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Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need)

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Issues

Urgent public health needs can occur, for example, during a flu pandemic or in a situation such as an opioid crisis. Addressing such an urgent need requires a mechanism that allows for a population-based response that is quick and efficient. Sometimes, a country will have already approved the drug necessary to address the crisis. However, there may be a situation where a drug that is needed urgently is not available for sale, but may be authorized for sale in another country. A regulatory pathway that allows for the importation and sale of such drugs could assist in quickly addressing an urgent Canadian public health need, and could result in saving Canadian lives.

In Canada, there are currently regulatory pathways that provide access to drugs that are not authorized for sale in Canada. These include Health Canada’s Special Access Programme (SAP) or the filing of a Clinical Trial Application (CTA). However, there is no regulatory mechanism available in Canada to address an urgent public health need through a population-based approach. The SAP was designed to address individual patient needs and, therefore, requires an application to be made for the drug by the treating physician. The authorization that is issued is for a specific quantity of drug and must be issued once again if treatment for additional patients is sought. This system works well for the individual

patient–practitioner situation, but was never intended for use in a population health treatment context to address a public health emergency such as the current opioid crisis in Canada. Clinical trials are typically designed and conducted for the purpose of studying a drug's effect and are not an efficient means for the ongoing treatment of patients. In addition, the filing of a CTA represents an even greater administrative burden than that of making an application under the SAP.

Opioid use disorder is an urgent public health need in Canada at this time. This disorder is a medical condition associated with addiction to and dependence on opioids. Health Canada has authorized a number of drugs for use in treating opioid use disorder. These include methadone as well as buprenorphine/naloxone combinations and naltrexone. While most of the drugs used to treat opioid use disorder are available on the Canadian market, there are a number of drugs that have been authorized in foreign jurisdictions that have not been authorized for sale in Canada. Reasons for this may include a business decision by the manufacturer to not apply for an authorization in Canada because it is a smaller market, or a business decision to seek authorization in Canada at a later date.

Objectives

The objective of the proposed regulatory amendments is to enable access to drugs that would help address an urgent public health need (e.g. opioid use disorder) that have been authorized for sale in either the United States, the European Union, or Switzerland, but are not yet available in Canada.

Description

Unlike the current schemes laid out in the *Food and Drug Regulations* (FDR) that authorize the importation and sale of a drug in Canada by means of an application, review and authorization process, this proposal would simply allow for the importation of a drug included on the "List of Drugs for an Urgent Public Health Need" (the List) to address an urgent public health need, such as the treatment of opioid use disorder. All drugs on the List would be authorized for sale in the United States, the European Union, or Switzerland.

The List would be incorporated by reference into the FDR, published on the Government of Canada website, and maintained by the Minister of Health (the Minister). The List (Appendix A) would contain the following details respecting a drug: the brand name, the medicinal ingredient(s), the strength, the dosage form, the route of administration, the identifying code or number assigned by the foreign regulatory authority that authorized its sale, the name of the foreign regulatory authority and the country or countries from which the drug can be imported into Canada, the jurisdiction notifying the Minister of the need for the drug, the date of notification by the public health official, as well as the identified urgent public health need.

The Minister would, at her discretion, add drugs to the List based on a notification made by a provincial or territorial Chief Medical Officer of Health, the Chief Public Health Officer of the Public Health Agency of Canada or the First Nations and Inuit Health Branch (FNIHB) of the Department of Health (the Department), or the Surgeon General of the Canadian Armed Forces (collectively referred to as "public health officials"). This notification would need to be in writing and identify the urgent public health need for the use of the drug within their respective jurisdictions.

A drug would be removed from the List if more than one year has elapsed since the last notification (regardless of jurisdiction) by the public health official, unless the Minister is once again notified of the continued need for the drug to address the same public health need, in the jurisdiction. While the importation of a drug may be prohibited if one year has elapsed with no further notifications from jurisdictions, it is important to note that the sale of the drug would be permitted in order to deplete the quantities already imported. Further details on the notification process would be set out in a publicly available document, as would Health Canada's procedures for managing the List.

