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QUESTIONS AND ANSWERS

Access to Drugs in Exceptional Circumstances

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Health Products and Food Branch

Canada

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p><i>Health Canada</i></p>	<p>The Health Products and Food Branch's (HPFB) mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by:</p> <ul style="list-style-type: none"> • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. <p><i>Health Products and Food Branch</i></p> <p>The Regulatory Operations and Regions Branch's mission is to lead compliance and enforcement and complementary scientific programs to inform and protect Canadians from health risks associated with products, substances and their environment. Compliance and enforcement activities are a key element of safeguarding the drugs and health products to which Canadians have access.</p> <p><i>Regulatory Operations and Regions Branch</i></p>
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FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada's mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document. This is in order to allow the Department to adequately assess the safety, effectiveness or quality and ongoing compliance and enforcement of a therapeutic product to which Canadians have access. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

As part of its regulatory responsibilities, Health Canada is responsible for compliance monitoring and enforcement activities related to health products in order to verify that regulatory requirements are being applied appropriately.

This guidance document has been developed in a question and answer format. It should be read in conjunction with the relevant sections of other applicable guidance documents, as amended from time to time.

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1 INTRODUCTION

Urgent¹ public health needs can occur, for example, during a flu pandemic, situations such as the opioid crisis or a military health emergency. Sometimes a drug that is needed for immediate use to respond to an exceptional public health crisis is not authorized for sale in Canada, but may be authorized for sale in another country.

Pathways that provide access to drugs that are not authorised for sale in Canada² and that are intended for emergency use include Health Canada's Special Access Programme (SAP), the issuance of an Interim Order by the Minister of Health, and *Access to Drugs in Exceptional Circumstances* (Division 10 of the *Food and Drug Regulations*).

The SAP administers the “*Sale of New Drugs for Emergency Treatment*”, an exemption to the *Food and Drugs Act (FDA)* and the *Food and Drug Regulations (FDR)*. It is designed to address individual patient needs, and as such, requires an application to be made for the drug by the treating practitioner. The authorization issued is for a specific quantity of drug and a subsequent authorization is required if treatment for additional patients is sought.

The issuance of an Interim Order by the Minister of Health (section 30.1 of the *FDA*), when immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment, is a legislative instrument that can be used for a population-based response, but is valid for a maximum of one year and is not renewable. While Interim Orders can be modelled to address a particular emergency, as they are valid for only a short period of time, and therefore may not be an appropriate mechanism for addressing an on-going urgent public health need.

When a public health need is exceptional, such that existing emergency response measures are insufficient, and access to a drug that is not authorised for sale in Canada is necessary to decrease or eliminate a risk to public health, the “*Access to Drugs in Exceptional Circumstances*” regulatory pathway provides a mechanism for a population-based response. This pathway allows for the importation and sale of drugs that are not authorised in Canada but authorised for sale in another country (i.e., the United States of America, European Union or Switzerland) to respond to an exceptional public health crisis.

In situations where an exceptional public health crisis is occurring or imminent and requires immediate action, public health officials may consider using the “*Access to Drugs in Exceptional Circumstances*” regulatory pathway which allows the importation and sale of a foreign authorised drug that has been identified on a List, referred to as the *List of Drugs for an Urgent Public Health Need*.

¹ Urgent is defined as immediate attention or action as opposed to an anticipated need.

² Clinical trial applications provide access to unauthorized drugs in Canada however they are designed and conducted to study whether drugs are effective and safe. They are not a means of providing access to an unauthorized drug to address a public or military health emergency.

1.1 Policy Objective

To ensure that drugs on the “*List of Drugs for an Urgent Public Health Need*” (referred hereto as the “List”) are imported and sold in accordance with the requirements of Part C, Division 10 of the *FDR*, and specifically that:

- listed drugs imported by drug establishment license (DEL³) holders comply with storage and handling requirements pursuant to the applicable requirements in Divisions 1A, 2, 3 and 4 as outlined in Part C, Division 10; and
- health care institutions report serious adverse drug reactions.

It should be noted that, if a drug on the List is a controlled substance, requirements from the *Controlled Drugs and Substances Act (CDSA)* and its *Regulations* apply.

1.2 Scope and Application

This guidance document provides an overview of the regulatory process under Division 10 of the *FDR* for the importation of drugs for an urgent public health need and outlines the roles and responsibilities of Health Canada, public health officials, DEL holders, and health care institutions.

