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CONTROLLED DRUGS AND SUBSTANCES ACT

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Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, makes the annexed *Controlled Substances Regulations* under subsection 55(1) [a] of the *Controlled Drugs and Substances Act* [b].

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Restricted Drugs

Controlled Substances Regulations

Interpretation

Definitions

1 (1) The following definitions apply in these Regulations.

Act
means the *Controlled Drugs and Substances Act*. (*Loi*)

adult
means an individual who is 18 years of age or older. (*adulte*)

advertisement
includes any representation by any means for the purpose of promoting, directly or indirectly, the sale or other disposal of a controlled substance. (*publicité*)

cannabis offence
means

(a) an offence under subsection 9(1) or (2), 10(1) or (2), 11(1) or (2), 12(1), (4), (5), (6) or (7), 13(1) or 14(1) of the *Cannabis Act*; or

(b) a conspiracy or an attempt to commit, being an accessory after the fact in relation to, or any counselling in relation to, an offence referred to in paragraph (a). (*infraction relative au cannabis*)

CAS registry number
means the identification number assigned to a chemical by the Chemical Abstracts Service, a division of the American Chemical Society. (*numéro d'enregistrement CAS*)

competent authority
means a public authority of a foreign country that is authorized under the laws of that country to approve the importation or exportation of controlled substances into or from that country. (*autorité compétente*)

container
means an immediate container of a controlled substance, unless otherwise specified, but does not include a collection container. (*contenant*)

controlled drug
means a substance set out in Schedule 2. (*drogue contrôlée*)

destroy,

in relation to a controlled substance, means to alter or denature it to such an extent that its consumption is rendered impossible or improbable. (*destruction*)

drug identification number
means the identification number assigned to a drug under paragraph C.01.014.2(1)(a) of the *Food and Drug Regulations*. (*identification numérique*)

emergency medical service vehicle
means any conveyance authorized under the laws of a province to transport individuals to hospitals and on which emergency medical services are provided. (*véhicule de service médical d'urgence*)

emergency supply
means a controlled substance that is stored in a place that is either in a remote area where emergency medical treatment is not readily available or in an emergency medical service vehicle. (*approvisionnement d'urgence*)

finished product
means a finished product that contains a controlled substance set out in any of Schedules 1 to 4, that is in a form that is intended to be administered to an individual or animal and, in the case of a finished product that does not contain a restricted drug, that

(a) has a drug identification number; or

(b) is compounded by a pharmacist or pharmacy technician in accordance with these Regulations. (*produit fini*)

government laboratory
means a forensic or toxicology laboratory that is operated by the government of Canada or of a province and in which analytical testing involving controlled substances is conducted. (*laboratoire public*)

health professional
means an individual who is entitled under the laws of a province to practise a profession in a health care field and who is practising in that province. (*professionnel de la santé*)

hospital
means a facility

(a) that is licensed, approved or designated by a province under the laws of the province to provide health care or treatment to individuals or animals; or

(b) that is owned or operated by the government of Canada or of a province and that provides health services. (*hôpital*)

intern
means an individual who is entitled under the laws of a province to work as an intern in a health care field, or to work under a designation that the Minister considers equivalent, and who is working as such in that province. (*stagiaire*)

international obligation

means an obligation relative to a controlled substance set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres. (*obligation internationale*)

letter of authorization
means the letter of authorization issued under section C.08.010 of the *Food and Drug Regulations*. (*lettre d'autorisation*)

licensed dealer
means the holder of a licence issued under subsection 12(1). (*distributeur autorisé*)

midwife
means an individual who is entitled under the laws of a province to practise midwifery and who is practising midwifery in that province. (*sage-femme*)

mixture
means a mixture that contains a controlled substance set out in any of Schedules 1 to 4, but does not include a finished product. (*mélange*)

narcotic
means a substance set out in Schedule 1. (*stupéfiant*)

nurse practitioner
means an individual who is entitled under the laws of a province to practise as a nurse practitioner or to practise under an equivalent designation and who is practising as such in that province. For the purposes of this definition, a designation is equivalent when it designates an individual who

(a) is a registered nurse;

(b) possesses additional training and experience related to health care; and

(c) can autonomously make diagnoses, request diagnostic tests and interpret their results, prescribe drugs and perform other specific procedures under the laws of a province. (*infirmier praticien*)

order
does not include a prescription. (*commande*)

particular person
means a person that, in the course of that person's operations, unexpectedly receives a controlled substance from an individual for the purposes of destruction. (*personne particulière*)

peace officer
has the same meaning as in section 2 of the *Criminal Code*. (*agent de la paix*)

person in charge of a government laboratory
means an individual who has responsibility for managing all of a government laboratory's activities with respect to controlled substances. (*responsable d'un laboratoire public*)

person in charge of a hospital

means an individual who has responsibility for managing all of a hospital's activities with respect to controlled substances. (*responsable d'un hôpital*)

pharmacist
means an individual who is entitled under the laws of a province to practise pharmacy and who is practising pharmacy in that province. (*pharmacien*)

pharmacy technician
means an individual who is entitled under the laws of a province to practise as a pharmacy technician or to practise under a designation that the Minister considers equivalent and who is practising as such in that province. (*technicien en pharmacie*)

podiatrist
means an individual who is entitled under the laws of a province to practise podiatry or chiropody and who is practising podiatry or chiropody in that province. (*podiatre*)

prescription
means an authorization given by a practitioner that a stated amount of a controlled substance, other than a restricted drug, be sold or provided for the individual named or the animal identified in it. (*prescription*)

qualified person in charge
means the individual designated under subsection 9(1). (*responsable qualifié*)

restricted drug
means a substance that is set out in Schedule 4. (*drogue d'utilisation restreinte*)

Security Directive
means the *Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis*, as amended from time to time and published by the Government of Canada on its website. (*Directive en matière de sécurité*)

send
does not include sending by mail. (*expédition*)

senior person in charge
means the individual designated under section 8. (*responsable principal*)

***specialized in destruction*,**
in relation to a licensed dealer, describes a dealer whose licence specifies that it only deals in the destruction of controlled substances. (*spécialisé en destruction*)

targeted substance
means a substance set out in Schedule 3. (*substance ciblée*)

test kit
means a kit

(a) that contains a controlled substance and an adulterating or denaturing agent;

(b) that is used to test for a controlled substance; and

(c) the contents of which are not intended or likely to be consumed by, or administered to, an individual or animal. (*trousse d'essai*)

Interpretation — controlled substances

(2) For the application of these Regulations, a controlled substance refers to any of the following substances:

(a) a narcotic;

(b) a controlled drug;

(c) a targeted substance;

(d) a restricted drug.

Interpretation — practitioners

(3) For the purposes of the definition *practitioner* in subsection 2(1) of the Act, the following persons are prescribed:

(a) midwives;

(b) nurse practitioners; and

(c) podiatrists.

General

Non-application — member of police force

2 The following persons are exempt from the application of these Regulations if, in respect of their activity, they are exempt from the application of sections 5 to 7.1 of the Act by virtue of the *Controlled Drugs and Substances Act (Police Enforcement) Regulations*:

(a) a member of a *police force*, as defined in section 1 of those regulations; or

(b) a person acting under the direction and control of that member.

Controlled drug — Part 3 of Schedule 2

3 The Act and these Regulations do not apply in respect of a finished product that contains a controlled drug set out in Part 3 of Schedule 2 and that is

(a) in a form that allows the sustained release of an active ingredient over a certain period of time; and

(b) intended for insertion under the skin of a food-producing animal for the purpose of increasing weight gain and improving feed efficiency.

Authorizations — agents and mandataries

4 An agent or mandatary of a person, including an employee of that person or another person that is acting under a contract with that person, may conduct an activity if the following conditions are met:

(a) in the case of the person,

(i) the person is authorized under these Regulations to conduct the activity, and

(ii) if applicable, the provincial professional regulatory authority of the province in which they are practising does not prohibit the delegation of the activity to the agent or mandatary; and

(b) in the case of the agent or mandatary,

(i) if applicable, they are authorized by the provincial professional regulatory authority of the province in which they are practising to conduct the activity,

(ii) the agent or mandatary does so as part of their role as agent or mandatary or their employment duties and functions or in the performance of their contract, and

(iii) the agent or mandatary complies with the requirements that apply to the person referred to in paragraph (a).

Possession

Controlled Drugs, Narcotics and Targeted Substances

Authorized persons

5 (1) A person referred to in subsection (2) is authorized to possess any of the following controlled substances if the person has obtained the substance in accordance with these Regulations, in the course of acts conducted in connection with the administration or enforcement of an Act or regulation or from a person exempted under subsection 56(1) of the Act from the application of subsection 5(1) of the Act with respect to that controlled substance:

(a) a narcotic set out in Schedule 1;

(b) a controlled drug set out in Part 1 of Schedule 2;

(c) a targeted substance set out in Part 1 of Schedule 3.

Conditions

(2) An authorized person is

(a) a person that conducts an activity, with respect to the controlled substance, that is necessary for their business or the practice of their profession and that is

(i) a licensed dealer,

(ii) a pharmacist or pharmacy technician, other than one who is practising in a hospital, or

(iii) a practitioner who is registered and entitled to practise in

(A) the province in which they possess the controlled substance, or

(B) a province other than the province in which they possess the controlled substance, if they possess the substance for emergency medical purposes only;

(b) a hospital;

(c) the Minister;

(d) an inspector, member of the Royal Canadian Mounted Police, peace officer or member of the technical or scientific staff of the federal government, a provincial government or a university in Canada who possesses the controlled substance in connection with their employment;

(e) a particular person that possesses the substance for the purposes of destruction; or

(f) an individual who

(i) has obtained the controlled substance for their own use, for the use of another individual or for an animal in accordance with a prescription that was issued or obtained in accordance with these Regulations from one of the following persons:

(A) a practitioner, or

(B) a pharmacist, or

(ii) has imported the controlled substance

(A) for their own use,

(B) for the use and on the behalf of an accompanying individual, or

(C) for an animal for which the individual is responsible and that is accompanying the individual.

Agent or mandatary — person in paragraph (2)(d)

(3) An agent or mandatary of a person referred to in paragraph (2)(d) may only have a controlled substance set out in subsection (1) in their possession if

(a) they have reasonable grounds to believe that person is a person referred to in paragraph (2)(d); and

(b) they possess the controlled substance for the purpose of assisting that person in the administration or enforcement of an Act or regulation.

Export

(4) A licensed dealer, the Minister, a government laboratory or an individual referred to in section 226 may possess a controlled substance, other than a restricted drug, for the purpose of exporting it if the substance was obtained in accordance with these Regulations.

Restricted Drugs

Authorized persons

6 (1) The following persons are authorized to possess any restricted drug listed in Part 1 of Schedule 4 if that person has obtained the drug in accordance with these Regulations or in the course of acts conducted in connection with the administration or enforcement of an Act or regulation:

(a) a licensed dealer;

(b) a pharmacist or pharmacy technician, other than one who is practising in a hospital;

(c) a practitioner who is named in a letter of authorization;

(d) the Minister;

(e) an inspector, member of the Royal Canadian Mounted Police, peace officer or member of the technical or scientific staff of the federal government, a provincial government or a university in Canada who possesses the restricted drug in connection with their employment;

(f) a particular person that possesses the substance for the purposes of destruction; and

(g) an individual who has obtained the restricted drug for their own use from a practitioner named in a letter of authorization.

Agent or mandatary — person in paragraph (1)(e)

(2) An agent or mandatary of a person referred to in paragraph (1)(e) may only have a restricted drug listed in Part 1 of Schedule 4 in their possession if

(a) they have reasonable grounds to believe that person is a person referred to in paragraph (1)(e); and

(b) they possess the restricted drug for the purpose of assisting that person in the administration or enforcement of an Act or regulation.

