drug identification number assigned for that drug under subsection C.01.014.2(1), if applicable;

(c) the drug's brand name and proper name, or if it does not have a proper name its common name;

(d) the proper names of the drug's medicinal ingredients or, if they do not have proper names, their common names;

(e) the drug's therapeutic classification according to the Anatomical Therapeutic Chemical classification system (*ATC*), established by the World Health Organization Collaborating Centre for Drug Statistics Methodology — namely the level 3 description of, and level 4 code for, the drug;

(f) the drug's strength;

(g) the drug's dosage form;

(h) the quantity of the drug contained in its package;

(i) the drug's route of administration;

(j) the date on which the authorization holder will discontinue the sale of the drug; and

(k) the reason for the discontinuation of sale.

(2) The authorization holder shall post the information

(a) if they decide to discontinue the sale of the drug in more than six months, at least six months before the day on which they will discontinue its sale; and

(b) if they decide to discontinue the sale of the drug in six months or less, within five days after the day on which that decision is made.

(3) If any of the information that was posted by an authorization holder changes, they shall update that information on the website within two days after the day on which they make or become aware of the change.

Interpretation

Note: The requirements for C.01.014.10 are in addition to the discontinuation notification requirements in C.01.014.7.

1) If you are the authorization holder for a drug, you must report a drug discontinuation when you decide to permanently stop the sale of your drug in Canada.

2) You must report drug discontinuations by posting all mandatory information on the reporting website at: drugshortagescanada.ca (French language website is penuriesdemedicamentscanada.ca). Designated representatives may report drug discontinuations on behalf of the authorization holder.

3) You must report all information required by subsection C.01.014.10(1) of the Regulations. The drug authorization holder's name and drug identification number (DIN) where applicable—along with all other information required under paragraphs C.01.014.10(1)(c) to C.01.014.10(1)(g) and C.01.014.10(1)(i)—must be consistent with the information contained in Health Canada's Drug Product Database. Mandatory fields will be identified on the website.

   Note: English ATC codes and descriptions can be found on the WHO Collaborating Centre for Drug Statistics Methodology at the Norwegian Institute for Public Health's website at https://www.whocc.no/atc_ddd_index/.

4) You must post a method to contact your company. This method could be a telephone number, an email address, a website address, a postal address or any other information that can be used to communicate with the company.

5) You must report the date when you will discontinue or have discontinued sale of your drug.
   - If you are actively selling your drug and decide to discontinue its sale, the date of the discontinuation is the date you will last sell it.

The date of discontinuation is when you last sell your drug, not when it is last sold at retail.

   - When you are not actively selling your drug (i.e. you have stopped selling your drug but have not yet made the decision to stop sales permanently) and then decide to discontinue its sale, the discontinuation date is the date on which you make the decision to discontinue its sale. For more information, see Scenario 4 in the "Specific scenarios" section of this guide.

Timeline requirements for reporting

The Regulations require you to report drug shortages, discontinuations and changes in information relating to these events according to set timelines. This section helps you understand the timelines within which you must report or update reports.

Drug shortages

1. You anticipate a shortage for your drug and you believe it will begin more than six months from today.
    - Post a shortage report at least six months before you anticipate the shortage will begin.

2. You anticipate a shortage for your drug and you believe it will begin six months from today or less.
    - Post a shortage report within five calendar days from the day when you became aware that a shortage is likely to occur.

3. You became aware that your drug is in shortage. You did not anticipate the shortage.
    - Post a shortage report within five calendar days from the day you became aware of the shortage.

4. You became aware that your drug – for which you have already reported an anticipated shortage – is now in shortage.
    - Update the shortage report within two calendar days from the day you became aware that the shortage began, to indicate the date when the shortage started.

5. The information you posted about a drug shortage changed.
    - Update your shortage report within two calendar days of becoming aware of the change.

6. The shortage for your drug is resolved.
    - Update your shortage report within two calendar days from the day you can meet demand to include this date.

Drug discontinuations

7. You decide to discontinue the sale of a drug in Canada, and the date on which you intend to permanently stop sale is more than six months from today.
    - Post a discontinuation report at least six months before the day you will last sell your drug.

8. You decide to discontinue the sale of a drug in Canada, and the date on which you intend to permanently stop sale is six months from today or less.

- Post a discontinuation report within five calendar days from the day you made the decision to discontinue your drug.

