Health Canada Santé Canada

Guidance Document: Sale of Drugs- Public or Canadian Armed Forces Health Emergencies

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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

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Foreword

Guidance documents provide assistance to industry on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

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1. Introduction

Prior to selling a drug in Canada, manufacturers must receive authorization from Health Canada. Manufacturers wishing to pursue market authorization are required to submit information on a drug's safety, efficacy and quality and comply with the requirements of the *Food and Drugs Act* (FDA) and *the Food and Drug Regulations* (FDR). Health Canada reviews the submitted information and if it meets the requirements of the FDA and FDR, an authorization is issued to the manufacturer to sell the drug in Canada. Not all drugs are available on the Canadian market, as it is a manufacturer's decision whether to seek market authorization in Canada. There are circumstances in which the best available treatment for a particular public or military health emergency may be a drug that does not have a regulatory market authorization in Canada. That is, the drug is unauthorized as a drug identification number has not been assigned under subsection C.01.014.2(1) or a notice of compliance has not been issued under section C.08.004 or C.08.004.01 of the FDR.

Federal (including Indigenous Services Canada), provincial, territorial Chief Medical Officers of Health, municipal Medical Officers and the Surgeon General of the Canadian Armed Forces (CAF), referred to as public health officials (PHOs), are mandated to carry out emergency preparedness and response activities within their jurisdictions. Each province and territory, has legislative and regulatory tools governing their activities for public population health while the CAF has legislative and regulatory tools governing their activities for military population health. As part of their routine business, PHOs prepare, manage, and respond to emergencies, which includes purchasing drugs to be used in an emergency.

As part of their emergency preparedness planning, PHOs conduct a risk/threat assessment to identify emerging health risks. This assessment identifies populations that may be at increased risk in the context of the potential emergency. Based on the risk/threat assessment and consideration of treatments that could address the identified risks, the PHO may decide to procure treatments that could be used in the emergency.

The regulatory framework entitled *Sale of Drugs - Public or Canadian Armed Forces Health Emergencies* (referred to as block release) in Division 11 of the FDR, gives the Minister of Health the authority to consider applications from PHOs to purchase drugs that are not authorized for sale in Canada for public or military health emergency preparedness and response activities. Based on the information provided by the PHO, a manufacturer may be authorized to sell a quantity of an unauthorized drug to the requesting PHO for use in a public or military health emergency. The regulatory framework addresses two scenarios that are part of emergency preparedness and response activities. It allows the sale of a specified quantity of an unauthorized drug for immediate use in a public or military health emergency, event, or incident and/or for stockpiling in anticipation of a public or military health emergency, incident, or event.

1.1 Purpose

This guidance document is for PHOs who are responsible for public or military health emergency preparedness and response activities within their jurisdiction. It explains the intent and scope of the regulatory provisions under Division 11 of the FDR and provides:

- information required to comply with Part C, Division 11 of the *Food and Drug Regulations*;
- the process to make an application to request a drug that cannot otherwise be sold or distributed in Canada for use in a public or military health emergency, event, or incident; and
- information on the responsibilities of the PHOs in that process.

1.2 Scope and application

This guidance document applies to PHOs responsible for public or military health emergencies, who use Division 11 of the FDR to request drugs that are otherwise not authorized for sale in Canada.

For the purposes of this guidance document, "drugs" include pharmaceuticals, radiopharmaceuticals, biologics, and natural health products for human use in final dosage form. Drugs authorized under this regulatory framework (Division 11) are referred to as “block release drugs” and the term “emergency” includes incident and event.

1.3 Policy objective

To facilitate access to drugs for emergency preparedness and response activities by permitting PHOs to request a drug for use in an emergency that is otherwise not authorized for sale in Canada. Applications will be received, processed, and decided upon in accordance with Division 11 of the FDR by Health Canada.

1.4 Policy statements

- Emergency access should be exceptional. Where possible, drugs available on the Canadian market or extraordinary use new drugs should be the first choice of treatment for public or military health emergencies.
- For a drug to be considered under this regulatory framework, existing drugs marketed in Canada should be determined ineffective, unsuitable, or unavailable to diagnose, treat, mitigate or prevent a disease or condition, in the population affected or at risk, resulting from an imminent, actual or potential public or military health emergency.

- The regulatory authority supporting access to unauthorized drugs is discretionary. The decision to authorize or deny a request is made on a case-by-case basis taking into consideration the nature of the public or military health emergency, the availability of marketed alternatives and information provided to support the request on the use, safety and efficacy of the drug to be used in a population.
- The PHO who is named in an authorization (i.e., initial PHO) is responsible for monitoring and reporting on the response to the drug in the emergency. This includes monitoring information they receive relating to serious adverse drug reactions. PHOs are responsible for all quantities of drug received, distributed and used.
- Monitoring the response to the drug and health outcomes from its use provides helpful information to the initial PHO when assessing whether the drug continues to be the best choice for a public or military health emergency. The response to the drug includes assessing whether it is effective in the context of the emergency taking into consideration any serious adverse drug reactions.
- An authorization issued under Division 11 of the FDR does not mean that Health Canada has reviewed the drug's data for safety, efficacy and quality as is the case with drugs marketed in Canada. Health Canada relies on the information and risk assessments done by the initial PHO in determining whether the benefits of using a particular drug to address a public or military health emergency outweigh the risks.
- The dissemination of drug information by the initial PHO, and any subsequent PHO who obtained a quantity of drug from the initial PHO, is needed for the safe prescribing, storage, dispensing and use of a drug.

2. Overview of the regulatory framework

The regulatory framework under Part C, Division 11 of the FDR, referred to as "block release", permits PHOs to request an authorization from the Minister of Health (referred to as the Minister) for the sale of a specified quantity of an unauthorized drug for an identified use, to address a potential, imminent or actual public or military health emergency.

PHOs include the federal (including Indigenous Services Canada), provincial, and territorial Chief Medical Officers of Health and municipal Medical Officers of Health, who are responsible for public health in their jurisdiction and the Surgeon General of the CAF who is responsible for military health.