Export

(3) A licensed dealer, the Minister or a government laboratory may possess a restricted drug for the purpose of exporting it if the drug was obtained in accordance with these Regulations.

Licensed Dealers

Dealer's Licence

Requirement to Obtain

Activities

7 (1) Persons referred to in subsection (2) are required to obtain a dealer's licence for each site at which that person intends to conduct one of the following activities:

(a) producing a controlled substance, unless the person doing so is

(i) a pharmacist or pharmacy technician who is compounding a finished product in accordance with these Regulations, or

(ii) a government laboratory;

(b) packaging, selling, providing, delivering, sending or transporting a controlled substance, unless the person doing so is:

(i) a pharmacist or pharmacy technician who is not practising in a hospital,

(ii) a practitioner,

(iii) a hospital,

(iv) the Minister,

(v) a government laboratory,

(vi) a particular person, or

(vii) an individual referred to in section 223 or 224;

(c) importing or exporting a controlled substance, unless the person doing so is

(i) the Minister,

(ii) a government laboratory, or

(iii) an individual referred to in section 225 or 226; and

(d) destroying a controlled substance, if that is the only activity that the person intends to conduct.

Eligible persons

(2) The persons that are eligible to obtain a dealer's licence are

(a) an individual who ordinarily resides in Canada;

(b) an organization that has its head office in Canada or operates a branch office in Canada; or

(c) the holder of a position that includes responsibility for controlled substances on behalf of the government of Canada or of a province, a police force, a hospital or a university in Canada.

Preliminary Requirements

Senior person in charge

8 (1) An applicant for a dealer's licence must designate only one individual, who may be the applicant if the applicant is an individual, as the senior person in charge who has overall responsibility for management of the activities with respect to controlled substances that are specified in the licence application.

Qualifications

(2) Only an individual who has sufficient knowledge of the provisions of the Act and these Regulations that are applicable to the activities specified in the licence application to properly carry out their duties may be designated as a senior person in charge.

Qualified person in charge

9 (1) An applicant for a dealer's licence must designate only one individual, who may be the applicant if the applicant is an individual, as the qualified person in charge who is responsible for supervising the activities with respect to controlled substances that are specified in the licence application and for ensuring that those activities comply with these Regulations, as well as with any terms or conditions of the licence and any permit issued under these Regulations.

Alternate qualified person in charge

(2) An applicant for a dealer's licence may designate an individual, who may be the applicant if the applicant is an individual, as an alternate qualified person in charge who is authorized to replace the qualified person in charge when that person is absent.

Qualifications

(3) Only an individual who meets the following requirements may be designated as a qualified person in charge or an alternate qualified person in charge:

(a) they work at the site specified in the dealer's licence application;

(b) they

(i) hold a diploma, certificate or credential awarded by a post-secondary educational institution in Canada in a field or occupation that is relevant to their duties, such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, chemistry, biology, pharmacy technician, laboratory technician, pharmaceutical regulatory affairs or supply chain management or security, or

(ii) hold a diploma, certificate or credential that is awarded by a foreign educational institution in a field or occupation referred to in subparagraph (i) and hold one of the following assessments that establishes the equivalency of the diploma, certificate or credential to one of the documents referred to in that subparagraph:

(A) an *equivalency assessment* as defined in subsection 73(1) of the *Immigration and Refugee Protection Regulations*, or

(B) an equivalency assessment issued by an institution or organization that is responsible for issuing equivalency assessments and is recognized by a province;

(c) they have sufficient knowledge of and experience with the use and handling of the controlled substances specified in the dealer's licence application to properly carry out their duties; and

(d) they have sufficient knowledge of the provisions of the Act and these Regulations that are applicable to the activities specified in the dealer's licence application to properly carry out their duties.

Exception

(4) An applicant for a dealer's licence may designate an individual who does not meet any of the requirements set out in paragraph (3)(b) as a qualified person in charge or an alternate qualified person in charge if

(a) no other individual working at the site meets those requirements;

(b) those requirements are not necessary for the activities specified in the licence application; and

(c) the individual has sufficient knowledge acquired from any combination of education, training and work experience to properly carry out their duties.

Ineligibility

10 (1) An individual is not eligible to be a senior person in charge, a qualified person in charge or an alternate qualified person in charge if, during the 10 years before the day on which the dealer's licence application is submitted,

(a) in respect of a designated substance offence, a cannabis offence or any other offence referred to in subsection (2), the individual

(i) was convicted as an adult, or

(ii) was a *young person* who received an *adult sentence*, as those terms are defined in subsection 2(1) of the *Youth Criminal Justice Act*; or

(b) in respect of an offence committed outside Canada that, if committed in Canada, would have constituted a designated substance offence, a cannabis offence or any other offence referred to in subsection (2),

(i) the individual was convicted as an adult, or

(ii) if they committed the offence when they were at least 14 years old but less than 18 years old, the individual received a sentence that was longer than the maximum *youth sentence*, as that term is defined in subsection 2(1) of the *Youth Criminal Justice Act*, that could have been imposed under that Act for such an offence.

Other offences

(2) For the purposes of subsection (1), the other offences are

(a) an offence involving the financing of terrorism referred to in any of sections 83.02 to 83.04 of the *Criminal Code*;

(b) an offence involving fraud referred to in any of sections 380 to 382 of the *Criminal Code*;

(c) the offence of laundering proceeds of crime referred to in section 462.31 of the *Criminal Code*;

(d) an offence involving a criminal organization referred to in any of sections 467.11 to 467.13 of the *Criminal Code*; and

(e) a conspiracy or an attempt to commit, being an accessory after the fact in relation to, or any counselling in relation to, an offence referred to in any of paragraphs (a) to (d).

Issuance of a Licence

Application

11 (1) An application to obtain a dealer's licence must be submitted to the Minister and must contain

(a) if the licence is requested by

(i) an individual, the individual's name,

(ii) an organization, the name by which it intends to identify itself or under which it intends to conduct the activities specified in the licence application and, if applicable, its corporate name and any other name registered with a province, and

(iii) the holder of a position described in paragraph 7(2)(c), the applicant's name and the title of the position;

(b) the municipal address, telephone number and, if applicable, the email address of the site specified in the licence application and, if different from the municipal address, its mailing address;

(c) the name, date of birth, telephone number and email address of the proposed senior person in charge;

(d) with respect to each of the proposed qualified person in charge and any proposed alternate qualified person in charge,

(i) their name, date of birth, telephone number and email address,

(ii) the title of their position at the site,

(iii) the name and title of the position of their immediate supervisor at the site,

(iv) if applicable, the profession they practise that is relevant to their duties, the name of the province that authorizes them to practise it and their authorization number, and

(v) their education, training and work experience that are relevant to their duties;

(e) the activities that are to be conducted and the controlled substance in respect of which each of the activities is to be conducted;

(f) if the licence is requested in order to produce or package a controlled substance set out in any of Schedules 1 to 4, for each substance,

(i) its name, its CAS registry number, if any, as well as its form, the quantity that the applicant intends to produce under the licence and the period during which that quantity would be produced, and

(ii) if it is to be produced or packaged for another licensed dealer under a custom order, the name, and if applicable, title, as well as the municipal address and licence number of the other licensed dealer;

(g) if the licence is requested to produce or package a mixture or finished product, for each mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) its drug identification number, if any,

(iv) if it is to be produced or packaged by or for another licensed dealer under a custom order, the name, and if applicable, title, as well as the municipal address and licence number of the other licensed dealer, and

(v) if the applicant's name appears on any *label*, as defined in section 2 of the *Food and Drugs Act*, of the finished product, a copy of that label;

(h) if the licence is requested for an activity that is not described in paragraph (f) or (g), the name of the controlled substance for which the activity is to be conducted and the purpose of the activity;

(i) a detailed description of the security measures in place at the site, determined in accordance with the Security Directive; and

(j) a detailed description of the method of recording information that the applicant proposes to use for the purposes of section 86.

Documents

(2) The application must be accompanied by the following documents:

(a) if the applicant is an organization, a copy of

(i) the certificate of incorporation or other constituting instrument,

(ii) any document filed with the province in which its site is located that states the name by which it intends to identify itself or under which it intends to conduct the activities specified in the licence application and, if applicable, its corporate name and any other name registered with a province, and

(iii) the permit or licence that is issued by the municipality in which its site is located that authorizes the business to operate, if applicable;

(b) individual declarations, signed and dated by each of the proposed senior person in charge, the qualified person in charge and any proposed alternate qualified person in charge, attesting that the signatory is not ineligible for a reason specified in section 10;

(c) a document issued by a Canadian police force or by a business that is accredited by the Royal Canadian Mounted Police in relation to each person referred to in paragraph (b) indicating whether, during the 10 years before the day on which the application is submitted, the person was convicted as specified in subparagraph 10(1)(a)(i) or received a sentence as specified in subparagraph 10(1)(a)(ii);

(d) if any of the persons referred to in paragraph (b) has ordinarily resided in a country other than Canada during the 10 years before the day on which the application is submitted, a document issued by a police force of that country indicating whether in that period that person was convicted as specified in subparagraph 10(1)(b)(i) or received a sentence as specified in subparagraph 10(1)(b)(ii);

(e) a declaration, signed and dated by the proposed senior person in charge, attesting that they have the knowledge required under subsection 8(2) and that the proposed qualified person in charge and any proposed alternate qualified person in charge have the knowledge and experience required under paragraphs 9(3)(c) and (d);

(f) with respect to the proposed qualified person in charge or any proposed alternate qualified person in charge, a copy of their diploma, certificate or credential referred to in paragraph 9(3)(b) and, if applicable, the equivalency assessment referred to in subparagraph 9(3)(b)(ii); and

(g) if the proposed qualified person in charge or any proposed alternate qualified person in charge does not meet the requirement set out in paragraph 9(3)(b), a detailed description of the education, training and work experience that is required under paragraph 9(4)(c), together with supporting documents, such as a copy of a course transcript or an attestation by the person who provided the training.

Signature and attestation

(3) The application must

(a) be signed and dated by the proposed senior person in charge; and

(b) include an attestation by that person that

(i) all of the information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) they have the authority to bind the applicant.

Additional information and documents

(4) The applicant must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Issuance

12 (1) Subject to section 14, on completion of the review of the licence application, the Minister must issue a dealer's licence, with or without terms and conditions, that contains

(a) the licence number;

(b) if the licensed dealer is an individual, their name and, if applicable, title, or if the licensed dealer is an organization, the name by which it intends to identify itself or under which it intends to conduct the activities specified in the licence;

(c) the specified activities and, for each activity, the name of the controlled substance that is set out in any of Schedules 1 to 4 or that is contained in a mixture or finished product;

(d) the municipal address of the site at which the activity is to be conducted;

(e) the security level at the site, determined in accordance with the Security Directive;

(f) the effective date of the licence;

(g) the expiry date of the licence, which must not be later than three years after its effective date;

(h) any terms and conditions that the Minister has reasonable grounds to believe are necessary to

(i) ensure that an international obligation is respected,

(ii) ensure conformity with the requirements associated with the security level that is referred to in paragraph (e), or

(iii) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use; and

(i) if the licensed dealer produces a controlled substance that is set out in any of Schedules 1 to 4, the quantity that the licensed dealer may produce and the production period.

Licence integrity

(2) A person must not alter or deface in any manner a dealer's licence.

Validity

13 A dealer's licence is valid until the expiry date set out in the licence or, if it is earlier, the date of the suspension or revocation of the licence under section 32 or 33.