9. The information you posted about a drug discontinuation changed.
    - Update the discontinuation report within two calendar days of becoming aware of or making the change.

Reporting website

C.01.014.11

The Minister shall maintain a hyperlink to the website referred to in subsection C.01.014.9(1) on the Department of Health website.

Interpretation

The reporting website is available through the Health Canada website at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/shortages-penuries/index-eng.php

or directly at: drugshortagescanada.ca.

Reporting twelve months without sale

C.01.014.12

(1) If a period of 12 months has elapsed since an authorization holder for a drug last sold the drug, they shall notify the Minister of that fact within 30 days after the day on which that period ends.

(2) The authorization holder shall, within 30 days after the day on which they resume the sale of the drug, notify the Minister of that fact.

Interpretation

Note: Additional Health Canada guidance for the reporting of a period of 12 months since the authorization holder last sold a drug can be found in the guidance document *Cancellation of a Drug Identification Number (DIN) and Notification of the Discontinuation of Sales.*

1) You must notify Health Canada within 30 calendar days if you have not sold your drug on the Canadian market for a period of 12 consecutive months. You also must notify Health Canada when you recommence selling your drug. In either case, the reason for the notification should be indicated in the cover letter of the regulatory transaction provided to Health Canada.

   Documents for submissions in "non-eCTD electronic-only" format must be sent by one of the following ways:
   - by email to SIPD-DINREQUEST@HC-SC.GC.CA,
   - on electronic media to :

   Office of Submissions and Intellectual Property (OSIP)
   Finance Building
   101 Tunney's Pasture Driveway
   Address Locator: 0201A1
   Ottawa, Ontario
   K1A 0K9

   Documents for submission in eCTD format must be sent via the Common Electronic Submissions Gateway (CESG).

   For more information on how to submit transactions to Health Canada, please refer to section "Transmission of Electronic Data" of the:

   (a) *Guidance Document: Preparation of Drug Regulatory Activities in Electronic Common Technical Document Format*, for regulatory activities in eCTD format; and

   (b) *Guidance Document: Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format*, for regulatory activities in "non-eCTD electronic-only" format.

2) The requirement to inform Health Canada is independent from the requirements to post drug shortages and discontinuations on the reporting website. Therefore, when you have not made a sale on the Canadian market for twelve consecutive months and your drug is in shortage, you must:

   - notify Health Canada (due to the 12 months without sale); and;
   - keep your drug shortage report up-to-date on the reporting website.

   The same applies when you resume selling your drug: you must notify Health Canada and update your drug shortage report as required.

3) The requirement does not apply to drugs that have never been sold. If you have been issued an authorization (DIN or NOC) for your drug and have never sold it, you do not have to

notify Health Canada that 12 months have elapsed since you obtained your authorization (DIN or NOC).

6. Specific scenarios

The scenarios that follow illustrate how to report drug shortages and discontinuations in a variety of situations and describe the drug authorization holder's reporting obligations.

Please note that the scenarios in this section are illustrative only. Drug authorization holders should consult the Regulations for the obligations which apply to their particular circumstances.

Scenario 1 – Allocation: Managing demand, no shortage

You have two direct Canadian clients for your drug, Client A and Client B. You receive an order from Client A that represents about one year's supply of your drug for that client. You have enough stock to supply both clients' normal demand for the next six months and you plan to release a new lot in six months' time to continue meeting demand. You expect an order from Client B soon. You contact Client A and confirm that their monthly demand has not changed. Therefore, you only supply Client A with a six months' supply, which allows you to use the balance of your stock to meet Client B's anticipated demand for the next six months. You have no reason to believe that the release of the next lot will be delayed and thus you anticipate being able to meet future demand.

Obligations and timelines

You are meeting demand by filling the revised orders on time and in their entirety and you anticipate the next lot will be ready in time to meet future demand. There is no shortage to report for your drug.

Scenario 2 – Allocation: Managing demand, shortage

You have two direct Canadian clients for your drug, Client A and Client B. You receive an order from Client A that represents about one year's supply of your drug for that client. You have enough stock to supply both clients' normal demand for the next six months and you plan to release a new lot in six months' time to continue meeting demand. You anticipate an order from Client B soon. Nonetheless, you decide to fill Client A's order in full which leaves you with insufficient stock to meet Client B's anticipated order.

Soon after, you receive an order from Client B for a year's worth supply and cannot fill it in full and on time. After contacting Client B, you determine that your supply is only enough to meet Client B's needs for one month. However, you anticipate that you can resume meeting demand once you release your new lot.