The term initial PHO refers to the PHO who has received an authorization under subsection C.11.003(1) of the block release framework. The term subsequent PHO means any public health official, other than the initial PHO, who obtains the quantity of drug, or a portion of the quantity, that is specified in an authorization issued under C.11.003(1) of the block release framework.

Provincial legislation governing emergency preparedness and response activities varies in how emergencies are defined, however they are all similar in that there is a significant health risk to the public which may result in a large number of individuals facing a serious or life-threatening disease or condition. Rather than defining emergencies that would trigger use of this regulatory framework, the regulations set out conditions to be met for an authorization of a drug. The sale of a requested drug is permitted only when the conditions have been met and the information provided by a PHO supports the requested use of the drug in an emergency. An emergency (which includes an incident and event) is an occurrence or imminent threat of a health hazard or disease that poses a significant risk to the public health. An incident is an action, whether intended or unintended, that is likely to lead to grave consequences; and an event is an immediate and significant risk to public health.

When considering use of this regulatory framework the PHO is expected to have identified a drug to be used to address a particular emergency based on available information and a risk/threat assessment of the public or military health emergency.

If the drug requested is for an actual public health or military emergency and it has been authorised for sale in the United States, the European Union, or Switzerland for the specified use, the regulatory framework *Access to Drugs in Exceptional Circumstances* (https://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances.html) (Part C, Division 10 of the FDR) referred to as the Urgent Public Health Need (UPHN) List (https://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/list-drugs-urgent-public-health-need.html) may also be a viable access mechanism. However, the UPHN framework cannot be used for stockpiling purposes.

2.1 Application to request a drug – section C.11.002

The PHO making an application under Division 11 to request a drug for emergency preparedness (i.e., stockpiling), or to respond to an imminent or actual emergency, must provide information that demonstrates the requested drug is appropriate for use in the emergency based on information available on the drug and a risk/threat assessment of the emergency. Information to be provided includes a description of the intended use of the drug to address the emergency, any information or document available to the PHO, or published in a medical or scientific journal, concerning the safety, efficacy and quality of the drug in respect of the use. For military health emergencies, certain information on the emergency may not be provided due to the classified nature of some military operations.

Through the supporting information provided in the application and a statement by the PHO, the following conditions must be met in order to seek authorization for the sale of a drug that is not marketed in Canada:

(i) there is an actual, imminent or potential emergency, event or incident affecting public health or the health of the members of the Canadian Armed Forces, that is likely to result in humans, in a serious or life-threatening disease, disorder or abnormal physical state;

(ii) immediate action is or would likely be required to diagnose, treat, mitigate or prevent the disease, disorder or abnormal physical state, or its symptoms;

(iii) conventional therapies, if any, have failed, are unsuitable or are unavailable in Canada at the time the application is made; and

(iv) the known and potential benefits associated with the use of the drug outweigh the known and potential risks associated with its use.

Other information that must be provided in the application, if known by the PHO, includes:

- names of the foreign regulatory authorities that have authorized the requested drug for the same use as its approved indication (if any) in the foreign country;
- names of the foreign regulatory authorities that have received an application for authorization to sell the drug in their jurisdictions for the use requested but have not yet made a decision in respect of that application at the time the public health official makes their application; and
- names of the foreign regulatory authorities that have refused to issue the requested drug a market authorisation and the reasons for refusal. The initial PHO should discuss this requirement with the manufacturer from whom they wish to purchase the drug.

The Minister has the authority to request any additional information or documents that are determined necessary for the purpose of reviewing the application.

2.2 Issuance of an authorization – subsections C.11.003(1) and (2)

The Minister reviews the information provided by the PHO to support the use of the requested drug for the identified emergency. In reviewing the application, Health Canada considers whether there is an alternative mechanism that would permit the sale of the drug to address the emergency.

Information submitted to support an application to request a drug under the block release framework does not undergo a regulatory and scientific review as is the case when Health Canada reviews a drug to receive market authorization in Canada for sale to the public. Rather, the information and risk assessment of the emergency done by the PHO is relied upon in determining whether the drug's benefits outweigh the risks in addressing the public or military health emergency, and any other information that is available to Health Canada at the time the request is assessed.

Following the review of the application, a Letter of Authorization may be issued that permits a manufacturer to sell the quantity of drug identified in the authorization to the PHO for the identified emergency or event i.e., for immediate use to respond to an emergency, or for stockpiling to support preparedness planning in anticipation of the drug's use in an emergency. Health Canada may deny issuing an authorization based on the information provided with the application, and any other information that may be available at the time of the application. The reason for not issuing an authorization could include the conditions not being met, the information provided not supporting the safe use of the drug, or an alternative

mechanism being available. The PHO will be given an opportunity to be heard when the issuance of a denial is being reconsidered (refer to section 3.6 of this guidance).

Drugs can only be distributed and/or sold for the use stated in the authorization. Should the initial PHO wish to use the block release drug for a use or emergency other than the authorized use or emergency, a new application must be made.

2.3 Change in information that was submitted to support the request – section C.11.004

There may be circumstances where the information the PHO provided in the application to request the drug has changed. The initial PHO must, within 30 days of becoming aware of such changes, notify the Minister, in writing, with any change to the following information that was submitted with the application:

- Information about the drug [subsection C.11.002(2)(g)]:
    - its brand name, if any, and either its proper name, common name and chemical name or its identifying name, code, number or mark,
    - its medicinal ingredients,
    - its strength,
    - its dosage form,
    - the recommended dosage for the use of the drug that is intended to address the emergency, event or incident,
    - its recommended route of administration,
    - the indications that have been approved by any foreign regulatory authority, if applicable,
    - its contraindications,
    - a summary of its safety profile, and
    - the recommended storage conditions for the drug;
- the known and potential benefits associated with the use of the drug for its intended use outweigh the known and potential risks associated with that use [subparagraph C.11.002(2)(i)(iv)];
- information concerning the safety, efficacy and quality of the drug in respect of the specified use, including information published in a medical or scientific journal [paragraph C.11.002(2)(j)];
- additional information the Minister requested to inform the decision to authorize the request [section C.11.002(3)].

2.4 Exemption to the FDA and the FDR – section C.11.005

The sale of the quantity of drug identified in an authorization is subject to the FDA with some exceptions. In the case of a drug represented on Schedule C or D of the Act, the drug is exempt from Section 12 of the FDA [subsection C.11.005(2)].