2 THE REGULATIONS AND THEIR PURPOSE

The regulations entitled “*Access to Drugs in Exceptional Circumstances*” (referred hereto as “the *Regulations*”) enable the importation of drugs that have been authorized for sale either in the United States of America, the European Union, or Switzerland, but are not authorized in Canada, to address an urgent public health need identified by a designated Canadian public health official.

In accordance with the *Regulations* (C.10.001(1)), a Public Health Official (PHO) means:

- (a) the Chief Public Health Officer appointed under subsection 6(1) of the *Public Health Agency of Canada Act*;
- (b) the Chief Medical Officer of Health, or equivalent, of a province;
- (c) the Surgeon General of the Canadian Armed Forces; or
- (d) the Chief Medical Officer of Public Health for the First Nations and Inuit Health Branch of the Department of Health.

³ A DEL is a licence issued to a person in Canada allowing them to conduct licensable activities in a building which has been assessed as being in compliance with the requirements of Divisions 2 to 4 of the *Food and Drug Regulations*.

Unlike other regulatory mechanisms laid out in the *FDR* that authorize the importation and sale of a drug in Canada, these *Regulations* allow the importation and sale of a drug which has been identified on a list, incorporated by reference⁴ in the *FDR*, entitled “List of Drugs for an Urgent Public Health Need”.

2.1 How do requirements for drugs subject to these *Regulations* differ from other federal regulatory requirements applied to drugs in Canada?

Prior to selling a drug in Canada, a manufacturer is required to submit information on a drug’s safety, efficacy and quality and to comply with the provisions of the *FDA* and *FDR*, including obtaining market authorization from Health Canada. Since responding to an urgent public health need is an exceptional situation requiring immediate action, the regular review timelines of a drug may not be feasible. Therefore, drugs that are placed on the List are exempt from certain regulatory requirements under the *FDR*, including the review of a drug’s safety, efficacy and quality.

Even though the listed drugs have not been reviewed by Health Canada, confidence that they meet a similar standard of scrutiny to that of a Canadian authorized drug is provided by the fact that these drugs have undergone a thorough examination by a regulatory authority in the United States, the European Union or Switzerland, and that these drugs must be imported directly from those countries by licensed importers.

While drugs on the List are exempt from certain provisions within the *FDR*, it is important to note that the requirements of the *FDA* still apply. This allows the Department to take appropriate action should a safety issue be identified. Furthermore, if a drug on the List is designated as a controlled substance by the foreign country, it would be considered a controlled substance in Canada⁵ therefore, the requirements of the *CDSA* and its *Regulations* would apply.

⁴ Documents incorporated by reference have the same force of law as the regulation in which they are incorporated. The use of appropriately incorporated documents can make the regulatory system more responsive such that rather than needing to amend a regulation to revise a list, the list can be changed as needed, without an amendment to the regulations.

⁵ National classification systems are to be implemented based on the United Nations Single Convention on Narcotic Drugs 1961, as amended by its 1972 Protocol.

3 ROLES AND RESPONSIBILITIES

3.1 What is the role of Health Canada?

The Minister of Health is responsible for managing the List and will take into account:

- that the intended use or purpose of the foreign drug (i.e. its foreign indication) is the same use or purpose that has been identified by a PHO to address the urgent public health need; and
- if there is a drug in Canada which is equivalent to the foreign drug i.e., there is a drug authorized in Canada for the same indication as the intended use or purpose for the urgent public health need.

Health Canada will also support monitoring of the safety of drugs on the List through the collection of adverse drug reactions reports and engagement with foreign regulators and provincial authorities on emerging safety issues in those jurisdictions. The Department must also assess whether importation of drugs on the List is being conducted by valid license holders who are compliant with the *FDA* and/or *CDSA*. Finally, the Minister may order the recall of any drug on the List, if the Department is informed by the foreign regulator that has approved the drug, or by a provincial authority, or by the importer, that the drug presents a serious and imminent risk of injury to health. A drug will be removed from the List should a safety issue arise or the urgent public health need no longer exist.

3.2 What is the role of Public Health Officials?

PHOs are to notify the Minister of an urgent public health need that requires the immediate use of a foreign drug, as well as the specific use or purpose of that drug.

Prior to notifying the Minister of an urgent public health need, the PHOs should:

- assess the risks and benefits associated with introducing a foreign drug into their jurisdiction in light of available evidence;
- contact the foreign manufacturer and/or their Canadian affiliate to obtain the necessary information (e.g. drug information) and to identify conditions of sale (e.g. mandatory health professional training, controlled distribution, etc.) set forth by the foreign manufacturer, or the foreign regulator to determine whether these conditions can be fulfilled within their jurisdiction.