Establishment licence (EL) holders would be allowed to import and wholesale a drug on the List. They would be required to notify Health Canada within 15 days after the importation and provide Health Canada with details such as the quantity of drug being imported. EL holders would also be required to

maintain records of the drug's distribution in Canada, ensure that storage requirements under Part C, Division 2, of the FDR are maintained, and notify Health Canada if they undertake a recall of the drug. These requirements would be similar to those that already exist for EL holders.

The proposed Regulations would exempt drugs that are placed on the List from many requirements under the FDR respecting the sale and importation of a drug. Confidence that the drug meets a similar standard of safety, efficacy and quality to that of a Canadian authorized drug would be provided by the fact that these drugs have, in being authorized for sale in either the United States, the European Union, or Switzerland, undergone a thorough examination by trusted regulatory partners and would be imported directly from those countries by EL holders. At this time, the countries are limited to the United States, the European Union, and Switzerland, as current experience shows that typically, drugs are first marketed in these countries. In addition, these regulatory partners adhere to similar standards and requirements as in Canada.

The sections of the FDR that would apply to a drug on the List include, for example, inspector powers, requirements to keep records to enable a recall and report a recall, as well as certain requirements to control the quality of the drug, including those respecting its storage and transportation. As many drugs used to treat opioid use disorder are controlled drugs, the List could include these drugs, which would also be subject to the requirements of the *Controlled Drugs and Substances Act* and the *Narcotic Control Regulations*. This includes diacetylmorphine (heroin), which has been demonstrated to be effective in treating some patients who are unresponsive to first-line treatments such as methadone.

While the drugs on the List would be exempt from most of the provisions of the FDR, it is important to note that the requirements of the *Food and Drugs Act* would still apply to these drugs. This would allow the Department to recall the drug should a safety concern be discovered indicating that action was necessary to prevent a serious or imminent risk of injury to health.

Health care institutions that provide acute care services, including those that provide emergency services, would be required to report information respecting a serious adverse drug reaction (serious ADR) associated with a drug on the List within 30 days of the event first being documented. The definition of a serious ADR under subsection C.01.001(1) of the FDR would apply. The information that these institutions would be required to report would be limited to the name of the institution, the identifying code of the drug on the List, and a description of the serious ADR. Institutions would be required to provide this information in writing, either in a paper-based format or by electronic means according to the capabilities of their existing information management systems.

This aspect of the proposal would be the first application of the Governor in Council's ability, gained through the passing of the*Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*, to make regulations respecting the reporting of serious ADRs by health care institutions.

As this proposal would result in an enabling regulation meant to address a serious and ongoing public health crisis, it is proposed that the new regulations would be brought into force immediately upon registration by the Clerk of the Privy Council. At the same time, an Order in Council would bring into force the sections of *Vanessa's Law* necessary to implement requirements for serious ADR reporting by health care institutions.

These proposed Regulations would provide an alternate pathway for accessing drugs as a response to an urgent public health need, and at this time, for the treatment of opioid use disorder. The use of this alternate pathway would not be mandatory, as the existing pathways through the SAP and the filing of a CTA would remain.

"One-for-One" Rule

The "One-for-One" Rule applies to this proposal, and it is considered an "IN" for the purpose of reporting administrative burden. The estimated cost will be offset by an equivalent reduction in the administrative credits available within the health portfolio.

The proposal is a permissive regulation that creates an optional regulatory means to import drugs for use in a health emergency, such as a flu pandemic or for the treatment of opioid use disorder.
The administrative requirements placed on EL holders that are importing and wholesaling drugs under the proposed Regulations for urgent needs would be less than the current regulations regarding importation and distribution of drugs with Canadian market authorizations. However, the proposal would impose administrative requirements on EL holders, namely the requirement to notify Health Canada within 15 days of the importation of a drug on the List and the need to keep records to support a potential drug recall.
While the requirements of the *Controlled Drugs and Substances Act* would also apply, this would not impose a new burden on businesses, since meeting these existing requirements would not require the creation of new standard operating procedures or the need for staff to familiarize themselves with new reporting and record-keeping requirements.
It is estimated that there would be no more than 20 bulk shipments, per year, of drugs from the List and that an EL holder would spend 15 minutes preparing the notification of importation for Health Canada, and another 30 minutes generating the necessary records required under the recall provisions. Furthermore, there are approximately 970 businesses that could import drugs that are on the List, but this number declines if the product is on the controlled substances list.
The administrative costs are calculated using an average cost of $60 per hour, based on costs provided by industry for similar regulatory reporting tasks.
In accordance with the *Red Tape Reduction Regulations*, the administrative burden to EL holders was calculated over 10 years and discounted using a rate of 7%. The present value (2012) of the total annualized incremental administrative costs to EL holders has been estimated to be $589, or approximately $1 per business. These costs would only be borne by EL holders that choose to import drugs that are on the List.