The sale of drugs authorized under Division 11, the block release regulatory framework, are exempt from provisions of the FDR except for the requirements of this Division, and the following:

- Sections of Part A:
  - A.01.010 - definition of terms in the FDR;
  - A.01.014 - requirement for how a lot number is to appear on the drug's label or accompanying document; and
- Paragraphs C.01.001 (1) and (1.1) - definition of terms
- Section C.01.020 in Part C, Division 1 - mandatory hospital reporting
- Section C.10.001 in Part C, Division 10 - definitions

2.5 Labelling of drugs – section C.11.006

The initial and subsequent PHOs are responsible to ensure those handling and administering the drug have the information they need for the safe administration of the drug to patients. The initial PHO must ensure a drug bears a label, or is accompanied by a document that sets out the following information in English and French:

(a) the name and civic address of the drug's manufacturer;
(b) a statement that the Minister has authorized the sale of the drug to address the emergency, event or incident described in the authorization;
(c) a statement that the drug is to be used only for the use described in the authorization;
(d) the drug's brand name, if any, and either its proper name, common name and chemical name or its identifying name, code, number or mark;
(e) the drug's medicinal ingredients;
(f) the drug's strength;
(g) the drug's dosage form;
(h) the drug's recommended dosage and route of administration;
(i) the drug's lot number, if known;
(j) all warnings and precautions in respect of the use of the drug, if any;
(k) the drug's expiration date, or, if there is no expiration date, the stability testing date or the date on which the drug should be retested, as specified by the manufacturer;
(l) the drug's recommended storage conditions; and
(m) the net contents of the drug's container, in terms of the weight, volume, size or number of units of the drug in the container.

The initial PHO must provide the drug labelled or accompanied by a document that has the above information. Any subsequent PHO who receives a quantity of the drug from the initial PHO must ensure the drug bears the label or is accompanied by the document provided by the initial PHO [subsection C.11.006(2)].

2.5.1 Change in information on the label, or the accompanying document - subsections C.11.006 (3), (4), and (5)

The initial PHO must update the drug's label or accompanying document if they become aware of a change to any of the following information:

- the name and civic address of the drug's manufacturer;
- the drug's recommended dosage and route of administration;
- all warnings and precautions in respect of the use of the drug, if any;
- the drug's expiration date, or, if there is no expiration date, the stability testing date or the date on which the drug should be retested, as specified by the manufacturer;
- the drug's recommended storage conditions.

The initial PHO must also ensure they notify of the change, in writing and without delay, any person to whom they have sold any quantity of the drug.

Any subsequent PHO who is notified by the initial PHO of the change, must notify of the change, in writing and without delay, anyone to whom they have sold the drug. Any person who has been notified by the initial PHO or subsequent PHO of the change, must ensure the updated information accompanies the drug in their possession [subsections C.11.006 (4) and (5)].

2.6 Making information available to persons administering the drug and those receiving the drug – section C.11.007

Subsection C.11.007(1) requires the initial PHO, or any subsequent PHO, to provide certain information in English and French to the persons who administer the drug or to whom the drug is administered as per the following:

(a) to the persons to whom the drug is administered and the persons who administer the drug, the known and potential benefits and risks associated with the use for which the sale of the drug is authorized, the recommended duration of use, if any, of the drug and instructions on how to report serious adverse drug reactions; and

(b) to the persons who administers the drug, the information referred to in paragraphs C.11.002(2)(a), (b) and (e) and subparagraphs C.11.002(2)(g)(v), (vii) and (viii), if that information is not set out on the drug's label or accompanying document. The relevant paragraphs and subparagraphs of section C.11.002(2) are as follows:

> (a) the name of the public health official and include information setting out how they may be contacted at any time;
> (b) the name of the manufacturer and include information setting out how they may be contacted at any time;
> (e) description of the use of the drug that is intended to address the emergency, event or incident;

(g) the following information about the drug:
(v) the recommended dosage for the use of the drug that is intended to address the emergency, event or incident,
(vii) the indications that have been approved by any foreign regulatory authority, if applicable, and
(viii) the drug's contraindications.

If there are any changes to the information in (a) or (b), the initial PHO is required to notify, in writing and without delay, anyone to whom they have distributed the drug [subsection C.11.007(2)].

2.7 Reporting serious adverse drug reactions – section C.11.008

Given the differences between military and public health emergencies the SG of the CAF is responsible for reporting to the Minister on serious adverse drug reaction (ADRs) whereas for public health emergencies, hospitals are required to report serious ADRs for block release drugs.

2.7.1 Military health emergencies – subsection C.11.008(1)

If the PHO named in an authorization is the SG of the CAF they must submit a written report to the Minister in respect of any serious adverse drug reaction to the drug, and include in the report the information referred to in paragraph C.01.020.1(2)(b) to (l) of the FDR, no later than the 30th day after the day on which they become aware of the serious adverse drug reaction.

The following information in subsection C.01.020.1(2) of the FDR is to be included in the report:

(b) the drug's brand name, proper name or common name;
(c.1) in the case of a drug whose sale has been authorized under subsection C.11.003(1), its identifying name, code, number or mark;
(d) the drug identification number assigned for the drug, if applicable;
(e) the patient's age and sex;
(f) a description of the serious adverse drug reaction;
(g) the date on which the serious adverse drug reaction was first documented;
(h) the date on which the patient first used the drug and, if applicable, the date on which the patient stopped using the drug;
(i) the date on which the serious adverse drug reaction first occurred and, if applicable, the date on which the patient's health was restored to its state prior to the reaction;
(j) any medical condition of the patient that directly relates to the serious adverse drug reaction;
(k) any concomitant therapeutic products used by the patient; and
(l) the effect of the serious adverse drug reaction on the patient's health.

2.7.2 Public health emergencies – subsection C.11.008(2)

If the PHO named in the authorization is not the SG of CAF, the PHO is not required to submit a written report to the Minister. For public health emergencies, hospitals are required to report serious ADRs within 30 days after the day on which the serious adverse drug reaction is first documented within the hospital as per the mandatory reporting requirements for serious adverse drug reactions in section C.01.020.1 of the FDR.