PHOs should consider whether additional measures are necessary to monitor the distribution and use of the drug on the List. They should also consider whether supplementary information should be provided to patients or health care professionals when the drug is distributed in their

jurisdiction to allow safe prescribing, dispensing and use of the drug. Mechanisms to receive timely notification from the foreign manufacturer of post-market actions related to safety, effectiveness, and quality should be established along with procedures to share this information with Health Canada so that the appropriate action can be taken if necessary.

3.3 What is the role of Drug Establishment License (DEL) Holders?

DEL holders must comply with these *Regulations* if importing or wholesaling a drug on the List. DEL holders must have a valid license and must have been inspected and assessed as being in compliance with the requirements of Divisions 2 to 4 of the *FDR*.

As licensed distributors can only distribute products that possess a DIN, they are considered outside the scope of this regulatory scheme.

3.4 What is the role of health care institutions?

Health care institutions that provide acute care services, including those that provide emergency services, are required to report information respecting a serious adverse drug reaction⁶ suspected to be associated with a drug imported under the *Regulations*. The health care institution is required to report the serious adverse drug reaction associated with a drug on the List within 30 days of the event first being documented.

4 LIST OF DRUGS FOR AN URGENT PUBLIC HEALTH NEED AND PUBLIC HEALTH OFFICIAL NOTIFICATIONS

4.1 What is the List?

The List is a web-based list of drugs established as a result of section C.10.002(e) of the *FDR*. The List identifies drugs that are eligible for importation into Canada and use in a specific Canadian jurisdiction to address an urgent public health need. The List is maintained by the Minister of Health.

To import and sell a drug on the List, a PHO must have notified the Minister, in writing, of an urgent public health need for the immediate use of the drug within their jurisdiction.

⁶ Under Division 1, C.01.001, “serious adverse drug reaction means a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death”

4.2 What information is included in the List?

The List contains the following drug-related information:

- Brand name;
- Medicinal ingredient(s);
- Dosage form;
- Strength;
- Route of administration;
- Identifying code or number assigned by the foreign regulatory authority which authorized its sale;

The following information, which is obtained from PHO notifications, is also included on the List:

- Name of the foreign regulatory authority who authorized the drug;
- Country from which the drug can be imported;
- Canadian jurisdiction notifying for the drug (and the jurisdiction in which the drug can be used);
- Urgent public health need;
- Intended use or purpose of the drug;
- Date of the notification made by the PHO.

4.3 Which drugs can be included on the List?

The List is restricted to drugs that have been authorized for sale in the United States of America, the European Union, or Switzerland. The drug must have been approved for the same use or purpose in those foreign jurisdictions as the intended use or purpose of the drug in the Canadian jurisdiction.

The *Patent Act* will continue to apply to products imported in accordance with the *Regulations*. Health Canada will not be confirming the status of Canadian patents prior to placing a drug on the List. It is the responsibility of anyone importing the drug to take the steps necessary to avoid patent infringement.

4.4 How are drugs added to the List?

To be eligible for importation and sale under this regulatory scheme, a drug must be included on the List and a PHO must have notified the Minister in writing of an urgent public health need for the use of the drug within their jurisdiction.

The Minister is responsible for adding drugs to the List. Although the Minister can become aware of a need to add a drug to the List through various means, the impetus to consider adding a drug will usually originate from a notification made by a PHO regarding an urgent public health need for the immediate use of the drug in their jurisdiction. The Minister has discretionary authority when adding a drug to the List.

To notify the Minister, the PHO must complete the *Notification of Urgent Public Health Need Form*. This form requires that PHOs identify a drug and describe the urgent public health need in their jurisdiction for the immediate use of that drug. The PHO should also supply a drug information document (such as the equivalent of a Canadian Product Monograph) to validate information provided in the form and confirm that the approved indication(s) of the foreign authorized drug is the same as the intended use or purpose for the urgent public health need.

Once a notification is received and the form is complete, Health Canada will review the notification to ensure that all regulatory provisions have been met and that the urgent public health need expressed by the PHO falls within the scope of this regulatory scheme.

Information related to the drug as well as information from the PHO notification (as specified in section 4.2) will be added to the List. This List will be updated on the Health Canada website and stakeholders will also be informed of the updated List by email and through Health Canada's Drug Products RSS feed.

4.4.1 What is meant by an urgent public health need?

When considering notifying the Minister of an urgent public health need whereby a foreign authorized drug would need to be imported, the public health event should be exceptional in nature, such that current emergency response measures are not sufficient to deal with it, and access to the drug is necessary to decrease or eliminate the risk to public health. The PHO should demonstrate that the following applies to their urgent public health need:

- the event could have a serious impact on public health and immediate action is necessary to protect public health;
- the event is unusual or unexpected.