Small business lens

Since the estimated annual costs of this proposal are less than one million dollars, the small business lens does not apply.

Consultation

In developing the Interim Order for naloxone hydrochloride nasal spray (see footnote 1) in the summer of 2016, Health Canada heard from provincial and territorial health authorities about their urgent need to have access to any available and effective drugs that might be useful in addressing the ongoing opioid crisis. As a result of this feedback and ongoing interactions with public health officials, Health Canada is now proposing a means to allow for the importation and sale of drugs to address an urgent public health need, including drugs that are currently unavailable to Canadian patients to treat opioid use disorder.
In March 2017, Health Canada discussed details of this proposal with representatives of the provincial, territorial and national health authorities, including Chief Medical Officers of Health. Health care institutions were also consulted on this proposal. At the time of consultation, it was proposed that public health officials would be the ones that would be allowed to import a drug on the List as well as the ones to whom the record-keeping and notification obligations would apply.
While there was some support for an initiative to improve access to drugs to treat opioid use disorder, it became apparent from these discussions that public health officials had neither the experience nor the capacity to take on the responsibility of managing the importation and distribution of these drugs and of fulfilling the proposed record-keeping and reporting obligations. In light of this, the proposal was revised to allow for entities that have demonstrated experience with these activities, namely importers and wholesalers that already hold an establishment licence, to import and wholesale these drugs.
At least one provincial medical health officer inquired as to whether diacetylmorphine (heroin) could be added to the List and made available through the proposed scheme. At this time, a considerable number

of patients who were subjects in a recent clinical trial to determine the efficacy of using diacetylmorphine to treat opioid use disorder are gaining access to the drug through the SAP.
As part of policy development around the broader requirement for mandatory reporting by health care institutions of serious ADRs set out in section 21.8 of *Vanessa's Law*, Health Canada held consultation sessions with health care institutions. Concerns raised during this broader consultation included varying capabilities with respect to programs, systems, and the ability to accommodate a federal requirement for reporting. Several respondents expressed concerns with the ability to establish a causal relationship between a drug and an adverse event, and suggested that it should be sufficient to file a report based on just a suspicion of causality. Many suggested that acute care institutions would represent a reasonable starting point in capturing the majority of events.
In March 2017, over 90 people representing over 40 health care institutions were engaged to discuss reporting of serious ADRs under this particular proposal. Comments revolved around the administration of the List, uses for the approved drugs, reporting requirements, and sharing of serious ADRs (i.e. whether there would be sharing of information related to these events). Several participants expressed concerns similar to those raised by chief medical health officials regarding the procurement and distribution of these drugs.
In response to these observations, the proposal places the reporting requirement at the level of acute health care institutions, given that it is likely that the majority of patients with serious ADRs would be treated in these types of institutions. Furthermore, the reporting requirement balance the need to identify important safety concerns and the need to not impose unnecessary administrative burdens on health care institutions.

Rationale

This proposal would provide an alternative pathway to access unauthorized drugs to address an urgent public health need, such as a flu pandemic or the treatment of opioid use disorder. The risks associated with foregoing the normal means of market authorization of a drug through the filing and assessment of a new drug submission (NDS) is mitigated by the fact that only drugs that have been subject to similar scrutiny by trusted regulatory partners, and authorized for sale by them, would be allowed for sale in Canada. In managing the List, Health Canada would not consider adding a drug that is the equivalent of a drug already authorized for sale in Canada and would consider removing a drug from the List once an equivalent is authorized. In this way, manufacturers would not gain an unfair commercial advantage by this scheme.
In choosing this option, Health Canada considered a number of alternatives. As noted above, an earlier proposal that would have placed the burden on public health officials was rejected as being unworkable. The possibility of using the Minister's ability under section 30.1 of the *Food and Drugs Act* to issue an interim order was examined and rejected for two main reasons. First, the threshold for making such an order, although easily met in the case of a life-saving drug such as naloxone (intended to treat opioid overdose), was not considered attainable for drugs used to address an urgent public health need, as the health risks could not be considered as "serious and imminent." Second, since interim orders are valid only for a maximum of one year, and a public health need may be ongoing, such an order would have to be renewed each year, which is not the intent of an interim order.
While Health Canada will explore measures to encourage manufacturers to obtain market authorization for a drug, obtaining an authorization under the existing regulatory pathways may not provide the timely access that would occur under the current proposal.