Refusal

14 (1) The Minister must refuse to issue a dealer's licence if

(a) the applicant does not meet the requirement set out in subsection 7(2);

(b) during the 10 years before the day on which the licence application is submitted, the applicant has contravened

(i) a provision of the Act, the *Cannabis Act* or their regulations, or

(ii) a term or condition of a licence or permit issued to the applicant under any regulations made under the Act or issued to the applicant under the *Cannabis Act* or its regulations;

(c) during the 10 years before the day on which the application is submitted, the proposed senior person in charge or qualified person in charge or any proposed alternate qualified person in charge was convicted as specified in subparagraph 10(1)(a)(i) or (b)(i) or received a sentence as specified in subparagraph 10(1)(a)(ii) or (b)(ii);

(d) an activity for which the licence is requested would contravene an international obligation;

(e) in the case of a narcotic, an activity for which the licence is requested is the cultivation, propagation or harvesting of opium poppy other than for scientific purposes;

(f) the applicant does not have in place at the site the security measures set out in the Security Directive in respect of an activity for which the licence is requested;

(g) the method referred to in paragraph 11(1)(j) does not permit the recording of information as required under section 86;

(h) the applicant has not provided the Minister with the information or documents required under subsection 11(4) or before the date specified in the written request referred to in that subsection, or the information or documents that the applicant has provided before that date are not sufficient to complete the review of the licence application;

(i) the Minister has reasonable grounds to believe that the applicant has submitted false or misleading information or false or falsified documents in or in support of the licence application;

(j) information received from a peace officer, a competent authority or the United Nations gives the Minister reasonable grounds to believe that the applicant has been involved in the diversion of a controlled substance to an illicit market or use or has been involved in an activity that contravenes an international obligation; or

(k) the Minister has reasonable grounds to believe that the issuance of the licence would likely create a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Exceptions

(2) The Minister must not refuse to issue a licence under paragraph (1)(b) or (i) if the applicant meets the following conditions unless the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a controlled substance from being

diverted to an illicit market or use:

(a) the applicant does not have a history of non-compliance with the provisions of the Act, the *Cannabis Act* or their regulations; and

(b) the applicant has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the provisions of the Act, the *Cannabis Act* and their regulations.

Prior notice

(3) Before refusing to issue a licence, the Minister must

(a) provide the applicant with a prior written notice that sets out the Minister's reasons and gives the applicant an opportunity to be heard; and

(b) consider the applicant's submissions, if applicable.

Renewal of a Licence

Application

15 (1) To apply to renew a dealer's licence, a licensed dealer must submit to the Minister an application that contains the information and documents referred to in subsections 11(1) and (2).

Signature and attestation

(2) The application must

(a) be signed and dated by the senior person in charge of the site specified in the application; and

(b) include an attestation by that person that

(i) all of the information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) they have the authority to bind the licensed dealer.

Additional information and documents

(3) The licensed dealer must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Renewal

16 (1) Subject to section 18, on completion of the review of the renewal application, the Minister must issue a renewed dealer's licence that contains the information specified in subsection 12(1).

Terms or conditions

(2) When renewing a dealer's licence, the Minister may, if the Minister has reasonable grounds to believe that it is necessary to do so, add a term or condition to it or modify or delete a term or condition in order to

(a) ensure that an international obligation is respected;

(b) ensure conformity with the requirements associated with the security level specified in the licence or the new level required as a result of the licence renewal; or

(c) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Validity

17 A renewed dealer's licence is valid until the expiry date set out in the licence or, if it is earlier, the date of the suspension or revocation of the licence under section 32 or 33.

Refusal

18 (1) The Minister must refuse to renew a dealer's licence if

(a) the licensed dealer no longer meets the requirement set out in subsection 7(2);

(b) during the 10 years before the day on which the renewal application is submitted, the licensed dealer has contravened

(i) a provision of the Act, the *Cannabis Act* or their regulations, or

(ii) a term or condition of a licence or permit issued to the dealer under a regulation made under the Act or issued to the dealer under the *Cannabis Act* or its regulations;

(c) during the 10 years before the day on which the renewal application is submitted, the proposed senior person in charge or qualified person in charge or any proposed alternate qualified person in charge was convicted as specified in subparagraph 10(1)(a)(i) or (b)(i) or received a sentence as specified in subparagraph 10(1)(a)(ii) or (b)(ii);

(d) an activity for which the renewal is requested would contravene an international obligation;

(e) in the case of a narcotic, an activity for which the renewal is requested is the cultivation, propagation or harvesting of opium poppy other than for scientific purposes;

(f) the licensed dealer does not have in place at the site the security measures set out in the Security Directive in respect of an activity for which the renewal is requested;

(g) the method referred to in paragraph 11(1)(j) does not permit the recording of information as required under section 86;

(h) the licensed dealer has not provided the Minister with the information or documents required under subsection 15(3) or by the date specified in the written request referred to in that

subsection, or the information or documents that the dealer has provided before that date are not sufficient to complete the review of the renewal application;

(i) the Minister has reasonable grounds to believe that the licensed dealer has submitted false or misleading information or false or falsified documents in or in support of the renewal application;

(j) information received from a peace officer, a competent authority or the United Nations gives the Minister reasonable grounds to believe that the licensed dealer has been involved in the diversion of a controlled substance to an illicit market or use or has been involved in an activity that contravened an international obligation; or

(k) the Minister has reasonable grounds to believe that the renewal of the licence would likely create a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Exceptions

(2) The Minister must not refuse to renew a licence under paragraph (1)(b) or (i) if the licensed dealer meets the following conditions unless the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use:

(a) the licensed dealer does not have a history of non-compliance with the provisions of the Act, the *Cannabis Act* or their regulations; and

(b) the licensed dealer has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the provisions of the Act, the *Cannabis Act* and their regulations.

Prior notice

(3) Before refusing to renew a licence, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Amendment of a Licence

Application

19 (1) Before making a change affecting any information that is contained in their dealer's licence, a licensed dealer must submit to the Minister an application to amend the licence that contains a description of the proposed amendment, as well as the information and documents referred to in subsections 11(1) and (2) that are relevant to the proposed amendment.

Signature and attestation

(2) The application must

(a) be signed and dated by the senior person in charge of the site specified in the application; and

(b) include an attestation by that person that

(i) all of the information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) they have the authority to bind the licensed dealer.

Additional information and documents

(3) The licensed dealer must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Amendment

20 (1) Subject to section 22, on completion of the review of the amendment application, the Minister must amend the dealer's licence.

Terms or conditions

(2) When amending a dealer's licence, the Minister may, if the Minister has reasonable grounds to believe that it is necessary to do so, add a term or condition to it or modify or delete a term or condition in order to

(a) ensure that an international obligation is respected;

(b) ensure conformity with the requirements associated with the security level specified in the licence or the new level required as a result of the amendment; or

(c) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Validity

21 An amended dealer's licence is valid until the expiry date set out in the licence or, if it is earlier, the date of the suspension or revocation of the licence under section 32 or 33.

Refusal

22 (1) The Minister must refuse to amend a dealer's licence if

(a) the licensed dealer no longer meets the requirement set out in subsection 7(2);

(b) during the 10 years before the day on which the amendment application is submitted, the senior person in charge or qualified person in charge or any alternate qualified person in charge was convicted as specified in subparagraph 10(1)(a)(i) or (b)(i) or received a sentence as specified in subparagraph 10(1)(a)(ii) or (b)(ii);

(c) an activity for which the amendment is requested would contravene an international obligation;

(d) in the case of a narcotic, an activity for which the amendment is requested is the cultivation, propagation or harvesting of opium poppy other than for scientific purposes;

(e) the licensed dealer does not have in place at the site the security measures set out in the Security Directive in respect of an activity for which the amendment is requested;

(f) the method referred to in paragraph 11(1)(j) does not permit the recording of information as required under section 86;

(g) the licensed dealer has not provided the Minister with the information or documents required under subsection 19(3) or before the date specified in the written request referred to in that subsection, or the information or documents that the dealer has provided before that date are not sufficient to complete the review of the amendment application;

(h) the Minister has reasonable grounds to believe that the licensed dealer has submitted false or misleading information or false or falsified documents in or in support of the amendment application; or

(i) the Minister has reasonable grounds to believe that the amendment of the licence would likely create a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Exceptions

(2) The Minister must not refuse to amend a licence under paragraph (1)(h) if the licensed dealer meets the following conditions unless the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use:

(a) the licensed dealer does not have a history of non-compliance with the provisions of the Act, the *Cannabis Act* or their regulations; and

(b) the licensed dealer has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the provisions of the Act, the *Cannabis Act* and their regulations.

Prior notice

(3) Before refusing to amend a licence, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Changes Requiring Prior Approval by the Minister

Application

23 (1) A licensed dealer must obtain the Minister's approval before making any of the following changes by submitting a written application to the Minister:

(a) a change affecting the security measures in place at the site specified in the dealer's licence;

(b) a change affecting the method of recording information referred to in paragraph 11(1)(j);

(c) the replacement of the senior person in charge;

(d) the replacement of the qualified person in charge; or

(e) the replacement or addition of an alternate qualified person in charge.

Information and documents

(2) The licensed dealer must provide the Minister with the following with respect to a change referred to in subsection (1):

(a) in the case of a change affecting the security measures in place at the site specified in the dealer's licence or the method of recording information referred to in paragraph 11(1)(j), details of the change;

(b) in the case of a replacement of the senior person in charge,

(i) the information specified in paragraph 11(1)(c), and

(ii) the documents specified in paragraphs 11(2)(b) to (e); and

(c) in the case of a replacement of the qualified person in charge or a replacement or addition of an alternate qualified person in charge,

(i) the information specified in paragraph 11(1)(d), and

(ii) the documents specified in paragraphs 11(2)(b) to (f).

Additional information and documents

(3) The licensed dealer must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Approval

24 (1) Subject to section 25, on completion of the review of the application for approval of the change, the Minister must approve the change.

Terms or conditions

(2) When approving a change, the Minister may, if the Minister has reasonable grounds to believe that it is necessary to do so, add a term or condition to the licence or modify or delete a term or condition in order to

(a) ensure that an international obligation is respected;

(b) ensure conformity with the requirements associated with the security level specified in the licence; or

(c) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Refusal

25 (1) The Minister must refuse to approve the change if

(a) during the 10 years before the day on which the application for approval of the change is submitted, the proposed senior person in charge or qualified person in charge or any proposed alternate qualified person in charge was convicted as specified in subparagraph 10(1)(a)(i) or (b)(i) or received a sentence as specified in subparagraph 10(1)(a)(ii) or (b)(ii);

(b) the licensed dealer has not provided the Minister with the information or documents required under subsection 23(3) or before the date specified in the written request referred to in that subsection, or the information or documents that the dealer has provided before that date are not sufficient to complete the review of the application for approval of the change;

(c) the Minister has reasonable grounds to believe that the licensed dealer has submitted false or misleading information or false or falsified documents in or in support of the application for approval of the change; or

(d) the Minister has reasonable grounds to believe that the change would likely create a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Exceptions

(2) The Minister must not refuse to approve a change under paragraph (1)(c) if the licensed dealer has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the provisions of the Act, the *Cannabis Act* and their regulations unless the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use.

Prior notice

(3) Before refusing to approve a change, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Changes Requiring a Notice to the Minister

Prior notice

26 (1) A licensed dealer must notify the Minister in writing before

(a) producing or packaging a mixture or finished product that is not set out in the most recent update of the information and label referred to in paragraph 11(1)(g); or

(b) making a change to a mixture or finished product that is set out in that most recent update, if the change affects any of the information or label that has previously been submitted.

Information and document

(2) The notice must contain the information that is necessary to update the information or label referred to in paragraph 11(1)(g) and must be accompanied by a document containing all the information referred to in that paragraph, including those updates, and a copy of the label referred to in that paragraph or, if applicable, a copy of the updated label.