2.8 Monitoring the response to the drug – section C.11.009

The initial PHO must monitor the response to the drug in the emergency, event or incident and take reasonable steps to obtain information on the response of the drug. This includes monitoring information received on serious adverse drug reactions [subsection C.11.009(1)].

The Minister may request the initial PHO submit a written report on the monitoring of the response to the drug in the emergency, event or incident during a specified time period. This report would include any corrective actions taken as a result of the monitoring of the drug.

2.9 Maintaining information on the sale and use of the drug – section C.11.010

The initial PHO must maintain all information about the sale, i.e., distribution, and use of the drug in a way that would allow the PHO to submit to the Minister the information, notices and reports referred to in sections C.11.004, C.11.008 and subsection C.11.009(2).

In addition, the initial PHO and any subsequent PHO are required to maintain all information about the sale and use of the drug in a way that allows them to communicate with persons to whom the drug has been administered if the health of those persons may be endangered by its use.

2.10 Record retention – section C.11.011

The initial PHO or any subsequent PHO, as the case may be, must retain the information, notices and reports referred to in sections C.11.004 (notification to the Minister of any change to the information used to support the request section); C.11.008 (serious adverse drug reaction reports); subsection C.11.009(2) (report on monitoring response to the drug and any corrective measures taken); and section C.11.010 (information about the sale and use of the drug), as applicable, for 15 years after the end of the period to which the information, notices and reports relate.

2.11 Annual reporting of remaining stock – section C.11.012

The initial PHO must account to the Minister for any unused quantity of stockpiled drug remaining in their possession at the end of the preceding calendar year by the 30th of January that follows the first full calendar year during which the drug is stockpiled and then by January 30th of each subsequent year.

2.12 Cancellation of an authorization – section C.11.013

If the Minister has reasonable grounds to believe that the drug presents a serious or imminent risk of injury to human health [subsection C.11.013(1)] an authorization may be cancelled.

If an authorization is cancelled all exemptions from the FDR granted by the authorization cease to apply to any unused quantity of the block release drug as of the day the cancellation comes in effect.

The initial PHO must, without delay, notify of the cancellation any person to whom they have directly distributed any quantity of drug [subsection C.11.013(2)].

2.13 Sale of a drug from an initial PHO to a practitioner named in an authorization issued under Division 8 of the FDR - section C.11.014

The Minister may issue an authorization permitting an initial PHO who is either the Chief Public Health Officer appointed under subsection 6(1) of the Public Health Agency of Canada Act; the Surgeon General of the Canadian Armed Forces; or the Chief Medical Officer of Public Health for the Department of Indigenous Services, to sell a quantity of stockpiled drug to a practitioner who is treating a patient in a medical emergency [subsection C.11.014(1)].

To be considered, the manufacturer of the drug must have been issued a letter of authorization under subsection C.08.010(1) of the FDR that authorizes the sale of a specified quantity of the drug to that practitioner for the emergency treatment of that person. The authorization under this Division (Division 11) no longer applies. As such, the initial PHO is not responsible for that quantity of drug that has been sold to the practitioner.

3. Guidance for implementation

Health Canada's Special Access Program for drugs (SAP) is responsible for administering Division 11 (the block release framework), in Part C of the FDR.

3.1 PHO making an application to request a drug

The PHO may make an application for a drug under Division 11, the block release framework, through Health Canada's SAP by completing "Form E - Block Release Request".

Completed forms should be sent via facsimile (i.e., fax), to:

- Special Access Program
  Health Canada, Tunney's Pasture
  Address Locator 3105A
  K1A 0K9

  Tel: 613-941-2108
  Fax: 613-941-3194
  E-mail: hc.sapd-pasm.sc@canada.ca

A cover sheet is not required for forms sent by fax. By telephone, PHOs should be prepared to provide all the required information using the form as a guide. A written request must follow.

The SAP operates 24 hours a day, 365 days a year. Regular business hours are weekdays from 8:30 am to 4:30 pm Eastern Standard Time. Outside of regular business hours and during statutory holidays, an On Call service is available at 613-941-2108.

Applications are triaged to ensure that urgent matters take precedence over less urgent matters. For example, applications for a drug for an immediate emergency is given priority over applications for stockpiling.

Upon receipt of an application, the SAP will send an acknowledgement of receipt to the PHO and proceed to assess the information that has been submitted to support the need for a drug to be used in a public or military health emergency. The form is reviewed to ensure that all sections are complete, the information provided is legible, and the request is signed and dated.

3.2 Information required when filing an application

In making an application, the PHO must specify whether the drug is required for immediate use or for stockpiling purposes. The PHO must also provide:

- a description of the public or military health event, incident or emergency;
- an explanation of why the event requires a drug that is not authorized for sale in Canada;
- an explanation of what serious condition or injury could arise from the event based on their risk/threat assessment; and
- information to support the safety and efficacy of the drug for the specific use requested.

PHOs are required to demonstrate in the application that the conditions, as outlined in section 2.1 of this guidance, have been met.

PHOs are strongly encouraged to contact manufacturers early in the process to discuss the application, confirm availability of the drug and determine whether terms/conditions would apply. PHOs should obtain as much information as possible from the manufacturer to further inform their decision to choose a particular drug for an identified emergency. Prior to making an application PHOs should:

- assess the risks and benefits of the drug in the context of the public or military health emergency;
- identify and contact the manufacturer to obtain the necessary information (e.g., prescribing information, chemical information about the drug, drug's approval in foreign countries, etc.) and to identify conditions of sale (e.g. mandatory health professional training, controlled distribution, etc.) set forth by the manufacturer, or the foreign regulator to determine whether these conditions can be fulfilled within the PHO's jurisdiction; and
- obtain information from the manufacturer about the status of the drug and its market authorization, or if under development, the stage of its development.

The manufacturer decides whether the drug will be supplied. They are under no obligation to sell an unauthorized drug to a PHO and Health Canada cannot compel a manufacturer to do so. The manufacturer may also impose certain restrictions or conditions on the release of the drug to ensure its use is in accordance with the latest information available. For instance, the manufacturer may restrict the amount of drug released or the indications for which the drug is used. Questions concerning shipping or the cost of the drug should be directed to the manufacturer.