Benefits and costs

The proposal is a permissive regulation that allows for an optional regulatory means for the importation of drugs meant to address an urgent public health need. There is no requirement to utilize these regulations, as access to drugs that do not currently have market authorization in Canada can still be obtained through the SAP or CTAs.

Benefits

The benefits of the proposed Regulations are dependent on how many health officials choose to use this optional means for the importation of drugs not already approved for the Canadian market, how many drugs are placed on the proposed List by the Minister of Health, and how many patients require drugs that are not already marketed in Canada. The benefits are therefore difficult to quantify, as it is impossible to estimate the number of lives that can be saved through timely access to life-saving drugs, or the economic benefit of fewer work hours lost due to illness during a public health emergency.

With regard to treating opioid use disorder, the proposed Regulations would not reduce the number of people becoming addicted to both licit and illicit opioids. However, the proposal has the potential to increase the effectiveness of treatment for more patients, reducing the number that would relapse. Nevertheless, the successful treatment of opioid use disorder is dependent on many other variables, and it is impossible to state how the access to the drugs made available by the proposed Regulations would affect treatment success rates precisely. Furthermore, successful treatment could allow more illicit users to be brought into treatment and would reduce the social and economic costs to society. Several studies have shown the net positive socio-economic benefit of effective treatment programs. (see footnote 2)

The proposal could also help address future health emergencies and mitigate associated costs. Using the 2003 SARS crisis in Toronto as an example, over the six-month outbreak in Toronto, there were 44 deaths, 400 hospitalizations and 25 000 people quarantined. (see footnote 3) The tourist industry reported an economic loss of $350 million and the retail sector reported seasonal adjusted losses of $380 million. (see footnote 4) If a drug that was not available in Canada was approved in another jurisdiction and could be rapidly deployed in Canada, there is the potential for substantial positive health outcomes and economic benefits in the event of a health crisis.

Finally, the proposal would also have positive benefits on drug importers, since they would be able to have access to a new revenue stream as they are contracted to import and distribute drugs placed on the List.

Costs

The total costs associated with this optional regulatory approach for importing drugs for use in a health emergency is also dependent on the number of drugs being imported, the number of health crises that occur and the number of serious ADRs that occur and are attributed to the drugs on the List.

By utilizing the powers under *Vanessa's Law* to require adverse reaction reporting from health care institutions that provide acute care services, the proposed Regulations would place an administrative burden on these facilities, estimated at approximately $3,400 per year. This calculation is based on the assumption that each report would cost $100, (see footnote 5) and that there would be 34 (see footnote 6) ADR reports per year. This suggests that the number of serious ADRs being reported would not overburden the acute care facilities.

The reporting requirement for those EL holders used for bulk importations are estimated at $900 annually. This is based on the assumption that, on an annual basis, there would be 20 (see footnote 7) bulk shipments of drugs from the List and that it would cost EL holders $45 (see footnote 8) per bulk shipment to meet the additional regulatory requirements.

These proposed requirements would not represent a higher burden compared to the existing requirements for the importation of a drug into Canada; in fact, the reporting requirements would be less burdensome, since the importer would not have access to, and therefore would not have to report, all the information that would be available during the importation of a drug already approved in Canada.

The cost to Government is considered to be insignificant as the review of adverse reaction reports from the SAP already occurs and the cost of maintaining the list of drugs for importation should not add any burden.

The total costs are therefore estimated to be $4,300 annually, or a present value cost of $28,797 over 10 years, discounted by 7%.