Notice — five days

27 A licensed dealer must notify the Minister in writing within five days after a person ceases to act as the qualified person in charge or an alternate qualified person in charge.

Notice — 10 days

28 (1) A licensed dealer must notify the Minister in writing within 10 days after one of the following changes occurs:

(a) a person ceases to act as the senior person in charge; or

(b) the licensed dealer ceases to produce or package a mixture or finished product that is set out in the most recent update of the information and label referred to in paragraph 11(1)(g).

Information and document

(2) A notice concerning a change referred to in paragraph (1)(b) must contain the information that is necessary to update the information referred to in paragraph 11(1)(g) and must be accompanied by a document containing all the information referred to in that paragraph, including those updates, and a copy of the label for any other controlled substance.

Notice of cessation of activities

29 (1) A licensed dealer that intends to cease conducting activities at their site — whether on or before the expiry of their licence — must notify the Minister in writing to that effect at least 30 days before ceasing those activities.

Content of notice

(2) The notice must be signed and dated by the senior person in charge and contain the following information:

(a) the expected date of the cessation of activities at the site;

(b) a description of the manner in which any remaining controlled substances on the site as of that date will be disposed of by the licensed dealer, including

(i) if some or all of them will be sold or provided to another licensed dealer that will be conducting activities at the same site, their name and, if applicable, title,

(ii) if some or all of them will be sold or provided to another licensed dealer that will not be conducting activities at the same site, their name and, if applicable, title, as well as the municipal address of their site, and

(iii) if some or all of them will be destroyed, the anticipated date of destruction and the municipal address of the place at which the destruction is to be carried out;

(c) the municipal address of the place at which the licensed dealer's documents will be kept after activities have ceased; and

(d) the name, municipal address, telephone number and, if applicable, the email address of a person whom the Minister may contact for further information after activities have ceased.

Update

(3) After having ceased to conduct the activities, the licensed dealer must submit to the Minister a detailed update of the information referred to in subsection (2) if it differs from what was set out in the notice. The update must be signed and dated by the senior person in charge.

Changes to the Terms and Conditions of a Licence

Addition or modification

30 (1) The Minister may, at any time other than at the issuance, renewal or amendment of a dealer's licence, add or modify a term or condition if the Minister has reasonable grounds to believe that it is necessary to do so to

(a) ensure conformity with the provisions of the Act, the *Cannabis Act* and their regulations;

(b) ensure that an international obligation is respected;

(c) ensure conformity with the requirements associated with the security level specified in the licence; or

(d) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Prior notice

(2) Before adding a term or condition to, or modifying a term or condition of, a licence, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Urgent circumstances

(3) Despite subsection (2), the Minister may immediately add a term or condition to, or modify a term or condition of, a licence, subject to subsection (4), if the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use.

Urgent circumstances — notice

(4) The addition or modification of a term or condition that is made under subsection (3) takes effect as soon as the Minister provides the licensed dealer with a written notice that

(a) sets out the reasons for the addition or modification;

(b) gives the dealer an opportunity to be heard; and

(c) if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.

Deletion of term or condition

31 (1) The Minister may delete a term or condition of a dealer's licence that the Minister determines is no longer necessary.

Notice

(2) The deletion takes effect as soon as the Minister provides the licensed dealer with a written notice to that effect.

Suspension and Revocation of a Licence

Suspension

32 (1) Subject to subsection (2), the Minister must immediately suspend a dealer's licence in respect of any activities in relation to any controlled substance if the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use.

Notice

(2) The suspension takes effect as soon as the Minister provides the licensed dealer with a written notice that

(a) sets out the authorized activity and controlled substance that are the subject of the suspension, as well as the reasons for the suspension;

(b) gives the dealer an opportunity to be heard; and

(c) if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.

Reinstatement of licence

(3) The Minister must reinstate the licence if the Minister has reasonable grounds to believe that the suspension is no longer necessary.

Revocation

33 (1) Subject to subsection (2), the Minister must revoke a dealer's licence if

(a) the licensed dealer no longer meets the requirement set out in subsection 7(2);

(b) the licensed dealer requests the Minister to do so or informs the Minister of the loss or theft of the licence or the actual or potential unauthorized use of the licence;

(c) the licensed dealer ceases to conduct activities at their site before the expiry of their licence;

(d) the licensed dealer does not take the corrective measures specified in an undertaking or notice;

(e) the licensed dealer has contravened

(i) a provision of the Act, the *Cannabis Act* or their regulations, or

(ii) a term or condition of a licence or permit issued to the dealer under a regulation made under the Act or issued to the dealer under the *Cannabis Act* or its regulations;

(f) during the 10 years before the day on which the licence is revoked, the senior person in charge, the qualified person in charge or any alternate qualified person in charge was convicted as specified in subparagraph 10(1)(a)(i) or (b)(i) or received a sentence as specified in subparagraph 10(1)(a)(ii) or (b)(ii);

(g) the Minister has reasonable grounds to believe that the licensed dealer submitted false or misleading information or false or falsified documents in or in support of an application relating to the licence; or

(h) information received from a peace officer, a competent authority or the United Nations gives the Minister reasonable grounds to believe that the licensed dealer has been involved in the diversion of a controlled substance to an illicit market or use or has been involved in an activity that contravened an international obligation.

Exceptions

(2) The Minister must not revoke a dealer's licence for a ground set out in paragraph (1)(e) or (g) if the licensed dealer meets the following conditions unless the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use:

(a) the licensed dealer does not have a history of non-compliance with the provisions of the Act, the *Cannabis Act* or their regulations; and

(b) the licensed dealer has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the provisions of the Act, the *Cannabis Act* and their regulations.

Prior notice

(3) Before revoking a licence, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Import Permit

Application

34 (1) A licensed dealer must submit to the Minister, before each importation of a controlled substance, an application for an import permit that contains the following information:

(a) their name and, if applicable, title, as well as their municipal address;

(b) their dealer's licence number and their business registration number assigned by the Minister of National Revenue;

(c) the name and municipal address of the proposed customs broker for the licensed dealer, if any;

(d) the name of the customs office where the importation is anticipated and the proposed date of importation;

(e) the name and municipal address, in the country of export, of the exporter from whom the controlled substance is being obtained;

(f) the name of the carrier that is proposed to transport the controlled substance to the customs office where the importation is anticipated;

(g) each proposed mode of transportation and any proposed country of transit or transhipment;

(h) in the case of a controlled substance set out in any of Schedules 1 to 4,

(i) its name as set out in the dealer's licence,

(ii) its CAS registry number, if any,

(iii) if it is a salt, the name of the salt,

(iv) its form,

(v) its purity and anhydrous content, and

(vi) its quantity; and

(i) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Signature and attestation

(2) The application must

(a) be signed and dated by the qualified person in charge or an alternate qualified person in charge; and

(b) include an attestation by that person that, to the best of their knowledge,

(i) the importation does not contravene the laws of the country of exportation or any country of transit or transhipment, and

(ii) all of the information and documents submitted in support of the application are correct and complete.

Additional information and documents

(3) The licensed dealer must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Issuance

35 (1) Subject to section 37, on completion of the review of the import permit application, the Minister must issue to the licensed dealer an import permit that contains

(a) the permit number;

(b) the information set out in subsection 34(1);

(c) the effective date of the permit;

(d) the expiry date of the permit, being the earlier of

(i) a date specified by the Minister that is not more than 180 days after its effective date, and

(ii) the expiry date of the dealer's licence; and

(e) any terms and conditions that the Minister has reasonable grounds to believe are necessary to

(i) ensure that an international obligation is respected, or

(ii) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Permit integrity

(2) A person must not alter or deface in any manner an import permit.

Validity

36 An import permit is valid until the earliest of

(a) the expiry date set out in the permit,

(b) the date of the suspension or revocation of the permit under section 40 or 41,

(c) the date of the suspension or revocation of the dealer's licence under section 32 or 33, and

(d) the date of the expiry, suspension or revocation of the export authorization that applies to the controlled substance to be imported and that is issued by the competent authority in the country of export.

Refusal

37 (1) The Minister must refuse to issue an import permit if

(a) the licensed dealer is not authorized by their dealer's licence to import the relevant controlled substance or their licence will expire before the date of importation;

(b) the Minister has reasonable grounds to believe that the importation would contravene an international obligation;

(c) the licensed dealer does not have in place at the site the security measures set out in the Security Directive in respect of the importation;

(d) the licensed dealer has not provided the Minister with the information or documents required under subsection 34(3) or before the date specified in the written request referred to in that subsection, or the information or documents that the dealer has provided before that date are not sufficient to complete the review of the permit application;

(e) the Minister has reasonable grounds to believe that the licensed dealer has submitted false or misleading information or false or falsified documents in or in support of the permit application;

(f) the Minister has reasonable grounds to believe that the importation would contravene the laws of the country of export or any country of transit or transhipment; or

(g) the Minister has reasonable grounds to believe that the issuance of the permit would likely create a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Prior notice

(2) Before refusing to issue an import permit, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Providing copy of permit

38 The holder of an import permit must provide a copy of the permit to the customs office at the time of importation.

Declaration

39 The holder of an import permit must provide the Minister, within 15 days after the day of release of the controlled substance specified in the permit in accordance with the *Customs Act*, with a declaration that contains the following information:

(a) their name and, if applicable, title;

(b) their dealer's licence number and the number of the import permit;

(c) the name of the customs office from which the controlled substance was released and the date of the release;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4,

(i) its name as set out in the dealer's licence,

(ii) if it is a salt, the name of the salt,

(iii) its form, and

(iv) its quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Suspension

40 (1) Subject to subsection (2), the Minister must immediately suspend an import permit if

(a) the dealer's licence is suspended;

(b) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use; or

(c) the Minister has reasonable grounds to believe that the importation would contravene the laws of the country of export or any country of transit or transhipment.

Notice

(2) The suspension takes effect as soon as the Minister provides the licensed dealer with a written notice that

(a) sets out the reasons for the suspension;

(b) gives the dealer an opportunity to be heard; and

(c) if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.

Reinstatement of permit

(3) The Minister must reinstate the import permit if the Minister has reasonable grounds to believe that the suspension is no longer necessary.

Revocation

41 (1) The Minister must revoke an import permit if

(a) the dealer's licence has been revoked;

(b) the licensed dealer requests the Minister to do so or informs the Minister of the loss or theft of the permit or the actual or potential unauthorized use of the permit;

(c) the licensed dealer does not carry out the corrective measures specified by the Minister under paragraph 40(2)(c) by the specified date; or

(d) the Minister has reasonable grounds to believe that the licensed dealer submitted misleading information or falsified documents in or in support of the application for the permit.

Prior notice

(2) Before revoking an import permit, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Export Permit

Application

42 (1) A licensed dealer must submit to the Minister, before each exportation of a controlled substance, an application for an export permit that contains the following information and document:

(a) their name and, if applicable, title, as well as their municipal address;

(b) their dealer's licence number and their business registration number assigned by the Minister of National Revenue;

(c) the name and municipal address of the proposed customs broker for the licensed dealer, if any;

(d) the name of the customs office where the exportation is anticipated and the proposed date of exportation;

(e) the name and municipal address of the importer in the country of final destination;

(f) the name of the carrier that is proposed to transport the controlled substance from the customs office where the exportation is anticipated;

(g) each proposed mode of transportation and any proposed country of transit or transhipment;

(h) in the case of a controlled substance set out in any of Schedules 1 to 4,

(i) its name as set out in the dealer's licence,

(ii) its CAS registry number, if any,

(iii) if it is a salt, the name of the salt,

(iv) its form,

(v) its purity and anhydrous content, and

(vi) its quantity;

(i) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any; and

(j) a copy of the import authorization issued by the competent authority in the country of final destination that sets out the name of the importer and the municipal address of their site in that country.