Subsequent applications for the same drug, use and emergency do not require information on the use, safety, efficacy and quality of the drug unless new information has become available since the PHO's initial application. All other information is required to support subsequent applications, such as, information about the emergency, the risks, etc.

3.2.1 Information about the drug to support the requested use

Drugs requested through the block release framework may have received market authorization from a foreign regulatory authority. However, they have not undergone regulatory review and approval in Canada. Drugs under development may be considered for use in emergency preparedness and response if evidence supports their use, and the benefits are anticipated to outweigh the risks for use of the drug in the emergency context. Since the requested drugs have not been reviewed for safety, efficacy or quality in Canada, the PHO is responsible for providing enough information in their application to demonstrate that the benefits of using the drug outweigh the risks.

The PHO must submit information that supports their decision to use the drug based on their risk/threat assessment of the public or military health emergency. The PHO must:

- explain how the emergency, event, or incident is likely to result in a serious or life-threatening disease, disorder or abnormal physical state;
- demonstrate whether conventional therapies, if any, have failed, are unsuitable or are unavailable in Canada at the time the application is made;
- demonstrate the known and potential benefits associated with the use of the drug outweigh the known and potential risks associated with that use; and
- provide information or documents available to them concerning the use, safety, efficacy and quality of the drug for its intended use including, but not limited to, information published in the medical or scientific literature.

3.2.1.1 Indication versus use

In making an application (Form E – Block Release Request) the PHO is to include the use for which the drug is being requested. The term "use of the drug" means, in the case of a marketed drug, indication. Indication is the term used when specific uses of a drug have been

authorized for the market by a regulatory body. The label of a foreign authorized drug will state the indication or use for which the drug was approved (i.e., for the diagnosis, mitigation, treatment or prevention of a disease or condition).

If the PHO requests a use of a foreign authorized drug that is different from its authorized indication, an additional rationale as to why the foreign authorized drug is the preferred drug to be used in the emergency must be provided along with evidence of the drug's safety and efficacy for that specified use. This may include but is not limited to information published in a medical or scientific literature.

3.2.1.2 Regulatory status of the foreign drug

If the requested drug has been approved by a foreign regulatory authority, all approved indications for use are to be provided in the application as well as the medicinal ingredient(s) of the drug; the strength; recommended dosage(s); route(s) of administration; contraindications; and known side-effects.

If the drug has not received a foreign market authorization, the countries in which a regulatory submission may have been filed should be identified, if known. If a foreign regulatory authority has refused to issue an authorisation permitting the sale of the drug in their jurisdiction, this information including the reasons for refusal should also be provided to the SAP.

For a drug under development that is not authorized for sale in any jurisdiction, the PHO must specify in the application the indication(s) for which the drug is under development.

3.2.1.3 Quantity of drug requested

The PHO is required to provide the quantity of drug needed to address the emergency, i.e., the number of tablets, vials, etc.

3.2.1.4 Address of manufacturer, PHO and shipping address

The PHO must provide the name of the manufacturer who will sell the drug and information on how to contact the manufacturer at any time. For shipping purposes, the PHO is to include the name and address of the foreign manufacturer's principal place of business and the establishment in which the drug was manufactured. The address to where the manufacturer is to ship the drug as well as the address of the PHO is also to be included.

3.3 SAP's review of the application and supporting information

In deciding whether to issue an authorization, the SAP considers if the data supporting the application is credible and supportive of the need. This includes data supporting the use of the drug for the identified emergency. The SAP relies on the risk threat assessment conducted by the PHO which identifies the potential emergency and what drug is necessary to respond to

that emergency. When assessing the information provided, the SAP may, at any time prior to making a decision, request additional information from the PHO on the drug and its use. The SAP also considers other information that may be available on the drug and its use for the identified emergency, at the time of the application, and may further consult within Health Canada to seek additional information and confirm, as needed, the Canadian and international regulatory status of the drug.

The SAP verifies there are no alternative mechanisms that could be used to address the emergency. This includes:

- confirming there are no marketed alternatives in Canada;
- determining if the requested drug is currently undergoing regulatory review in Canada, and is expected to be available on the market soon;
- determining if a clinical trial is possible for the requested drug;
- when the requested drug is for stockpiling, determining if the drug is under development and if human clinical trial data may not be available to support a full regulatory drug submission due to the ethical aspect of having to test the drug on a human. In such cases, the SAP may ask the manufacturer to file an extraordinary use new drug submission (EUND) (https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/submission-information-requirements-extraordinary-drugs-eunds.html) instead of having the PHO make an application under Division 11, the block release framework. Should the drug manufacturer agree to this, the PHO will be asked to wait until the drug receives an EUND authorization which would allow the PHO to address the emergency by purchasing the drug in Canada;
- when the requested drug is for immediate use, determining if it is authorized in one of the countries identified under the regulatory framework for Access to Drugs in Exceptional Circumstances (Part C, Division 10, of the FDR). If this is the case, the SAP would suggest the PHO use Access to Drugs in Exceptional Circumstances (i.e., the Urgent Public Health Need List) to address the emergency.

3.4 Issuance of an authorization

If the SAP is satisfied with the information provided by the PHO, a Letter of Authorization will be issued to the manufacturer allowing the sale of a quantity of the requested drug to the named PHO. Authorizations are based on:

- the PHO meeting the conditions specified in the regulations,
- the rationale and information provided to support the need for, and the safe use of, the drug,
- any other information available to the SAP at the time of the application, or additional information requested from the PHO prior to a final decision.

An authorization will be issued if:

- all conditions have been met as described in section 2.1 of this guidance;
- the SAP is satisfied with the PHO's assessment that the known and potential benefits outweigh the known and potential risks associated with the uses of the drug, based on all available information;
- there are no alternative mechanisms to obtain a drug that could address the emergency; and
- information in or referenced by the application is complete, accurate, and not false or misleading.

The Letter of Authorization will be sent by fax to the manufacturer with a copy to the PHO.

The initial PHO should have a plan in place for managing the purchased stock should it expire before being depleted (refer to section 4.10).