Examples of public health events that would fall within the scope of this regulatory pathway include infectious disease pandemics, military health emergencies, or other situations such as an opioid crisis. Given that this pathway is intended for the immediate use of a drug, this pathway is not intended to be used to stockpile a drug to prepare for a potential public health emergency.

4.5 How are drugs removed from the List?

4.5.1 Removal following one year

A drug will be removed from the List if one year has elapsed since the last date of notification made by a PHO, unless the Minister receives a subsequent notification from a PHO (using the *Notification of Urgent Public Health Need Form*) describing the continued need for the drug in their jurisdiction.

To ensure that the supply of a drug is not unintentionally interrupted and that all stakeholders are made aware, Health Canada will email stakeholders 90 days prior to removing a drug from the List to inform them of the impending removal. Once the 90 days have elapsed, the drug will be removed from the List and stakeholders will be informed of the updated List by email and through Health Canada's Drug Products RSS feed.

Once a drug has been removed from the List, the importation, sale and use of the drug is prohibited.

4.5.2 Removal from the List due to safety or other reasons

The Minister may remove a drug from the List based on new information regarding the safety, efficacy or quality of the drug. If the Minister of Health believes that the drug presents a serious and imminent risk of injury to health, the Minister may order the recall of the drug in question pursuant to section 21.3 of the *FDA*.

Should a PHO identify an issue associated with a listed drug warranting exclusion of the drug from their jurisdiction, or if the drug is no longer needed, the PHO should inform the Minister immediately that they wish to withdraw their original notification. PHOs may withdraw a notification by completing and submitting the *Notification of Urgent Public Health Need Form* to Health Canada. The PHO should further inform Health Canada as to what plans are in place for removing the drug from their jurisdiction. Health Canada will amend the List on the Health Canada website and will communicate the removal of a drug from the List to all stakeholders by email and through Health Canada's Drug Products RSS feed.

4.5.3 Removal from the List due to a drug receiving market authorization in Canada

In situations where an equivalent drug is issued an NOC or DIN in Canada for the same indication as the intended use or purpose of the listed drug, the listed drug may be removed from the List. In the scenario where a drug has been issued an NOC but is not

yet marketed, Health Canada will consider, on a case-by-case basis, maintaining the drug on the List (generally no more than 90 days), to continue allowing the importation and sale of the drug in order to prevent the interruption of patient treatments. Once a drug has been removed from the List, both importation and sale of the drug is prohibited.

5 IMPORTATION AND WHOLESALE OF A LISTED DRUG

5.1 Who can import and wholesale drugs on the List?

The *Regulations* are intended for DEL holders conducting activities as part of their regular business. Any application for a new DEL or amended DEL will be subject to a regular Good Manufacturing Practices (GMP) inspection for those activities against the full requirements of Division 2-4 of the *FDR*, and as such, fees under the *Fees in Respect of Drugs and Medical Devices Regulations* are applicable. A DEL is only issued if the full requirements of Division 2-4 have been met.

Section C.10.001 (2) specifies that a person who holds a DEL authorizing the import of the applicable drug category (e.g. pharmaceuticals, vaccines, etc.) may import the listed drug and Section C.10.002 (2) specifies that a person who holds a DEL authorizing the wholesale⁷ of the applicable drug category may wholesale the listed drug.

However:

- The importer is not required to have the relevant foreign buildings listed on either its DEL's foreign building annex or active pharmaceutical ingredient annex.
- The importer and wholesaler are not required to hold a DEL authorizing sterile dosage forms to conduct activities with respect to sterile drugs on the List.
- The importer and wholesaler are not required to hold a DEL authorizing the specific dosage form class of the drug on the List.

When importing a drug pursuant to C.10.001 (2) or wholesaling drugs pursuant to C.10.002 (2), DEL holders must comply with any applicable terms and conditions that are included on their licence. If the drug is a controlled substance, the DEL holder must also have a dealer's license as per the *CDSA*.

⁷

Section C.01A.001 (1) of the *Food and Drug Regulations* define "wholesaler" as follows: wholesaler means a person who is not a distributor described in section C.01A.003 and who sells any of the following drugs other than at retail sale: (a) a drug in dosage form that is listed in Schedule C or D to the Act, a drug that is a prescription drug or a controlled drug as defined in subsection G.01.001(1); (b) an active ingredient; or (c) a narcotic as defined in the *Narcotic Control Regulations*.