Implementation, enforcement and service standards

Health Canada has developed guidance document to aid in the management of the List. This guidance document details the process by which the Department would add a drug to or remove it from the List and the means by which a public health official could notify the Minister for the purposes of amending the List or keeping the drug on the List. A copy of the draft guidance document respecting this proposal is available on request by contacting Health Canada at the address below.

It is the intent of Health Canada to populate the List shortly after the time of publication of the Regulations in *Canada Gazette*, Part II. In support of this, the Department has begun to canvass public health officials as to which drugs they feel are currently the most needed.

As these proposed amendments would not impose substantial new obligations on existing stakeholders, it is expected that existing compliance and enforcement activities with respect to EL holders would suffice. At the border, it is expected that details provided on the List with respect to a drug would be sufficient for the Canada Border Services Agency (CBSA) to easily determine, by examining the foreign labelling of the drug, whether it would be eligible under this scheme for importation.

Any activities public health officials deem necessary to support the safe and effective use of the drug, including how the drug is provided to patients and whether the foreign labelling needs to be supplemented, would remain their responsibility.

Contact

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Appendix A — Example of the List of Drugs for an Urgent Public Health Need

Brand Name	Medicinal Ingredient(s)	Strength	Dosage Form	Route of Administration	Foreign Identifying Code or Number	Foreign Regulatory Authority	Co O

PROPOSED REGULATORY TEXT

Notice is given that the Governor in Council, pursuant to subsections 30(1) (see footnote a) and (1.2) (see footnote b) of the *Food and Drugs Act* (see footnote c), proposes to make the annexed *Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need)*.

Interested persons may make representations concerning the proposed Regulations within 15 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Bruno Rodrigue, Office of Legislative and Regulatory Modernization, Policy, Planning and International Affairs Directorate, Health Products and

Food Branch, Department of Health, Holland Cross, Tower B, 5th Floor, 1600 Scott Street, Address Locator: 3105A, Ottawa, Ontario K1A 0K9 (email: LRM_MLR_consultations@hc-sc.gc.ca).
Ottawa, April 13, 2017
Jurica Čapkun
Assistant Clerk of the Privy Council
Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need)
Amendment
1 Part C of the *Food and Drug Regulations* (see footnote 9) **is amended by adding the following after Division 9:**
DIVISION 10
Access to Drugs in Exceptional Circumstances
C.10.001 (1) The following definitions apply in this section.
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*)
public health official 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 Forces; or
- **(d)** the Chief Medical Officer of Public Health for the First Nations and Inuit Health Branch of the Department of Health. (*responsable de la santé publique*)

(2) Despite sections A.01.040 and C.01.004.1, any person who holds an establishment licence that authorizes the importation of a drug may import a drug for which a notice of compliance has not been issued under section C.08.004 or C.08.004.01, or for which a drug identification number has not been assigned under subsection C.01.014.2(1), if the following conditions are met:

- **(a)** a public health official has, within the past year, notified the Minister in writing of an urgent public health need for the use of the drug within their jurisdiction;
- **(b)** the drug is authorized to be sold for use in respect of the same urgent public health need by a foreign regulatory authority in the United States, Switzerland or the European Union;
- **(c)** the drug is in the same category as the category for which the licence was issued;
- **(d)** the drug is imported directly from the country in which it is authorized to be sold by the foreign regulatory authority; and
- **(e)** the drug is one for which the following information is set out in the *List of Drugs for an Urgent Public Health Need* that is published by the Government of Canada on its website, as amended from time to time:
    - **(i)** brand name,
    - **(ii)** medicinal ingredients,
    - **(iii)** dosage form,
    - **(iv)** strength,
    - **(v)** route of administration, and
    - **(vi)** identifying code or number, if any, assigned in the country in which the drug was authorized for sale.

(3) Sections C.01A.006 and C.01A.007 do not apply in respect of the importation of a drugunder subsection (2).
(4) For greater certainty, a licensee may, despite subsection C.01A.004(1), import a drug under subsection (2) without having their licence amended under section C.01A.006.

