Protected When Completed

Access to Drugs in Exceptional Circumstances

Notification of Urgent Public Health Need Form

Before a drug can be imported and sold in accordance with Part C, Division 10 of the Food and Drug Regulations, a public health official must have notified the Minister regarding an urgent public health need for the immediate use of the drug and the intended use or purpose of the drug within their respective jurisdiction. Such notifications must be renewed annually. This form, when complete and sent to Health Canada, constitutes this written notification.

This form can also be used to inform the Minister of a need to disallow the importation and sale of the drug for use in one's own jurisdiction. To this end, this form allows a public health official to withdraw a previous notification.

Section A: Public Health Official Information
Name:
Title:
Federal/provincial jurisdiction:
Telephone #:
Fax #:
Email address:

Complete **Section B** to notify the Minister of a new or continuing urgent public health need for the immediate use of a drug within your jurisdiction

or

Complete **Section C** to withdraw a previous notification

Section B: Notification of Urgent Public Health Need for the Immediate Use of a Drug and the Intended Use or Purpose of the Drug

Type of notification: ◯ First notification

Please submit a drug information document (such as the equivalent of a Canadian Product Monograph) which validates the information provided in this section of the form

◯ Renewal of notification

Controlled substance: ◯ Yes ◯ No

Brand name:

Medicinal ingredient(s):

Dosage form: ◯ Tablet ◯ Capsule ◯ Liquid ◯ Powder ◯ Cream ◯ Ointment ◯ Patch ◯ Other:

Strength:

Route of administration: ◯ Oral ◯ Intravenous ◯ Intramuscular ◯ Topical ◯ Subcutaneous ◯ Other:

Foreign identifying code or number (as assigned by the foreign regulatory authority):

Foreign manufacturer site (name and address):

Foreign regulatory authority which authorizes the sale of the drug:

Country from which the drug would be imported (must be the United States of America, Switzerland or a country in the European Union):

Foreign authorized indication of the drug (must be the same as the intended use or purpose of the drug in your jurisdiction):

Section B: Notification of Urgent Public Health Need for the Immediate Use of a Drug and the Intended Use or Purpose of the Drug

Describe the new or continuing urgent public health need and the intended use or purpose for which the drug would be used to address this need in your jurisdiction.

Please demonstrate that the following applies to your 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 and/or requires extraordinary measures

Section C: Withdrawal of a Previous Notification

Brand name:

Medicinal ingredient(s):

Dosage form: ○ Tablet ○ Capsule ○ Liquid ○ Powder ○ Cream ○ Ointment ○ Patch

○ Other:

Strength:

Route of administration: ○ Oral ○ Intravenous ○ Intramuscular ○ Topical

○ Subcutaneous ○ Other:

Foreign identifying code or number (as assigned by the foreign regulatory authority):

Describe why you are withdrawing a previous notification of an urgent public health need for use of the drug in your jurisdiction. Please describe the urgency of this request including when you would like this withdrawal to take effect.

Section D: Public Health Official Attestation, Considerations and Signature

Attestation:

I, the public health official, hold one of the following titles, as defined in the Food and Drug Regulations C.10.001:

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

Considerations when notifying the Minister of an urgent public health need for a drug:

Public health officials should undertake the following activities prior to notifying the Minister of an urgent public health need for a drug:

- Contact a representative of the foreign manufacturer and/or their Canadian affiliate to discuss the urgent public health need for the drug within their jurisdiction.
- Identify any conditions of sale set forth by the foreign manufacturer or the foreign regulator (e.g., mandatory health professional training, controlled distribution, etc.) to determine whether these conditions can be fulfilled within their jurisdiction.

Public health officials should also consider establishing mechanisms to:

- Monitor the distribution of imported drugs in their jurisdiction.
- Receive timely notification from the manufacturer of post-market actions related to safety, efficacy or quality (e.g., label updates, risk communications, recalls, etc.), to be shared with Health Canada so that appropriate action can be taken if needed.
- Support the dissemination of drug information within their jurisdiction to allow safe prescribing, dispensing and use of the drug, particularly those drugs that are labeled in a language other than French or English.

Have you contacted a representative of the foreign manufacturer?

Yes ◯ No ◯

Public health official's signature: **Date:**

Submit 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
Website: Access to Drugs in Exceptional Circumstances