5.2 Importation

5.2.1 What requirements, under the *FDR*, must be met to import a drug on the List?

In accordance with section C.01A.001 of the *FDR*, import means “to import into Canada a drug for the purpose of sale”.

To import a drug, pursuant to C.10.001 (2), the drug must appear on the List and the following conditions must be met:

- The importer must meet the DEL requirements listed in 5.1 above.
- The characteristics of the drug must be compliant with the information on the List and referenced in section 4.2.
- A PHO must have notified the Minister of an urgent public health need and the importation date must be within 1 year of the notification date on the List.
- The drug on the List must be imported directly from the country on the List.
- The product must be imported for the intended use or purpose specified on the List.

After the drug has been imported, the Importer can only sell the drug if:

- The drug is on the List at the time of the sale.
- The importer sells the drug into or within the Canadian jurisdiction identified on the List.

5.2.2 What are the notification requirements when importing a drug on the List?

Under the *Regulations*, in addition to meeting the applicable requirements of Division 1A and Division 2 to 4 of Part C of the *FDR*, importers are required to notify the Minister of every importation of drugs on the List within 15 days after the importation.

In accordance with section C.10.003 of the *Regulations*, every importer must notify Health Canada using the *Notification of Importation Form* and provide the following information as per C.10.003:

- (a) the name, title and contact information of the person who imported the drug;
- (b) the brand name of the drug;
- (c) the medicinal ingredient, strength, dosage form, route of administration, identifying code or number assigned, if any, in the country in which the drug was authorized for sale;
- (d) the name of the country from which the drug was imported; and
- (e) the total quantity of drug imported.

While the requirement is to notify after the importation, Health Canada strongly recommends that, where possible, the Department is also informed in advance of the importation. To facilitate importation in cases when providing information in advance, importers should provide the following information by email to drugs_urgent_need_besoin_urgent_medicaments@hc-sc.gc.ca information required as per C.10.003 (above); the Canadian port of entry; the establishment license number; the shipment tracking number if available (e.g., Cargo Control Number (CCN), Invoice Number), and flight details if arriving by air. With sufficient advance notice, Health Canada will inform ports of entry to facilitate importation.

If the drug is a controlled substance, a reporting form will accompany the import permit. This should be submitted to the Office of Controlled Substances via email at: OCS-BSC@hc-sc.gc.ca, within 15 days after the importation.

5.3 What requirements, under the *FDR*, must be met to wholesale a drug on the List?

In accordance with section C.01A.001 of the *FDR*, a wholesaler means a person who is not a distributor described in section C.01A.003 and who sells any of the following drugs other than at the retail sale: (a) a drug in dosage form that is listed in Schedule C or D to the Act, a drug that is a prescription drug or a controlled drug as defined in subsection G.01.001(1); (b) an active ingredient; or (c) a narcotic as defined in the *Narcotic Control Regulations*.

To wholesale a drug on the List, the following conditions must be met:

- Any person who wholesales the drug must do so in accordance with C.10.002(2).
- The wholesaler must meet the DEL requirements (refer to section 5.1).
- The drug must have been imported in compliance with C.10.001(2).
- The drug must be on the List at the time of the sale.
- The drug must be sold in the Canadian jurisdiction identified on the List.
- The drug must be sold for the purpose of the urgent public health need on the List.

5.4 What are the retail sale requirements?

Section C.10.002 (1) exempts drugs on the List from all sale requirements under the *FDR*, with the exception of those requirements in Division 10. If a drug has been removed from the List, both importation and sale of the drug is prohibited. The drug can only be sold within the Canadian jurisdiction identified on the List and for use in respect of the urgent public health need for which it was imported.

This requirement applies to all parties in the supply chain, including retailers (e.g. health care practitioner and pharmacists). In addition, all parties in the supply chain selling the drug should ensure that it is not past the expiry date as displayed on the foreign product label.

5.5 What happens if the drug is a controlled substance?

If a drug on the List contains a controlled substance, the *CDSA* and its *Regulations* would apply and the DEL holder would also need to have a valid dealer's license. Division 10 does not include any exemption to the application of the *CDSA*. The *CDSA* authorizes the holder to possess controlled substances and to conduct activities with these substances as specified on the license, including production, packaging, sale, sending, and transportation.

If the DEL holder does not have a dealer's license, an application must be submitted to Health Canada to obtain one and the specific active substance of the drug on the List must appear on the license. The processing time for such an application can be up to 180 business days. A security proposal must be submitted with the license application that provides a full description of the proposed security for the storage of controlled drugs and substances at the site, including details on how all of the listed requirements of the Directive on Physical Security Requirements for Controlled Substances would be met for the security level requested for the site. Once the requirements of the *CDSA* and its Regulations are met, the license may be issued. The license holder must then apply for an import permit which authorizes the entry of a specific shipment of controlled substances into Canada. Only a holder of a valid dealer's license may apply for an import permit. The processing time for import permit applications can be up to 30 business days.