3.5 Issuance of a denial

If the application is denied, the SAP will promptly send (or fax) a letter to the PHO with an explanation. The PHO will be given an opportunity to be heard before a final decision to reject the application is made (refer to section 3.6).

3.6 Reconsideration review process

The main objective of the Reconsideration Review Process (RRP) is to give the PHO an opportunity to be heard when the SAP is considering issuing a denial. It allows for an independent review of the recommendation and involves direct communication between the reconsideration reviewer and the PHO that made the application.

3.6.1 Review of denial recommendation

All reconsiderations are reviewed by a health professional. The health professional, who may be a pharmacist or practitioner within Health Canada, conducts a full independent review of the application and the supporting information. If the health professional determines that the information provided supports an authorization, a Letter of Authorization is issued. If the health professional cannot make a decision based on the information provided, the PHO is contacted and specific information is solicited to facilitate decision-making. Following review of the solicited information, if the health professional deems the information supportive of the application, a Letter of Authorization is issued and the request is considered closed.

If the information does not support the authorization, the health professional will contact the PHO to discuss the recommendation to deny the application. If the practitioner does not have any further supporting information to provide, the SAP will issue a Letter of Denial. The PHO may choose to withdraw their application rather than receiving a denial.

3.7 Amendments to a letter of authorization

If a Letter of Authorization (LOA) has errors such as mistakes in the spelling of the drug name, manufacturer name, etc. it will need to be amended. The initial PHO is to contact the SAP immediately as the information in the LOA must be accurate to import the drug into Canada and avoid delays in shipping. The SAP will amend the LOA to correct the mistakes and reissue the LOA.

Substantive facts that have been provided in an application and/or are indicated on the LOA, such as the route of administration, indication, etc., require a new application.

3.8 Cancellation of an authorization

An authorization may be cancelled to stop further distribution or use of a drug when the SAP has reasonable grounds to believe that the drug presents a serious or imminent risk of injury to human health based on, for example:

- new information which was not available at the time of the application, that may affect the risk-benefit profile of the drug, or
- information from serious adverse reaction reports.

In the event of a cancelled authorization, the initial PHO must, without delay, notify anyone to whom they have directly distributed any quantity of the drug that the authorization is cancelled. Any subsequent PHO, or any healthcare professional to whom the initial PHO distributed the drug to, are responsible to inform any other healthcare professional who may have received a quantity of the block release drug, of the cancellation.

Once the SAP cancels an authorization the quantity of drug identified in the Letter of Authorization is no longer exempt from the FDR. This means that any remaining stock of the drug cannot be sold or distributed. The drug is no longer authorized for use and should be destroyed or returned to the manufacturer.

The SAP expects the initial PHO to have a plan in place for managing their purchased stock i.e., how the drug would be disposed of, or returned to the manufacturer, following cancellation (refer to section 4.9). Should a product need to be returned to a foreign manufacturer, the initial PHO must contact the SAP for guidance on export requirements.

3.9 FDA and FDR authorities that apply to a drug authorized under the block release framework

Drugs authorized under the block release framework are subject to the FDA, except in the case of a drug represented on Schedule C or D of the Act, the drug is exempt from Section 12 of the FDA. Also, block release drugs are exempt from the FDR except for certain sections in Part A, where Health Canada has the authority to perform inspections of stockpiled drugs and drugs for immediate use. The purpose of these inspections is to confirm compliance with requirements set out in the Letter of Authorization, and verify the appropriate storage, transportation and handling of the drug.

3.10 Manufacturers issued a letter of authorization

The SAP issues a Letter of Authorization to the manufacturer. The Letter of Authorization authorizes the manufacturer to sell a specified quantity of a drug to the initial PHO for the use described in their application. Manufacturers are expected to ensure that significant new information respecting the safety, efficacy and quality of drugs authorized under the block release regulatory framework is made available to initial PHOs expeditiously. Should new information about a drug become available in other jurisdictions, the manufacturer should communicate this information to the PHO purchasing the drug.

Manufacturers may impose conditions on the sale of a drug to ensure that it is used in accordance with the latest information available. For instance, the manufacturer may restrict the amount of drug sold, or offer a protocol for the use of the drug.

Foreign manufacturers are responsible to meet the regulatory requirements of their own jurisdiction with respect to the export of drugs to Canada. In the case of a controlled drug, the manufacturer also requires an import permit from Health Canada's Office of Controlled Substances (https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/controlled-substances.html). This permit allows the drug to be shipped into Canada and ensures the appropriate authorities are notified.

Manufacturers should:

- clearly present with the shipment, the Letter of Authorization and other related documents such as import/export permits, to facilitate clearance by the Canada Border Services Agency (CBSA); and
- maintain complete and accurate records of all transactions in a manner that permits rapid response to requests from either Health Canada or the initial PHO.

4. PHO obligations

Drugs authorized for sale under the block release framework are to be accounted for by the initial PHO, since the drugs are authorized only for the use described in their application. Initial PHOs should ensure they have procedures in place to track stock that has been distributed or that remains in a stockpile, and to report on the monitoring of the response to the drug. It is recommended that subsequent PHOs also have procedures in place to track stock they have distributed. This is important as it helps to ensure appropriate oversight by the initial PHO.

4.1 Reporting serious adverse drug reactions

Drugs can cause serious ADRs, and Canadians can be hospitalized as a result of these events. Reports of serious ADRs are the first sign of emerging safety issues. A serious adverse drug reaction, as defined in Part C, Division 1, subsection C.01.001(1.1) of the FDR and for the purposes of the FDA, 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, and for the reaction to be considered serious, a minimum of one or any combination of the aforementioned outcomes should be fulfilled.

The initial PHO responsible for public health must provide information on how to report serious ADRs to anyone who is in possession of the drug, or to anyone who is being administered the drug. This may be done through a document that provides information as it relates to serious ADRs.