Signature and attestation

(2) The application must

(a) be signed and dated by the qualified person in charge or an alternate qualified person in charge; and

(b) include an attestation by that person that, to the best of their knowledge,

(i) the exportation does not contravene the laws of the country of final destination or any country of transit or transhipment, and

(ii) all of the information and documents submitted in support of the application are correct and complete.

Additional information and documents

(3) The licensed dealer must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Issuance

43 (1) Subject to section 45, on completion of the review of the export permit application, the Minister must issue to the licensed dealer an export permit that contains

(a) the permit number;

(b) the information set out in paragraphs 42(1)(a) to (i) and the number of the import authorization referred to in paragraph 42(1)(j);

(c) the effective date of the permit;

(d) the expiry date of the permit, being the earliest of

(i) a date specified by the Minister that is not more than 180 days after its effective date,

(ii) the expiry date of the dealer's licence, and

(iii) the expiry date of the import authorization issued by the competent authority in the country of final destination; and

(e) any terms and conditions that the Minister has reasonable grounds to believe are necessary to

(i) ensure that an international obligation is respected, or

(ii) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Permit integrity

(2) A person must not alter or deface in any manner an export permit.

Validity

44 An export permit is valid until the earliest of

(a) the expiry date set out in the permit,

(b) the date of the suspension or revocation of the permit under section 48 or 49,

(c) the date of the suspension or revocation of the dealer's licence under section 32 or 33, and

(d) the date of the expiry, suspension or revocation of the import authorization that applies to the controlled substance to be exported and that is issued by the competent authority in the country of final destination.

Refusal

45 (1) The Minister must refuse to issue an export permit if

(a) the licensed dealer is not authorized by their dealer's licence to export the relevant controlled substance or their dealer's licence will expire before the date of export;

(b) the Minister has reasonable grounds to believe that the exportation would contravene an international obligation;

(c) the licensed dealer has not provided the Minister with the information or documents required under subsection 42(3) or before the date specified in the written request referred to in that subsection, or the information or documents that the dealer has provided before that date are not sufficient to complete the review of the permit application;

(d) the Minister has reasonable grounds to believe that the licensed dealer has submitted false or misleading information or false or falsified documents in or in support of the permit application;

(e) the Minister has reasonable grounds to believe that the exportation would not be in conformity with the import authorization issued by the competent authority of the country of final destination;

(f) the Minister has reasonable grounds to believe that the exportation would contravene the laws of the country of final destination or any country of transit or transhipment; or

(g) the Minister has reasonable grounds to believe that the issuance of the permit would likely create a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Prior notice

(2) Before refusing to issue an export permit, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Providing copy of permit

46 The holder of an export permit must provide a copy of the permit to the customs office at the time of exportation.

Declaration

47 The holder of an export permit must provide the Minister, within 15 days after the day of export of the controlled substance specified in the permit, with a declaration that contains the following information:

(a) their name and, if applicable, title;

(b) their dealer's licence number and the number of the export permit;

(c) the name of the customs office from which the controlled substance was exported and the date of export;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4,

(i) its name as set out in the dealer's licence,

(ii) if it is a salt, the name of the salt,

(iii) its form, and

(iv) its quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Suspension

48 (1) Subject to subsection (2), the Minister must immediately suspend an export permit if

(a) the dealer's licence is suspended;

(b) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use; or

(c) the Minister has reasonable grounds to believe that the exportation would contravene the laws of the country of final destination or any country of transit or transhipment.

Notice

(2) The suspension takes effect as soon as the Minister provides the licensed dealer with a written notice that

(a) sets out the reasons for the suspension;

(b) gives the dealer an opportunity to be heard; and

(c) if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.

Reinstatement of permit

(3) The Minister must reinstate the export permit if the Minister has reasonable grounds to believe that the suspension is no longer necessary.

Revocation

49 (1) The Minister must revoke an export permit if

(a) the dealer's licence has been revoked;

(b) the licensed dealer requests the Minister to do so or informs the Minister of the loss or theft of the permit or the actual or potential unauthorized use of the permit;

(c) the licensed dealer does not carry out the corrective measures specified by the Minister under paragraph 48(2)(c) by the specified date; or

(d) the Minister has reasonable grounds to believe that the licensed dealer submitted misleading information or falsified documents in or in support of the application for the permit.

Prior notice

(2) Before revoking an export permit, the Minister must

(a) provide the licensed dealer with a prior written notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard; and

(b) consider the licensed dealer's submissions, if applicable.

Authorizations and General Conditions Applicable to Activities

Authorized activities

50 A licensed dealer may conduct the following activities if it does so in accordance with their dealer's licence and any permit issued under these Regulations:

(a) produce a controlled substance;

(b) sell or provide a controlled substance to

(i) another licensed dealer,

(ii) with the exception of a restricted drug, a pharmacist, other than one who is practising in a hospital,

(iii) a practitioner,

(iv) with the exception of a restricted drug, a hospital,

(v) a person exempted under subsection 56(1) of the Act with respect to that controlled substance, if there are terms and conditions for the sale or provision by a licensed dealer that are specified in the exemption,

(vi) the Minister, or

(vii) a government laboratory;

(c) transport, send or deliver a controlled substance; or

(d) import or export a controlled substance.

Packaging — conditions

51 A licensed dealer that packages a controlled substance may only do so in accordance with their dealer's licence issued under these Regulations.

Destruction

52 A licensed dealer specialized in destruction that destroys a controlled substance may only do so in accordance with their dealer's licence issued under these Regulations.

Qualified person in charge present

53 A licensed dealer may conduct an activity in relation to a controlled substance at their site only if the qualified person in charge or an alternate qualified person in charge is present at the site.

Identification

54 A licensed dealer must include their name, as set out in their dealer's licence, on all the means by which it identifies itself in regard to their activities in relation to a controlled substance, including labels, shipping documents, invoices and advertising.

Information and documents

55 A licensed dealer must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any relevant information or document to demonstrate their compliance with the provisions of the Act and these Regulations.

Sale of Controlled Substances

Sale to another licensed dealer

56 A licensed dealer that sells or provides a controlled substance to another licensed dealer may only do so if it first receives from the other licensed dealer a written order that is signed and dated and that contains the following:

(a) with respect to the other licensed dealer placing the order, their name and, if applicable, title, as well as their municipal address;

(b) with respect to the licensed dealer selling or providing the controlled substance, their name and, if applicable, title, as well as their municipal address;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity;

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any; and

(f) in the case of a controlled substance sold or provided for the purposes of destruction, a statement to that effect.

Sale to pharmacist

57 (1) A licensed dealer that sells or provides a controlled substance to a pharmacist may only do so if it first receives from the pharmacist a written order that is signed and dated and that contains the following information:

(a) with respect to the pharmacist, their name and the name and municipal address of the place where they practise;

(b) with respect to the licensed dealer, their name and, if applicable, title, as well as their municipal address;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Exception — prohibition

(2) A licensed dealer must not sell or provide to the pharmacist a controlled substance that is the subject of a prohibition on the pharmacist's professional practice imposed by the provincial professional regulatory authority.

Sale to practitioner

58 (1) A licensed dealer that sells or provides a controlled substance, other than a restricted drug, to a practitioner may only do so if it first receives from the practitioner a written order that is signed and dated and that contains the following information:

(a) with respect to the practitioner, their name and the name and municipal address of the place where they practise;

(b) with respect to the licensed dealer, their name and, if applicable, title, as well as their municipal address;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Restricted drugs

(2) A licensed dealer that sells or provides a restricted drug to a practitioner may only do so if

(a) the licensed dealer first receives a letter of authorization in which it is named;

(b) the practitioner is named in the letter of authorization and the municipal address of the place where they practise is specified in that letter; and

(c) the licensed dealer sells or provides the restricted drug only in the quantity specified in the letter of authorization and, if applicable, in the form and strength specified in that letter.

Exception — prohibition

(3) A licensed dealer must not sell or provide to the practitioner a controlled substance that is the subject of a prohibition on the practitioner's professional practice imposed by the provincial professional regulatory authority.

Sale to hospital

59 A licensed dealer that sells or provides a controlled substance to a hospital may only do so if it first receives from the hospital a written order that is signed and dated by a person permitted to place an order on the hospital's behalf and that contains the following information:

(a) with respect to the hospital, its name and municipal address, as well as the name and title of the person placing the order;

(b) with respect to the licensed dealer, their name and, if applicable, title, as well as their municipal address;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Sale to exempted person

60 A licensed dealer that sells or provides a controlled substance to a person exempted under subsection 56(1) of the Act with respect to that substance may only do so in accordance with the terms and conditions for the sale or provision by the licensed dealer that are specified in the exemption and if it first receives from the exempted person a copy of that exemption.

Sale to Minister

61 A licensed dealer that sells or provides a controlled substance to the Minister may only do so if it first receives from the Minister a written order that is signed and dated on the Minister's behalf and that contains the following information:

(a) with respect to the individual signing the order, their name and, if applicable, title, as well as the municipal address of the place where the controlled substance is to be delivered, sent or transported;

(b) with respect to the licensed dealer, their name and, if applicable, title, as well as their municipal address and licence number;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Sale to government laboratory

62 A licensed dealer that sells or provides a controlled substance to a government laboratory may only do so if it first receives from the government laboratory a written order that is signed and dated and that contains the following information:

(a) with respect to the government laboratory, its name and municipal address;

(b) with respect to the licensed dealer, their name and, if applicable, title, as well as their municipal address and licence number;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Anticipated multiple sales

63 (1) A licensed dealer that sells or provides a controlled substance, other than a restricted drug, may do so more than once in respect of one order, within six months after the order was made, if the order indicates

(a) the number of sales or provisions;

(b) the specific quantity for each sale or provision; and

(c) the intervals between each sale or provision.

Multiple sales — insufficient stock

(2) A licensed dealer may sell or provide a controlled substance more than once in respect of one order if, at the time of receipt of the order, the dealer temporarily does not have in stock the quantity of the substance ordered, in which case the dealer may sell or provide the quantity of the substance that the dealer has available and sell or provide the balance later.

Verification of Identity

Orders

64 A licensed dealer that receives an order from a person for a controlled substance must verify the person's name and, if applicable, their title as well as their signature if it is not known to the licensed dealer.

Delivery, Sending and Transportation

Requirements during transportation

65 (1) A licensed dealer that takes delivery of a controlled substance that it has imported or that delivers, sends or transports a controlled substance to another person may only do so if it

(a) ensures that its outermost container is inconspicuous, without any mark identifying its contents, and sealed in such a manner that the container cannot be opened without breaking the seal;

(b) ensures that all inner containers are sealed in such a manner that they cannot be opened without breaking the seal;

(c) takes all reasonable measures to ensure the security of the controlled substance while it is being delivered, sent or transported;

(d) uses a method of delivery, sending or transportation that ensures the tracking of the controlled substance until the consignee receives it;

(e) in the case of an imported controlled substance, delivers, sends or transports it directly to the site specified in their licence after it is released under the *Customs Act*; and

(f) in the case of a controlled substance that is to be exported, delivers, sends or transports it directly from the site specified in their licence to the customs office where it will be exported.

Exception

(2) Subsection (1) does not apply to a test kit that has a registration number.

Security

Protective measures

66 A licensed dealer must take all reasonable measures to ensure the security of any controlled substance, licence or permit in their possession.

Loss or theft — licences and permits

67 If a licensed dealer becomes aware of a loss or theft of their licence or permit, the dealer must provide a written report to the Minister within 72 hours after becoming aware of the loss or theft.