5.6 Do the Good Manufacturing Practices (GMP) apply to import and wholesale of drugs on the List?

Drugs on the List should, for the most part, continue to be handled by DEL holders as per existing processes and systems. Wholesalers and importers must have the expertise and knowledge to be able to work with the drug class including the ability to provide the necessary controls over environmental conditions and other factors during storage and transportation.

GMP requirements that apply to import and wholesale are respectively described in C.10.001(5) and C.10.002 (2).

DEL holders are familiar with the applicable GMP provisions and may refer to available guidance, including Good Manufacturing Practices (GMP) Guidelines - 2009 Edition, Version 2 (GUI-0001) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/good-manufacturing-practices-guidelines-2009-edition-version-2-0001.html>), for further details.

5.7 Who is responsible for conducting a recall?

Importers and wholesalers are responsible for conducting recalls. For the recall of a drug on the List, section C.01.051 of the *FDR* applies and requires the importer to notify Health Canada of when they have initiated a recall. More information about Health Canada's Recall Policy (POL-

0016) can be accessed on Health Canada's website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/recall-policy-0016.html>).

6 REPORTING OF SERIOUS ADVERSE DRUG REACTIONS

6.1 What is a serious adverse drug reaction?

A serious adverse drug reaction, as defined in the *FDR*, means a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death. This definition implies that the causal relationship between the drug and the occurrence of the adverse reaction is suspected.

6.2 Who is responsible for reporting serious adverse drug reactions?

Under these *Regulations*, every health care institution authorized by the laws of a province to provide acute care services is required to report serious adverse drug reactions that involve a drug from the List to Health Canada.

However, as with other health products, health professionals, patients and consumers are encouraged to report any suspected adverse drug reactions to Health Canada (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>).

6.3 What are the reporting requirements for serious adverse drug reactions?

In accordance with section C.10.004(1) of the *Regulations*, the following information about a serious adverse drug reaction must be provided, by health care institutions, in writing 30 days from the date that the reaction is first documented:

- (a) the name of the health care institution and the contact information of a representative of that institution;
- (b) the name, number or identifying code of the drug on the List that is suspected of causing the reaction; and
- (c) a description of the serious adverse drug reaction.

The health care institution should provide all information that is available and relevant in the initial adverse drug reaction report. Further to the above the following should be provided to enhance report quality:

- patient characteristics [age or age category (e.g., adolescent, adult, elderly), gender, patient identification number];
- the form, strength and dosage;
- therapy and reaction dates (dates the drug was started and stopped; and date the adverse reaction occurred and was resolved);
- relevant tests/lab data;
- relevant medical history;
- route of administration; and
- concomitant health products.

6.4 How to Report

Adverse reactions should be reported to the Canada Vigilance Program of the Marketed Health Products Directorate (MHPD) of Health Canada.

There are two easy ways to report an adverse reaction to the Canada Vigilance Program:

- Online via the MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) Canada online reporting module (Drug Health Product Register) accessible through the Health Canada website.
- By completing a Side Effect Reporting Form (available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>), which you can send by:
 - Postage paid mail to:
Canada Vigilance Program
Health Canada
Address Locator: 1908C
200 Eglantine Driveway
Ottawa ON
K1A 0K9
 - or
 - Fax (toll free) to 1-866-678-6789
- When completing the Side Effect Reporting Form for Consumers and Health Professionals it is important to note that some fields are marked as mandatory. The only required information is as indicated above; however, any additional information is useful.

The form and postage paid label are available on the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>).

7 HOW IS HEALTH CANADA APPLYING COMPLIANCE AND ENFORCEMENT?

Every person importing and selling drugs on the List is subject to Health Canada compliance and enforcement activities, in line with relevant Acts, Regulations and policies, including the Compliance and Enforcement Policy (Policy -0001).

8 CAN DRUGS ON THE LIST BE ADVERTISED?

While a drug on the List may be authorized for sale in its foreign jurisdiction, these regulations only permit the import and sale of these drugs in Canada (despite their not having been approved for sale in Canada (i.e., by way of a DIN or NOC). These regulations do not exempt these drugs from the *FDA*, or the *FDR*, or the *Narcotic Control Regulations* as they speak to (e.g. prohibit) the advertising of these drugs.