4.1.1 Surgeon General of the Canadian Armed Forces – serious adverse drug reaction reporting

The SG of CAF is responsible to report to the SAP on any serious ADRs experienced resulting from use of the block release drug. The SAP has adopted the International Conference of Harmonization (ICH) guidelines for ADR reporting in regards to what should be reported. Information that is to be included in the serious ADR report:

- the drug's brand name, proper name or common name;
- the identifying name, code, number or mark;
- the patient's age and sex;
- a description of the serious ADR;
- the date on which the serious ADR was first documented;
- the date on which the patient first used the drug and, if applicable, the date on which the patient stopped using the drug;
- the date on which the serious ADR first occurred and, if applicable, the date on which the patient's health was restored to its state prior to the reaction;
- any medical condition of the patient that directly relates to the serious ADR;
- any concomitant therapeutic products used by the patient; and
- the effect of the serious ADR on the patient's health.

Serious ADRs for military health emergencies should use the Council for International Organizations of Medical Sciences (CIOMS) form for reporting and send it by fax to the SAP.

4.1.2 Hospitals – serious adverse drug reaction mandatory reporting requirements

The initial PHO will inform hospitals if a block release drug is being used to address a public health emergency. Hospitals are required to report all serious ADR for drugs authorized under the block release framework for a public health emergency. This regulatory requirement applies to hospitals that are regulated through provincial or territorial legislation, as well as hospitals operated by the federal government.

When filing the serious ADR hospitals are to follow the guidance provided in the document entitled "*Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals*" (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices.html). For vaccines authorized under the block release framework for a public health emergency, hospitals must report any serious ADR related to these vaccines to Health Canada's Canada Vigilance Program (CVP) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html) as per the mandatory reporting requirements. The vaccine exemption does not apply to vaccines authorized under the block release framework for a public health emergency. CVP will give the initial PHO the serious ADR reports received.

4.2 Monitoring the drug and reporting

The PHO named in an authorization is responsible for monitoring the response to the drug. Initial PHOs must take reasonable steps to obtain information on the response to the drug, including actions taken to manage any serious ADRs.

Monitoring the use of the drug and serious ADRs allows the initial PHO to assess whether the drug continues to be the best choice for the emergency and the benefits continue to outweigh the risks.

The SAP may require the initial PHO to submit a written report if, for example, serious ADRs have been reported; new information has been identified; and/or a subsequent application has been made for the same drug. The SAP may request the report contain:

- results from monitoring the use of the drug as well as any corrective measures taken as a result of the monitoring
- a summary of the number of patients treated, with an overview of the response to treatment with the drug that demonstrates if the drug's desired affect has been achieved in the context of the emergency
- a determination if the drug's benefits continue to outweigh the risks based on the initial PHO's comparison of the serious ADR reports to the initial benefit-risk assessment submitted as part of the application.

4.3 New information after a letter of authorization is issued

New information about the drug may emerge over time. This can include:

- a change in the conditions of use,
- a change in the safety profile of the drug, the storage conditions, or new information on contraindications, or
- new information generated by the recall of the drug in another country.

The initial PHO must provide the SAP in writing, with any new information they may be aware of concerning the safety, efficacy, or quality of the drug for the authorized use, within 30 days after the day of becoming aware of it, using the form entitled “New information: safety, efficacy or quality”.

4.4 Labelling

The block release framework includes labelling requirements to help ensure the safe use and handling of the drug by providing relevant information to individuals administering the drug and to Canadians who are receiving the drug. Labelling includes storage conditions to ensure the drug’s integrity and appropriate storage and use.

To give additional clarity on the role of the PHO named in the authorization (i.e., the initial PHO) and the subsequent PHO, the regulations state that the initial PHO is responsible to ensure the drug bears a label or has an accompanying document if a label is not possible. The initial PHO must ensure the label clearly sets out the following information in English and French:

- the name and civic address of the drug’s manufacturer;
- a statement that the Minister has authorized the sale of the drug to address the emergency, event or incident described in the authorization;
- a statement that the drug is to be used only for the use described in the authorization;
- the drug’s brand name, if any, and either its proper name, common name and chemical name or its identifying name, code, number or mark;
- the drug’s medicinal ingredients;
- the drug’s strength;
- the drug’s dosage form;
- the drug’s recommended dosage and route of administration;
- the drug’s lot number, if known;
- all warnings and precautions in respect of the use of the drug, if any;
- the drug’s expiration date, or, if there is no expiration date, the stability testing date or the date on which the drug should be retested, as specified by the manufacturer;
- the drug’s recommended storage conditions for the drug; and
- the net contents of the drug’s container, in terms of the weight, volume, size or number of units of the drug in the container.

The subsequent PHO (to whom a quantity of drug has been distributed) needs to ensure that the label or the document containing information that would appear on a label, accompanies the drug throughout its distribution.

Should new information affect the labelling or the accompanying document, the initial PHO is responsible to update the information that has changed in the initial labelling or accompanying document. This does not mean physically preparing a new label – it could be a new document that is an addendum to the existing label or the accompanying document. The initial PHO is responsible to provide the updated information to the subsequent PHO or any

person to whom the initial PHO has distributed the drug to ensure the safe use and handling of the drug. The subsequent PHO is then responsible to provide this new information to anyone to whom they have distributed the drug.

4.5 Information to be made available to anyone administering the drug or anyone receiving the drug

The initial PHO or any subsequent public health official, as the case may be, must make the following information available to the following persons, in writing, in English and French:

(a) to the persons to whom the drug is administered and the persons who administer the drug, the known and potential benefits and risks associated with the use for which the sale of the drug is authorized, the recommended duration of use, if any, of the drug and instructions on how to report serious adverse drug reactions; and

(b) to the persons who administer the drug, the following information:

- the name of the PHO including information setting out how they may be contacted at any time;
- the name of the manufacturer including information setting out how they may be contacted at any time;
- describe the use of the drug that is intended to address the emergency, event or incident;
- the recommended dosage for the drug's use;
- the indications that have been approved by any foreign regulatory authority, if applicable; and
- the drug's contraindications.

The regulations require the PHO to provide their contact information to anyone administering the drug. It is expected the contact information to be provided would be that of the official(s) to whom the PHO has delegated their authority to perform their duties as it relates to the public health emergency. This information is to be provided to those administering the drug should problems be encountered with the administration of the drug that could result in a safety risk requiring urgent attention.