(5) Divisions 2 to 4, other than the following provisions, do not apply to the importation of a drug under subsection (2):

- **(a)** sections C.02.003.1 and C.02.004 as they apply to the storage of the drug by the licensee;
- **(b)** section C.02.006;
- **(c)** subsection C.02.012(1);
- **(d)** sections C.02.013 and C.02.014;
- **(e)** section C.02.015 as it applies to the storage and transportation of the drug by the licensee;
- **(f)** subsection C.02.021(1) as it applies to the storage of the drug by the licensee;
- **(g)** subsection C.02.022(1);
- **(h)** section C.02.023;
- **(i)** subsections C.02.024(1) and C.02.025(1);
- **(j)** section C.03.013; and
- **(k)** section C.04.001.1 as it applies to the storage of the drug by the licensee.

C.10.002 (1) A sale of a drug that is imported under subsection C.10.001(2) is exempt from the provisions of these Regulations only if the drug is sold for use in respect of the same urgent public health need for which it was imported.

(2) Any person who wholesales such a drug must hold an establishment licence to wholesale a drug in the same category and despite subsection (1), the following provisions apply in respect of the wholesale:

- **(a)** sections C.02.003.1 and C.02.004 as they apply to the storage of the drug by the licensee;
- **(b)** subsection C.02.012(1);
- **(c)** section C.02.013;
- **(d)** section C.02.015 as it applies to the storage and transportation of the drug by the licensee;
- **(e)** subsection C.02.022(1);
- **(f)** section C.02.023; and
- **(g)** subsection C.02.024(1).

C.10.003 Every licensee who imports a drug under subsection C.10.001(2) must notify the Minister within 15 days after the importation by providing the following information:

- **(a)** the name, title and contact information of the person who imported the drug;
- **(b)** the brand name of the drug;
- **(c)** the medicinal ingredients, strength, dosage form, route of administration and identifying code or number, if any assigned, 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 the drug imported.

C.10.004 (1) For the purposes of section 21.8 of the Act, the prescribed health care institutions that must provide information to the Minister about a serious adverse drug reaction that involves a drug imported under subsection C.10.001(2) are the health care institutions authorized by the laws of a province to provide acute care services.

(2) The following prescribed information about a serious adverse drug reaction must be provided to the Minister in writing within 30 days after the day on which 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 and identifying number or code of the drug that is suspected of causing the reaction; and
- **(c)** a description of the serious adverse drug reaction.

Coming into Force

2 These Regulations come into force on the day on which section 5 of the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*, chapter 24 of the Statutes of Canada, 2014, comes into force, but if they are registered after that day, they come into force on the day on which they are registered.

[16-1-o]

- Footnote 1
  Details of the Interim Order are available at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/notice-avis-nasal-eng.php.
- Footnote 2
  Journal of Mental Health Policy and Economics, March 2000, Volume 3, Issue 1, pp. 1–58.
- Footnote 3
  Varia, M., Wilson, S., Sarwal, S., McGeer, A., Gournis, E., Galanis, E., Henry, B.; Hospital Outbreak Investigation Team. Investigation of a nosocomial outbreak of severe acute respiratory syndrome (SARS) in Toronto, Canada. CMAJ 2003 Aug;169(4):285-292.
- Footnote 4
  National Advisory Committee on SARS and Public Health, Naylor, D., Learning from SARS: renewal of public health in Canada: A report of the National Advisory Committee on SARS and Public Health. Ottawa: Health Canada; 2003.
- Footnote 5
  This would cover the salaries of the staff creating the report, the physician verifying the report, and the administrator approving its release. Acute care facilities will have their own procedures in place. This breakdown is used only as an example.
- Footnote 6
  This estimate is derived from the number of ADRs associated with Vivitrol in the United States, scaled to Canada's population size.
- Footnote 7
  This estimate is based on the assumption that there would be two products imported every year on average, and that products would be imported in bulk shipments no more than 10 times per year.
- Footnote 8
  This estimate is based on the assumption that reporting each importation to Health Canada would cost $15 (assuming 15 minutes of work at an hourly rate of $60), and that record keeping for the purposes of fulfilling the recall provisions would require a further 30 minutes of work at the same hourly rate.
- Footnote 9
  C.R.C., c. 870
- Footnote a
  S.C. 2016, c. 9, s. 8
- Footnote b
  S.C. 2014, c. 24, ss. 6(1) and (3)
- Footnote c
  R.S., c. F-27

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