Loss or theft — agent or mandatary

68 (1) If an agent or mandatary of a licensed dealer becomes aware of a loss or theft of a controlled substance, the agent or mandatary must notify the licensed dealer immediately.

Written report

(2) If a licensed dealer becomes aware of a loss of a controlled substance that cannot be explained on the basis of normally accepted business activities, or of a theft of a controlled substance, or is notified by an agent or mandatary of such a loss or theft, the dealer must

(a) in the case of a loss, provide a written report to the Minister within 72 hours after becoming aware or being notified of the loss; or

(b) in the case of a theft, provide

(i) a written report to a police force within 24 hours after becoming aware or being notified of the theft, and

(ii) a written report to the Minister within 72 hours after becoming aware or being notified of the theft, including a confirmation that the report required under subparagraph (i) has been provided.

Suspicious transaction

69 (1) A licensed dealer must provide a written report containing the following information to the Minister within 72 hours after becoming aware of a transaction occurring in the course of their activities that it has reasonable grounds to suspect may be related to the diversion of a controlled substance to an illicit market or use:

(a) with respect to the licensed dealer,

(i) in the case of an individual, their name and, if applicable, title, as well as their municipal address and telephone number, or

(ii) in the case of an organization, its name, municipal address and telephone number, as well as the title of the position held by the individual making the report;

(b) with respect to the other party to the transaction, their name and municipal address;

(c) details of the transaction, including its date and time, as well as its type;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity;

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any; and

(f) a detailed description of the reasons for the dealer's suspicions.

Good faith

(2) No civil proceedings lie against a licensed dealer for having provided the report in good faith.

Non-disclosure

(3) A licensed dealer must not disclose that it has provided the report or disclose details of it with the intent to prejudice a criminal investigation, whether or not a criminal investigation has begun.

Partial protection against self-incrimination

70 A report provided under any of sections 67 to 69, or any evidence derived from it, is not to be used or received to incriminate the licensed dealer or their agent or mandatary in any criminal proceeding against them other than a prosecution under section 132, 136 or 137 of the *Criminal Code*.

Destruction of Controlled Substances

Destruction at site

71 A licensed dealer that intends to destroy a controlled substance at the site specified in their licence must ensure that the following conditions are met:

(a) the licensed dealer obtains the prior approval of the Minister;

(b) the destruction is carried out in the presence of two of the following persons, at least one of whom must be a person referred to in subparagraph (i):

(i) the senior person in charge, the qualified person in charge or an alternate qualified person in charge, or

(ii) a person who works for or provides services to the licensed dealer and holds a senior position;

(c) the destruction is carried out in accordance with a method that complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction; and

(d) as soon as the destruction is completed, the person who carried out the destruction and each of the two persons referred to in paragraph (b) who were present at the destruction sign and date a joint declaration attesting that the controlled substance was destroyed, to which each signatory must add in printed letters their name and, if applicable, title.

Destruction elsewhere than at site

72 A licensed dealer that intends to destroy a controlled substance elsewhere than at the site specified in their licence must ensure that the following conditions are met:

(a) the licensed dealer obtains the prior approval of the Minister;

(b) the licensed dealer takes all reasonable measures to ensure the security of the controlled substance while it is being transported in order to prevent its diversion to an illicit market or use;

(c) the destruction is carried out by a person working for a business that specializes in the destruction of dangerous goods, other than a licensed dealer specialized in destruction, and in the presence of another person working for that business;

(d) the destruction is carried out in accordance with a method that complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction; and

(e) as soon as the destruction is completed, the person who carried out the destruction provides the licensed dealer with a dated declaration attesting that the controlled substance was destroyed and containing

(i) the municipal address of the place of destruction,

(ii) the date of destruction,

(iii) the method of destruction,

(iv) in the case of a controlled substance set out in any of Schedules 1 to 4, its name and quantity,

(v) in the case of a mixture or finished product,

(A) subject to clause (D), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(B) subject to clause (D), its form, its strength, the number of containers and, if applicable, the number of units per container,

(C) subject to clause (D), its drug identification number, if any, and

(D) if the finished product has been previously returned by an individual for the purposes of destruction to a pharmacist, pharmacy technician, practitioner, hospital or particular person, only the identifier marked on the collection container of the finished product and the number of collection containers, and

(vi) the names, in printed letters, and signatures of the person who carried out the destruction and the other person who was present at the destruction.

Application for approval

73 (1) A licensed dealer must submit to the Minister an application that contains the following information in order to obtain the Minister's approval to destroy a controlled substance:

(a) their name and, if applicable, title, as well as their municipal address;

(b) their dealer's licence number;

(c) the municipal address of the place of destruction;

(d) the proposed date of destruction;

(e) a brief description of the method of destruction;

(f) if the destruction is to be carried out at the site specified in the dealer's licence, the names of the persons proposed for the purposes of paragraph 71(b) and information establishing that they meet the conditions of that paragraph;

(g) in the case of a controlled substance set out in any of Schedules 1 to 4, its name and quantity; and

(h) in the case of a mixture or finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) subject to subparagraph (iv), its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction to a pharmacist, pharmacy technician, practitioner, hospital or particular person, only the identifier marked on the collection container of the finished product and the number of collection containers.

Signature and attestation

(2) The application must

(a) be signed and dated by the qualified person in charge or an alternate qualified person in charge; and

(b) include an attestation by that person that

(i) the proposed method of destruction complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction, and

(ii) all of the information submitted in support of the application is correct and complete to the best of the signatory's knowledge.

Additional information and documents

(3) The licensed dealer must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Approval

74 On completion of the review of the approval application, the Minister must approve the destruction of the controlled substance unless

(a) in the case of a destruction that is to be carried out at the site specified in the dealer's licence, the persons proposed for the purposes of paragraph 71(b) do not meet the conditions of that paragraph;

(b) the Minister has reasonable grounds to believe that the controlled substance would not be destroyed;

(c) the Minister has reasonable grounds to believe that the licensed dealer has submitted false or misleading information or false or falsified documents in or in support of the approval application;

(d) the controlled substance or a portion of it is required for the purposes of a criminal or administrative investigation or a preliminary inquiry, trial or other proceeding under any Act or its regulations; or

(e) the Minister has reasonable grounds to believe that the approval would likely create a risk to public health or safety, including the risk that the controlled substance could be diverted to an illicit market or use.

Documents

Information

Substances ordered and received

75 A licensed dealer that orders or receives a controlled substance must record the following information:

(a) the name and, if applicable, title of the individual placing the order for the controlled substance or receiving it;

(b) with respect to the person from whom the controlled substance is ordered or received, their name and, if applicable, title, as well as their municipal address;

(c) the date of the order or receipt;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(e) in the case of a mixture or finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) subject to subparagraph (iv), its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction to a pharmacist, pharmacy technician, practitioner, hospital or particular person, only the identifier marked on the collection container of the finished product and the number of collection containers.

Substances sold

76 A licensed dealer that sells or provides a controlled substance must record the following information:

(a) the name and, if applicable, title of the individual selling or providing the controlled substance;

(b) with respect to the person to whom the controlled substance is sold or provided, their name and, if applicable, title, as well as their municipal address;

(c) the date of the sale or provision;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(e) in the case of a controlled substance that is a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Substances produced or packaged

77 A licensed dealer that produces or packages a controlled substance must record the following information with respect to the substance:

(a) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(b) in the case of a mixture or finished product,

(i) its name or, if applicable, its brand name, as well as the name and quantity of the controlled substance it uses to produce the mixture or finished product, or that is contained in the

mixture or finished product that it packages,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Substances in stock

78 A licensed dealer that stores a controlled substance must record the following information with respect to the substance:

(a) the date on which it is placed in stock;

(b) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(c) in the case of a mixture or finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) subject to subparagraph (iv), its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction to a pharmacist, pharmacy technician, practitioner, hospital or particular person, only the identifier marked on the collection container of the finished product and the number of collection containers.

Written orders

79 A licensed dealer that receives a written order for a controlled substance must record the following information:

(a) the name and, if applicable, title of the individual receiving the order; and

(b) the date of the order and the date on which it was received.

Transportation

80 A licensed dealer that delivers, sends or transports a controlled substance to another person must record the following information:

(a) the dealer's name and, if applicable, title, as well as their municipal address;

(b) if an agent or mandatary of the dealer delivers, sends or transports the controlled substance, their name;

(c) with respect to the other person, their name and, if applicable, title;

(d) the municipal address of the place where the controlled substance will be delivered, sent or transported;

(e) the date of the delivery, sending or transportation;

(f) the means of transportation;

(g) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(h) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Substances imported

81 A licensed dealer that imports a controlled substance must record the following information:

(a) the date of the importation;

(b) the name and municipal address of the exporter;

(c) the country of exportation and any country of transit or transhipment;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Substances exported

82 A licensed dealer that exports a controlled substance must record the following information:

(a) the date of the exportation;

(b) the name and municipal address of the importer;

(c) the country of final destination and any country of transit or transhipment;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Explainable loss of controlled substance

83 A licensed dealer that becomes aware of a loss of a controlled substance that can be explained on the basis of normally accepted business activities or that is notified by their agent or mandatary of such a loss, must record the following information:

(a) the date on which the dealer became aware or was notified of the loss;

(b) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity;

(c) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any; and

(d) the explanation for the loss.

Destruction

84 A licensed dealer that destroys a controlled substance at the site specified in their licence must record the following information:

(a) the name and, if applicable, title of the person who carried out the destruction and of the other persons who were present at the destruction;

(b) the municipal address of the place of destruction;

(c) the date of destruction;

(d) the method of destruction;

(e) in the case of a controlled substance set out in any of Schedules 1 to 4, its name and quantity; and

(f) in the case of a mixture or finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) subject to subparagraph (iv), its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction to a pharmacist, pharmacy technician, practitioner, hospital or particular person, only the identifier marked on the collection container of the finished product and the number of collection containers.

Monthly report

85 (1) Subject to subsection (2), a licensed dealer must provide to the Minister, within 15 days after the end of each month, a monthly report that contains the name and quantity of each controlled substance

(a) that is set out in any of Schedules 1 to 4 that the licensed dealer receives, produces, packages, sells, provides, imports, exports or destroys during the month;

(b) that is contained in a mixture or finished product that the licensed dealer receives, packages, sells, provides, imports, exports or destroys during the month or that the dealer has used to produce a mixture or finished product during the month;

(c) that is in the physical inventory taken at the site specified in their licence at the end of the month; and

(d) that has been lost in the course of conducting activities during the month and whose loss can be explained on the basis of normally accepted business activities.

Non-renewal or revocation of licence

(2) If a licensed dealer's licence expires without being renewed or is revoked, the dealer must provide to the Minister, within three months after the expiration or revocation, a report in respect of the portion of the month during which the licence was valid that contains the information referred to in subsection (1), in which the quantity in physical inventory is to be calculated as of the date of expiry or revocation.

Recording Information and Retention and Provision of Documents

Method of recording

86 A licensed dealer that records any information under these Regulations must do so using a method that permits an audit of it to be made at any time.

Documents to retain

87 A licensed dealer and a former licensed dealer must keep

(a) any document containing the information that it is required to record under these Regulations for two years after the day on which the last record is recorded in the document;

(b) every written order, in sequence as to date and number, for two years after the day on which it is received; and

(c) every declaration, report and letter of authorization for two years after the day on which it is provided or received.

Place

88 The documents must be accessible

(a) at the site specified in the licensed dealer's licence; or

(b) in the case of a document retained by a former licensed dealer, at a place in Canada.