Obligations and timelines

You must post an anticipated drug shortage report on the reporting website within five calendar days of making the decision to fill Client A's order. The shortage anticipated start date is the date when you anticipate you can no longer meet demand (in this case, it is when Client B's order expected). The anticipated shortage resolution date is when you anticipate the new lot will be released.

Scenario 3 – Shortage with emergency allocation

You have just been informed that your sole supplier of active ingredient for your drug is unable to supply you for an unknown period of time. Your drug has various uses, some being more important than others. You do not intend to discontinue the sale of your drug and you estimate you have about six months' supply of the drug. However, you decide to implement an emergency allocation strategy where you will ration the drug so that it is only used for the more important uses so your supply lasts longer. Therefore, you will stop meeting demand when you implement the emergency allocation strategy.

Obligations and timelines

You must post an anticipated drug shortage report on the reporting website within five calendar days of becoming aware that a shortage is likely to occur (in this case, where the sole supplier of the active ingredient for your drug is unable to supply you for an unknown period of time). Indicate the anticipated shortage start date as being the day when you will implement the emergency allocation strategy.

If you become unable to meet demand before the allocation strategy is implemented, you must, update your shortage report to indicate the date when the shortage began within 2 days of the shortage onset.

Scenario 4 – Discontinuation of a drug in shortage

Your drug is in shortage and you have not been able to supply your Canadian clients for some time. You have posted a drug shortage report on the reporting website and have kept it up to

date. After unsuccessfully trying to implement a solution to resume production, you decide to discontinue the sale of your drug.

Obligations and timelines

You have five calendar days from the day you made the decision to discontinue the sale of your drug to post a drug discontinuation report on the reporting website. The discontinuation date is the day on which you made the decision to discontinue the sale of your drug. You have two calendar days from the day you made the decision to discontinue the sale of your drug to indicate that you no longer intend to be meeting demand and update the reason for the shortage to indicate that the drug has been discontinued.

Scenario 5 – Shortage of a drug that will be discontinued

You decide to discontinue the sale of your drug in six months' time. You intend on continuing to meet demand until the discontinuation date. However, before the discontinuation occurs, a problem affecting your supply capacity for your drug prevents you from meeting demand for your drug for a period of time. You do not intend on changing the discontinuation date and continue selling your drug despite not meeting demand.

Obligations and timelines

You must post a drug discontinuation report on the reporting website within five calendar days of making the decision to discontinue the sale of your drug. When you become aware that a problem occurred that you anticipate will cause a shortage or has caused a shortage of your drug, you must post a drug shortage report on the reporting website within five calendar days of becoming aware.

The drug shortage may resolve if you resume meeting demand before the drug is discontinued. However, if you anticipate you will not be able to meet demand before the drug is discontinued, you must indicate that you no longer anticipate being able to meet demand for your drug within two calendar days of becoming aware that you will likely never meet demand.

In addition you must update your shortage report to indicate that the shortage is due to the discontinuation of the drug within two calendar days of the day the drug is discontinued.

7. Contact Information

For further information about drug shortages in Canada, please visit Health Canada's website. For questions about the drug shortage and discontinuation regulations, contact Health Canada at Drug.shortages-Penurie.de.medicament@hc-sc.gc.ca.

Appendices

Appendix A – Glossary

Acronyms

Act (the)	*Food and Drugs Act*
CDSA	*Controlled Drug and Substances Act*
DIN	Drug Authorization Number
MSSC	Multi-Stakeholder Steering Committee
NOC	Notice of Compliance
Regulations (the)	*Food and Drug Regulations*

Appendix B – References

Legislation

Controlled Drugs and Substances Act
laws-lois.justice.gc.ca/eng/acts/C-38.8/

Food and Drug Regulations
laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html

Food and Drugs Act
laws-lois.justice.gc.ca/eng/acts/f-27/

Other

Guidance Document: *Cancellation of a Drug Identification Number (DIN) and Notification of the Discontinuation of Sales*.

Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format
www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ectd/prep_ectd_format-eng.php

Guidance Document: Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format
www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ctd/gd_prep_non_ectd_ld-eng.php

Health Canada's Drug Product Database
www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php

Prescription Drug List
www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_list_fin_ord-eng.php

Reporting Website
www.drugshortagescanada.ca (French language website is www.penuriesdemedicamentscanada.ca)