For this reason, sections 3 and 9 of the *FDA*, the *FDR* (including sections C.08.002 C.01.044 of the *FDR*) and the *Narcotic Control Regulations* continue to apply to restrict and prohibit the advertising of any drug on the List. New drugs on the List cannot be advertised; drugs on this list that are narcotics or prescription drugs cannot be advertised to the public.

9 CONSIDERATIONS

Given that Health Canada has not reviewed a listed drug for its safety, effectiveness and quality, and that these drugs are exempt from Canadian labelling requirements, a collaborative approach involving all key stakeholders is critical to ensure patient safety. Health Canada will support monitoring of the safety of the drugs on the List through various activities such as collecting adverse reaction reports and continued engagement and information sharing with foreign regulators and provincial authorities on emerging safety issues in those jurisdictions. Health professionals, patients and consumers should also be encouraged to report medication incidents involving drugs on the List to the Canadian Medication Incident and Prevention System (<https://www.ismp-canada.org/cmiprs/>).

Health Canada strongly recommends that PHOs monitor distribution activities and use of drugs on the List. For all drugs imported under Division 10, particularly those labeled in a language other than French or English, PHOs should ensure that appropriate and up-to-date information is procured and provided to patients as well as health professionals administering the drug. Critical information includes, but is not limited to, information about a drug's intended use, contraindications, warnings and precautions, dosage, administration and storage requirements. In

situations where the administration of a drug requires supplementary training, PHOs should consider engaging health professional regulatory bodies and associations within their jurisdiction to ensure preparedness. PHOs are also encouraged to establish a mechanism to receive timely notification from the foreign manufacturer of an imported drug regarding post-market actions related the drug's safety, effectiveness or quality. This information should be shared with Health Canada so that appropriate action can be taken if necessary.