Quality of documents

89 The documents must be complete and readily retrievable and the information in them must be legible and indelible.

Providing documents

90 A licensed dealer and a former licensed dealer must provide any documents that the Minister requests in the time and manner that the Minister specifies.

Pharmacists and Pharmacy Technicians

Non-application

Pharmacists practising in hospital

91 For the purposes of sections 92 to 126, the terms *pharmacist*, *pharmacy technician* and *intern*, as defined in subsection 1(1), are to be read as excluding those who are practising in a hospital, except as otherwise provided.

Sale of Controlled Substances

Sale to licensed dealer

92 (1) A pharmacist may sell or provide a controlled substance, other than a restricted drug, to a licensed dealer if

(a) in the case of a controlled substance previously returned by an individual or particular person for the purposes of destruction,

(i) the licensed dealer is specialized in destruction, and

(ii) the pharmacist first receives from that licensed dealer specialized in destruction a written order that is signed and dated and that contains the information set out in subsection (3); and

(b) in the case of any other controlled substance,

(i) one of the following conditions is met:

(A) the licensed dealer is the one that sold or provided that controlled substance to the pharmacist, or

(B) the sale or provision is for the purposes of testing or destruction, and

(ii) the pharmacist first receives from the licensed dealer a written order that is signed and dated and that contains the information set out in subsection (3).

Restricted drugs

(2) A pharmacist may sell or provide a restricted drug to a licensed dealer if

(a) the restricted drug was previously returned by an individual or particular person for the purposes of destruction;

(b) the licensed dealer is specialized in destruction; and

(c) the pharmacist first receives from that licensed dealer specialized in destruction a written order that is signed and dated and that contains the information set out in subsection (3).

Written orders

(3) The information that must be contained in the written order is the following:

(a) with respect to the licensed dealer, their name and, if applicable, title, as well as their municipal address;

(b) with respect to the pharmacist, their name and the name and municipal address of the place where they practise;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity;

(e) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) subject to subparagraph (iv), its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual or particular person for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers; and

(f) in the case of a controlled substance sold or provided for the purposes of destruction, a statement to that effect.

Sale to another pharmacist

93 (1) Subject to subsection (2), a pharmacist may, in the case of an emergency, sell or provide a controlled substance, other than a restricted drug, to another pharmacist if they first receive from the other pharmacist either a written order that is signed and dated and that contains the following information or a verbal order:

(a) with respect to the other pharmacist placing the order, their name and the name and municipal address of the place where they practise;

(b) with respect to the pharmacist selling or providing the controlled substance, their name and the name and municipal address of the place where they practise;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity;

(e) in the case of a finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any; and

(f) a declaration from the other pharmacist that they require the controlled substance for emergency purposes.

No emergency

(2) A pharmacist may, in circumstances other than an emergency, sell or provide a controlled substance, other than a restricted drug, to another pharmacist if they do so for the purpose of fulfilling a prescription received at the pharmacy where the other pharmacist practises or if the pharmacy where they practise is ceasing its operations and if they first receive from the other pharmacist a written order that is signed and dated and that contains the following information:

(a) with respect to the other pharmacist placing the order, their name and the name and municipal address of the place where they practise;

(b) with respect to the pharmacist selling or providing the controlled substance, their name and the name and municipal address of the place where the sale or provision is conducted;

(c) the number assigned to the prescription, if applicable;

(d) the date of the order;

(e) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(f) in the case of a finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Exception — prohibition

(3) A pharmacist must not sell or provide to the other pharmacist a controlled substance that is the subject of a prohibition on the other pharmacist's professional practice imposed by the provincial professional regulatory authority.

Sale to practitioner

94 (1) A pharmacist may sell or provide a controlled substance, other than a restricted drug, to a practitioner if they first receive from the practitioner a written order that is signed and dated and that contains the following information or, in the case of an emergency, either such a written order or a verbal order:

(a) with respect to the practitioner, their name and the name and municipal address of the place where they practise;

(b) with respect to the pharmacist, their name and the name and municipal address of the place where they practise;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Exception — prohibition

(2) A pharmacist must not sell or provide to the practitioner a controlled substance that is the subject of a prohibition on the practitioner's professional practice imposed by the provincial professional regulatory authority.

Sale to hospital

95 A pharmacist may sell or provide a controlled substance, other than a restricted drug, to a hospital if they first receive from the hospital a written order that is signed and dated by a person permitted to place an order on the hospital's behalf and that contains the following information or, in the case of an emergency, either such a written order or a verbal order from such a person:

(a) with respect to the hospital, its name and municipal address, as well as the name and title of the person placing the order;

(b) with respect to the pharmacist, their name and the name and municipal address of the place where they practise;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Sale to exempted person

96 A pharmacist may sell or provide a controlled substance, other than a restricted drug, to a person exempted under subsection 56(1) of the Act with respect to that controlled substance if

(a) the pharmacist first receives from the exempted person a copy of the exemption;

(b) there are terms and conditions for the sale or provision by the pharmacist that are specified in the exemption; and

(c) the sale or provision is carried out in accordance with those terms and conditions.

Sale to Minister

97 A pharmacist may sell or provide a controlled substance to the Minister if they first receive from the Minister a written order that is signed and dated on the Minister's behalf and that contains the following information:

(a) with respect to the individual signing the order, their name and, if applicable, title, as well as the municipal address of the place where the controlled substance is to be delivered, sent or transported;

(b) with respect to the pharmacist, their name and the name and municipal address of the place where they practise;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Sale to individual

98 (1) A pharmacist may sell or provide a controlled substance to an individual if

(a) the sale or provision is for the individual's own use, for the use of another individual or for an animal;

(b) the controlled substance is in the form of a finished product that does not contain a restricted drug; and

(c) subject to subsection (2), the pharmacist first receives the following in respect of the controlled substance from one of the following persons:

(i) in the case of the individual, a written prescription,

(ii) in the case of another pharmacist or a pharmacy technician,

(A) a written prescription, or

(B) a copy of the document on which the information with respect to a verbal prescription has been recorded under section 117, or

(iii) in the case of a practitioner, a written or verbal prescription.

Finished product containing low dose of codeine

(2) A pharmacist may sell or provide, without a prescription, a finished product containing codeine phosphate to an individual if

(a) the finished product contains

(i) in the case of a finished product in solid form, not more than 8 mg or its equivalent of codeine phosphate per unit, or

(ii) in the case of a finished product in liquid form, not more than 20 mg or its equivalent of codeine phosphate per 30 mL;

(b) the finished product contains

(i) two additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-half of the regular minimum single dose for each such ingredient, or

(ii) three additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-third of the regular minimum single dose for each such ingredient;

(c) the pharmacist has reasonable grounds to believe that the finished product will only be used for recognized medical purposes; and

(d) the pharmacist ensures that the following caution or its equivalent is conspicuously and legibly printed on the finished product's *inner label* and *outer label*, as those terms are defined in section A.01.010 of the *Food and Drug Regulations*:

"This product contains codeine and should not be administered to children except on the advice of a physician, dentist or nurse practitioner."

Compounding of Finished Products

Orders and prescriptions

99 (1) A pharmacist or pharmacy technician may compound a finished product, other than one containing a restricted drug, if they do so for the purpose of fulfilling a prescription and if they first receive the following with respect to the finished product from one of the following persons:

(a) in the case of an individual, a written prescription;

(b) in the case of another pharmacist,

(i) a written order that is signed and dated and that contains the information set out in subsection (2) or, in the case of an emergency, either such a written order or a verbal order,

(ii) a written prescription, or

(iii) a copy of the document on which the information with respect to a verbal prescription is recorded under section 117;

(c) in the case of another pharmacy technician,

(i) a written prescription, or

(ii) a copy of the document on which the information with respect to a verbal prescription is recorded under section 117;

(d) in the case of a practitioner,

(i) if they are not practising in a hospital, a written order that is signed and dated and that contains the information set out in subsection (2) or, in the case of an emergency, either such a written order or a verbal order, or

(ii) a written or verbal prescription; or

(e) in the case of a hospital, a written order that is signed and dated by a person permitted to place an order on the hospital's behalf and that contains the information set out in subsection (2) or, in the case of an emergency, either such a written order or a verbal order from such a person.

Written orders

(2) The information that must be contained in the written order is the following:

(a) with respect to the person placing the order,

(i) in the case of another pharmacist, their name and the name and municipal address of the place where they practise,

(ii) in the case of a practitioner, their name and the name and municipal address of the place where they practise, and

(iii) in the case of a hospital, its name and municipal address, as well as the name of the person permitted to place the order on its behalf;

(b) with respect to the pharmacist or pharmacy technician compounding the finished product, their name and the name and municipal address of the place where they practise;

(c) the date of the order;

(d) with respect to the finished product,

(i) its name, and

(ii) its form, strength, the number of containers and, if applicable, the number of units per container; and

(e) if applicable, a declaration from the other pharmacist that they require the finished product for emergency purposes.

Substitution of Controlled Substances

Sale and compounding

100 A pharmacist who sells or provides a controlled substance or who compounds a finished product may, before the sale, provision or compounding, substitute a controlled substance for another controlled substance identified in a prescription, if the pharmacist is authorized to do so under the laws of the province where the sale, provision or compounding takes place.

Prescriptions

Extension of prescription

101 A pharmacist may extend a prescription if the new expiration date of the extended prescription is not later than two years after the day on which the pharmacist received the prescription.

Transfer of prescription

102 A pharmacist or pharmacy technician may transfer a prescription to another pharmacist or pharmacy technician if

(a) they transfer it within two years after the day on which the prescription was received; and

(b) they provide

(i) in the case of a controlled substance prescribed in writing, the written prescription, or

(ii) in the case of a controlled substance prescribed verbally, a copy of the document on which the information with respect to that verbal prescription is recorded under section 117.

Verification of Identity

Orders and prescriptions

103 A pharmacist or pharmacy technician who receives an order or prescription from a person for a controlled substance must verify the person's name and, if applicable, their title as well as their signature if it is not known to the pharmacist.

Packaging and Labelling

Receipt of substance from individual

104 A pharmacist or pharmacy technician who receives a controlled substance from an individual for the purposes of destruction must keep the substance in a collection container that is in a secure location to which only persons whom the pharmacist or technician has authorized have access and that is marked in a manner that is sufficient to identify the container.

Storage

Authorized access

105 A pharmacist must ensure that

(a) any controlled substance is stored in a secure location at the place where they practise; and

(b) only persons whom the pharmacist has authorized have access to that secure location.

Delivery, Sending and Transportation

Authorization

106 A pharmacist or pharmacy technician may deliver, send or transport a controlled substance.

Requirements during transportation

107 A pharmacist or pharmacy technician who delivers, sends or transports a controlled substance to another person may only do so if they

(a) ensure that, if the controlled substance is being delivered, sent or transported to a licensed dealer specialized in destruction, the substance is placed in a container that is sealed in such a manner that it cannot be opened without breaking the seal and is marked in a manner sufficient to identify the container;

(b) take all reasonable measures to ensure the security of the controlled substance while it is being delivered, sent or transported; and

(c) use a method of delivery, sending or transportation that ensures the tracking of the controlled substance until the consignee receives it.

Security

Protective measures

108 A pharmacist or pharmacy technician must take all reasonable measures to ensure the security of any controlled substance in their possession.

Loss or theft — agent or mandatary

109 (1) If an agent or mandatary of a pharmacist becomes aware of a loss or theft of a controlled substance, the agent or mandatary must notify the pharmacist immediately.

Written report

(2) If a pharmacist becomes aware of a loss or theft of a controlled substance, or is notified by an agent or mandatary of such a loss or theft, the pharmacist must provide a written report to the Minister within 10 days after the day on which they become aware of the loss or theft or are notified.