4.6 Storage and handling

All drugs must be stored according to the conditions described on the product label. Controls for storage conditions that are specified on the label (e.g., temperature, humidity, light, etc.) must be in place to ensure the integrity of the drug.

For the distribution and transportation of the drug, the necessary environmental controls must be in place if specific storage conditions (such as temperature, relative humidity and lighting) are required for products. Drugs should be transported in accordance with established procedures, in a way that ensures the products' quality and safety as described by the labelling or accompanying documents.

When using contracted third parties, it is the PHO's responsibility to ensure they transport the drugs within the established procedures.

4.7 Maintaining records

The initial and subsequent PHO must maintain all records in respect of a block release drug for a period of 15 years. These records include serious ADRs, reports on the results of the use of the drug, information about the sale, distribution and use of the drug (including records of patients who were administered the drug), and any new information concerning the safety and efficacy of the drug, for the authorized use or purpose, that was not part of the initial application.

Health Canada has adopted this approach since data on drugs authorized under this framework have not undergone extensive review in Canada for safety, efficacy and quality as is the case for a drug receiving a market authorization.

4.8 Reporting on the remaining inventory of unused block release drugs

To ensure appropriate management and oversight of block release drugs, the SAP needs to know how much stock remains. Therefore, the initial PHO is responsible for providing the SAP with an inventory count of block release drugs that remain in their possession using Form F - Report on Remaining Inventory of Unused Block Release Drugs.

4.9 Cancelled authorization

The SAP may cancel an authorization if a drug is deemed unsafe and presents a serious or imminent risk of injury to human health. The initial PHO may ask the SAP to cancel an authorization if they have evidence that the block release drug presents an undue safety risk, or that use of the block release drug must be stopped for other reasons. Cancelling an authorization results in the quantity of unused stock being subject to the FDR, i.e., the drug is no longer exempt from the FDR and is prohibited from further sale or distribution.

As a general rule, unused supply of a drug should be returned to the manufacturer. Some manufacturers require and enforce this as a matter of policy. As such, the initial PHO should discuss with the manufacturer the disposal or return of the drug.

It is expected that following the cancellation of an authorization remaining unused stock will be returned to the foreign manufacturer or destroyed by the initial PHO. Should the initial PHO return stock to the foreign manufacturer, the SAP should be contacted for guidance on export requirements.

The initial PHO is responsible for communicating the cancellation of an authorization to anyone to whom they have distributed the drug. It is expected that any subsequent PHO who received a quantity of drug would inform any other persons to whom they have distributed the drug that the authorization has been cancelled.

4.10 Expired stock

Initial PHOs should have a plan for the disposal of expired stock. It is recommended that contractual agreements with the manufacturer include arrangements on how the stock will be managed should the block release drug expire.

Expired stock should be returned to the manufacturer for destruction in accordance with contractual agreements or destroyed by the PHO. Should the expired stock be returned to a foreign manufacturer, the initial PHO should contact the SAP for guidance on export requirements. To replace stock that has expired, the initial PHO must make a new application to request a new quantity of the drug.

5. Transfer of a quantity of drug to a practitioner

Under Division 8 of the FDR, practitioners can request a drug that is not authorized for sale in Canada, through the SAP, to treat their patient in a medical emergency. Sometimes, the specialized drug may not be immediately available. Given the type of drugs stockpiled for public or military health emergencies, the PHO of PHAC, CAF or Indigenous Services Canada (ISC) may hold (under block release) the drug being sought by a practitioner.

To facilitate immediate treatment for a patient, Health Canada may allow the transfer of a quantity of drug from the PHO of PHAC, CAF or ISC to a requesting practitioner for the same use for which a drug was stockpiled.

To allow the transfer of stock from the PHO of PHAC, CAF or ISC to a practitioner, the manufacturer of the drug must receive authorization from the SAP to sell the quantity of the drug to the requesting practitioner. Following an authorization issued by the SAP, the distribution from the PHO of PHAC, CAF or ISC to the practitioner can take place.

The PHO of PHAC, CAF or ISC is not responsible for the transferred quantity of drug as the block release requirements no longer apply. The requesting practitioner who received the quantity of drug from the PHO is responsible to meet the requirements under Division 8, i.e., follow-up reporting on the outcome of use of the drug and reporting on adverse drug reactions.

Appendix A – Definitions

Brand name - with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French, (a) that is assigned to the drug by its manufacturer, (b) under which the drug is sold or advertised, and (c) that is used to distinguish the drug.

Common name - with reference to a drug, the name in English or French by which the drug is (a) commonly known; and (b) as designated in scientific or technical journals, other than the publications referred to in Schedule B to the Act.

Conventional therapies - treatments that are widely accepted and used by most health care professionals using authorized drugs that have been approved for an indication in Canada either through a new drug submission or an extraordinary use new drug submission. In certain circumstances, therapies which do not have authorized indications, but which are considered standard-of-care or are well-supported by substantial literature evidence could also be considered conventional therapy. Treatment with medical devices are also considered conventional therapies when widely accepted and used by most health care professionals as well as procedures that are not subject to Health Canada approval (for example: surgery, radiotherapy, etc.).

Drug - includes any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings, (b) restoring, correcting or modifying organic functions in human beings.

Expiration date – (a) in the case of a drug in dosage form, the earlier of the following dates, expressed at minimum as a year and month: (i) the date up to and including which the drug maintains its labelled potency, purity and physical characteristics, and (ii) the date after which the manufacturer recommends that the drug not be used; and (b) in the case of an active ingredient, whichever of the following dates is applicable, expressed at minimum as a year and month: (i) the retest date, or (ii) the date after which the manufacturer recommends that the active ingredient not be used.

Extraordinary use new drug (EUND) - drugs that have been authorized based on non-clinical and limited clinical information

Foreign regulatory authority - means 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*)

Proper name – the name assigned to the drug as specified in a manufacturer's licence

Public Health Official - In accordance with section C.11.001(1) of the *Food and Drug Regulations*, 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 Medical Officer of Health, or equivalent, of a municipality; (d) the Surgeon General of the Canadian Armed Forces; or (e) the Chief Medical Officer of Public Health for the Department of Indigenous Services Canada.

Serious Adverse Drug Reaction - 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.