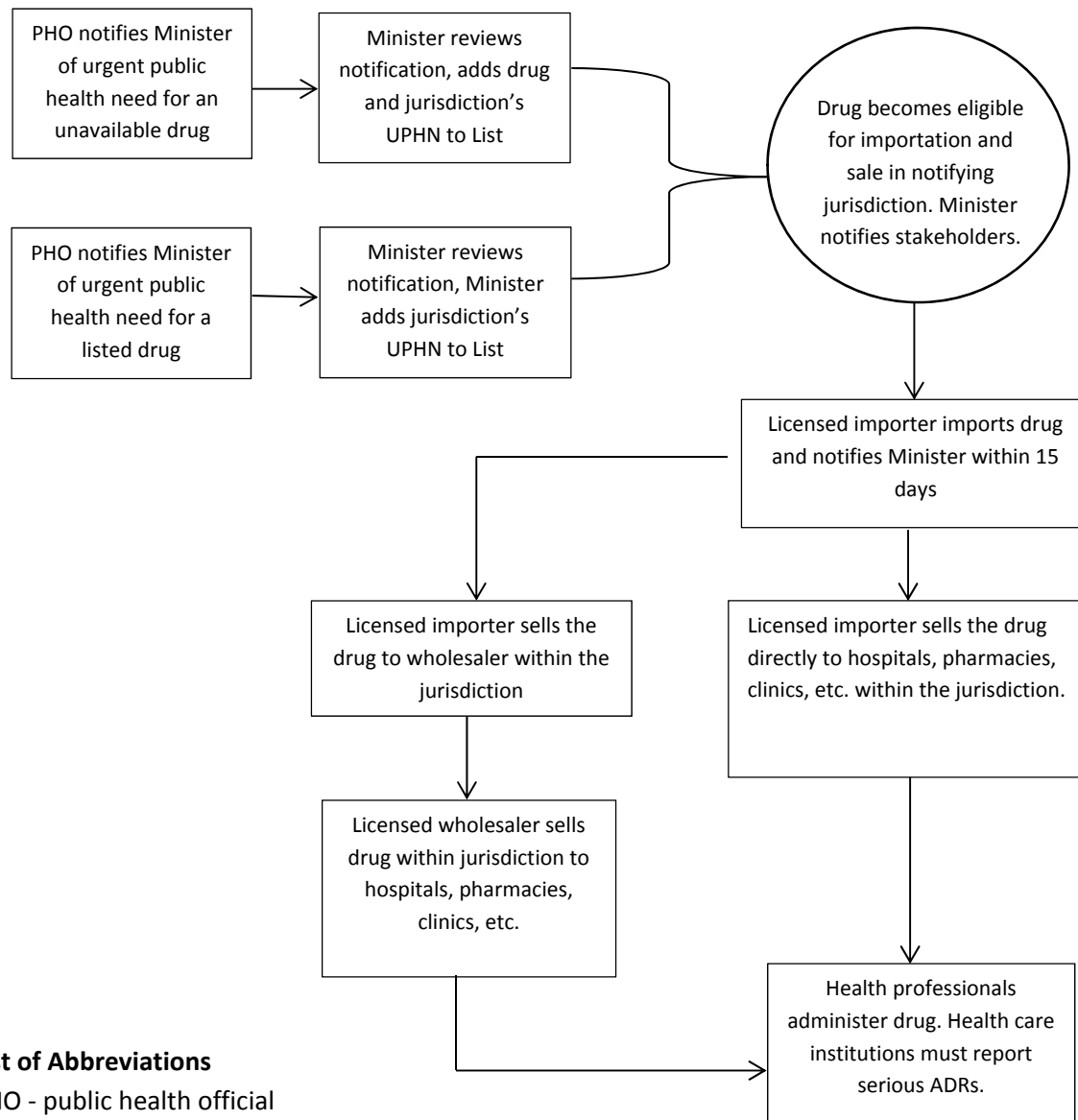
10 CONTACT INFORMATION

Completed notification forms should be faxed, or sent by email to:

Office of Risk Management
Therapeutic Products Directorate
Health Products and Food Branch
Address Locator: 3106B
Health Canada
Ottawa, Ontario
K1A 0K9

Fax: 613-952-7756

E-mail: drugs_urgent_need_besoin_urgent_medicaments@hc-sc.gc.ca

APPENDIX 1: PROCESS MAP - ACCESS TO DRUGS IN EXCEPTIONAL CIRCUMSTANCES**Adding a jurisdiction's urgent public health need and a drug to the List⁸****List of Abbreviations**

PHO - public health official

ADR - adverse drug reaction

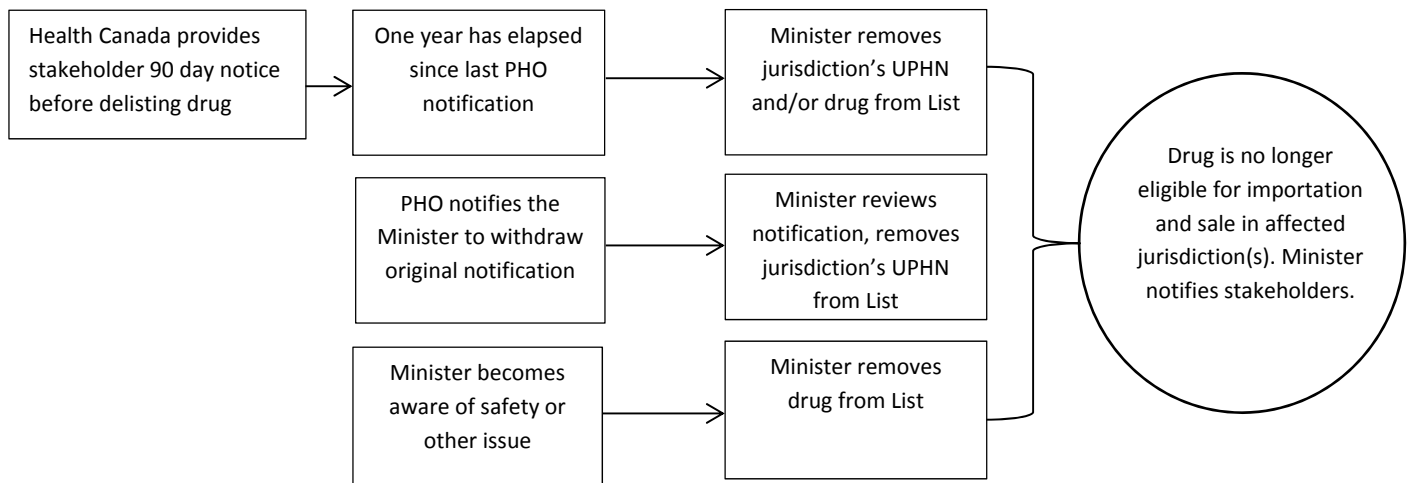
UPHN - urgent public health need

⁸

The Minister has discretionary authority when adding a drug to the List.

APPENDIX 2: PROCESS MAP - ACCESS TO DRUGS IN EXCEPTIONAL CIRCUMSTANCES

Removing a drug and/or a jurisdiction's urgent public health need from the List⁹



List of Abbreviations

PHO - public health official

UPHN - urgent public health need

⁹

The Minister has discretionary authority when removing a drug from the List.