Partial protection against self-incrimination

(3) The report, or any evidence derived from it, is not to be used or received to incriminate the pharmacist or their agent or mandatary in any criminal proceeding against them other than a prosecution under section 132, 136 or 137 of the *Criminal Code*.

Destruction of Controlled Substances

Conditions

110 (1) The destruction of a controlled substance in a pharmacy may only be carried out by a pharmacist or pharmacy technician and if the following conditions are met:

(a) the destruction is witnessed by another person among the following:

(i) a pharmacist, pharmacy technician or intern, including one who is practising in a hospital,

(ii) a practitioner, or

(iii) any other health professional;

(b) the destruction is carried out in accordance with a method that complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction; and

(c) immediately following the destruction, the person who carried out the destruction and the witness sign and date a joint declaration attesting that the controlled substance was destroyed, to which each signatory must add their name in printed letters.

Substance returned by individual

(2) A pharmacist must, if the destruction of a controlled substance previously returned by an individual or particular person for the purposes of destruction was not carried out, sell or provide the substance to a licensed dealer specialized in destruction.

Documents

Information

Substances ordered and received

111 A pharmacist who orders a controlled substance or a pharmacist or pharmacy technician who receives a controlled substance, other than one that has been previously returned by an individual or particular person for the purposes of destruction, must record the following information:

(a) their name;

(b) with respect to the person from whom the controlled substance is ordered or received, their name and, if applicable, title, as well as their municipal address;

(c) the date of the order or receipt;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Substances sold — persons other than individuals

112 A pharmacist who sells or provides a controlled substance to a person, other than an individual referred to in section 113, must record the following information:

(a) the pharmacist's name;

(b) with respect to the person, their name and, if applicable, title, as well as their municipal address;

(c) the date of the sale or provision;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity;

(e) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) subject to subparagraph (iv), its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual or particular person for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers; and

(f) if applicable, the reason for the emergency sale or provision.

Finished product sold — individuals

113 A pharmacist who sells or provides a finished product to an individual for their own use, for the use of another individual or for an animal must record the following information:

(a) the pharmacist's name;

(b) the name of the individual who is named in the prescription or who is responsible for the animal identified in the prescription and, if applicable, the name of the animal;

(c) the name of the practitioner who issued the prescription, as well as the name and municipal address of the place where they practise;

(d) the number assigned to the prescription;

(e) the date of the sale or provision;

(f) with respect to the finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any; and

(g) if applicable, the number of times that the prescription may be refilled and, if specified, the intervals between refills.

Finished products compounded

114 A pharmacist or pharmacy technician who compounds a finished product must record the following information:

(a) their name;

(b) the name of the individual who is named in the prescription or who is responsible for the animal identified in the prescription and, if applicable, the name of the animal;

(c) the name of the practitioner who issued the prescription, as well as the name and municipal address of the place where they practise;

(d) the number assigned to the prescription;

(e) the date of compounding the finished product; and

(f) with respect to the finished product,

(i) its name, and

(ii) its form, strength, the number of containers and, if applicable, the number of units per container.

Controlled substance substitutions

115 A pharmacist who substitutes a controlled substance for another controlled substance identified in a prescription must record the following information:

(a) their name;

(b) the number assigned to the original prescription;

(c) the date of the substitution;

(d) the name of the controlled substance identified in the prescription; and

(e) the name of the substitute controlled substance.

Written orders and prescriptions

116 A pharmacist or pharmacy technician who receives a written order for a controlled substance or a written prescription from a practitioner must record the following information:

(a) the pharmacist's or pharmacy technician's name; and

(b) the date of the order or prescription and the date on which it was received.

Verbal orders and prescriptions

117 A pharmacist or pharmacy technician who receives a verbal order for a controlled substance or a verbal prescription must record the following information:

(a) their name;

(b) with respect to the person placing the order or issuing the prescription,

(i) in the case of an order from another pharmacist,

(A) their name and the name and municipal address of the place where they practise, and

(B) a declaration from the other pharmacist that they require the controlled substance for emergency purposes,

(ii) in the case of a prescription or order from a practitioner,

(A) their name and the name and municipal address of the place where they practise, and

(B) if it is an order, a declaration from the practitioner that they require the controlled substance for emergency purposes, or

(iii) in the case of an order from a hospital,

(A) its name and municipal address, as well as the name of the person permitted to place the order on its behalf, and

(B) a declaration from that person that the hospital requires the controlled substance for emergency purposes;

(c) the date of receipt of the order or prescription;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity;

(e) in the case of a finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any; and

(f) if applicable, the number of refills authorized in the prescription and, if specified, the interval between refills.

Prescriptions refilled and extended

118 A pharmacist who refills or extends a prescription must record the following information:

(a) their name;

(b) the number assigned to the original prescription;

(c) the date of the prescription refill or extension; and

(d) if applicable, the new expiration date of the extended prescription.

Prescription transfers — transferring pharmacist

119 (1) A pharmacist or pharmacy technician who transfers a prescription to another pharmacist or pharmacy technician must record the following information:

(a) their name;

(b) with respect to the other pharmacist or pharmacy technician, their name and the name and municipal address of the place where they practise;

(c) the number assigned to the prescription;

(d) the date of the prescription transfer;

(e) the date of the last refill of the prescription and, if applicable, the number of authorized refills remaining and, if specified, the interval between refills; and

(f) if applicable, the date of the prescription extension and the new expiration date of the extended prescription.

Prescription transfer — receiving pharmacist

(2) The pharmacist or pharmacy technician who receives the transferred prescription must record the following information:

(a) their name;

(b) with respect to the pharmacist or pharmacy technician from whom they receive the transferred prescription, their name and the name and municipal address of the place where they practise;

(c) the number assigned to the prescription;

(d) the date of receipt of the prescription;

(e) the date of the last refill of the prescription and, if applicable, the number of authorized refills remaining and, if specified, the interval between refills; and

(f) if applicable, the date of the prescription extension and the new expiration date of the extended prescription.

Transportation

120 A pharmacist or pharmacy technician who delivers, sends or transports a controlled substance must record the following information:

(a) their name and the name and municipal address of the place where they practise;

(b) if an agent or mandatary of the pharmacist delivers, sends or transports the controlled substance, their name;

(c) if the controlled substance is delivered, sent or transported to another person, the following information with respect to that person:

(i) if it is not a person referred to in subparagraph (ii), their name and, if applicable, title, or

(ii) if they are an individual who is named in a prescription or who is responsible for an animal identified in a prescription, their name and, if applicable, the name of the animal;

(d) the municipal address of the place where the controlled substance is delivered, sent or transported;

(e) the date of the delivery, sending or transportation;

(f) the means of transportation;

(g) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(h) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) subject to subparagraph (iv), its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual or particular person for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers.

Destruction

121 A pharmacist or pharmacy technician who destroys a controlled substance must record the following information:

(a) their name;

(b) the name of the witness to the destruction;

(c) the municipal address of the place of destruction;

(d) the date of destruction;

(e) the method of destruction;

(f) in the case of a controlled substance set out in any of Schedules 1 to 3, its name and quantity; and

(g) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) subject to subparagraph (iv), its form, its strength, the number of containers and, if applicable, the number of units per container,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual or particular person for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers.

Recording Information and Retention and Provision of Documents

Method of recording

122 A pharmacist or pharmacy technician who records any information under these Regulations must do so using a method that permits an audit of it to be made at any time.

Documents to retain

123 (1) A pharmacist who is responsible for the operations of a pharmacy where the information was recorded under these Regulations or, if a pharmacy ceases its operations, the person who was responsible for those operations on the date those operations ceased must, subject to subsection (2), ensure that

(a) any document containing the information that must be recorded under these Regulations is kept for two years after the day on which the last record is recorded in the document;

(b) every written order and prescription is kept, in sequence as to date and number, for two years after the day on which it is received; and

(c) every declaration and report is kept for two years after the day on which it is provided or received.

Substances sold or provided

(2) All documents regarding the sale or provision of a controlled substance must be kept separately, in sequence as to date and number.

Place

124 The documents must be accessible

(a) at the pharmacy where the information was recorded; or

(b) if that pharmacy has ceased its operations, at a place in Canada.

Quality of documents

125 The documents must be complete and readily retrievable and the information in them must be legible and indelible.

Providing documents

126 A pharmacist who is responsible for a pharmacy's operations or, if a pharmacy has ceased its operations, the person who was responsible for those operations on the date those operations ceased must provide any documents that the Minister requests in the time and manner that the Minister specifies.

Practitioners

Prescriptions

Conditions

127 A practitioner may issue a written prescription that they sign and date or a verbal prescription if

(a) the practitioner is treating, in their professional capacity, the individual for whom, or the animal for which, the prescription is issued; and

(b) the controlled substance set out in the prescription is needed to treat the individual's or animal's medical condition.

Sale of Controlled Substances

Sale to licensed dealer

128 (1) A practitioner may sell or provide a controlled substance to a licensed dealer if,

(a) in the case of a controlled substance previously returned by an individual for the purposes of destruction,

(i) the licensed dealer is specialized in destruction, and

(ii) the practitioner first receives from that licensed dealer specialized in destruction a written order that is signed and dated and that contains the information set out in subsection (2); and

(b) in the case of any other controlled substance,

(i) one of the following conditions is met:

(A) the licensed dealer is the one that sold or provided that controlled substance to the practitioner, or

(B) the practitioner sells or provides the controlled substance for the purposes of testing or destruction, and

(ii) the practitioner first receives from the licensed dealer a written order that is signed and dated and that contains the information set out in subsection (2).

Written orders

(2) The information that must be contained in the written order is the following:

(a) with respect to the licensed dealer, their name and, if applicable, title, as well as their municipal address;

(b) with respect to the practitioner, their name and the name and municipal address of the place where they practise;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity;

(e) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name,

(ii) subject to subparagraph (iv), its form, strength and quantity,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers; and

(f) in the case of a controlled substance sold or provided for the purposes of destruction, a statement to that effect.

Sale to Minister

129 A practitioner may sell or provide a controlled substance to the Minister if they first receive from the Minister a written order that is signed and dated on the Minister's behalf and that contains the following information:

(a) with respect to the individual signing the order, their name and, if applicable, title, as well as the municipal address of the place where the controlled substance is to be delivered, sent or transported;

(b) with respect to the practitioner, their name and the name and municipal address of the place where they practise;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any.

Sale to individual

130 (1) A practitioner may sell or provide a controlled substance, other than a restricted drug, to an individual if

(a) the sale or provision is for the individual's own use, for the use of another individual or for an animal; and

(b) the practitioner first issues a written prescription for the individual for whom, or the animal for which, the controlled substance is sold or provided.

Restricted drugs

(2) A practitioner may sell or provide a restricted drug to an individual for their own use if

(a) the practitioner is treating the individual in their professional capacity; and

(b) the practitioner has received a copy of the letter of authorization in which they are named.

Administration of Controlled Substances

General condition

131 (1) A practitioner may administer a controlled substance, other than a restricted drug, to an individual or animal if the practitioner first issues a written prescription.

Restricted drugs

(2) A practitioner may administer a restricted drug to an individual if

(a) the practitioner is treating the individual in their professional capacity; and

(b) the practitioner has received a copy of the letter of authorization in which they are named.

Emergency supply

132 (1) A practitioner of medicine who is responsible for an emergency supply must ensure that

(a) the emergency supply does not contain a restricted drug; and

(b) they have an agent or mandatary who is present at the place where the emergency supply is stored and who will, under their direction, administer the controlled substance under their

control.

Administration — conditions

(2) In an emergency, the agent or mandatary of the practitioner of medicine may administer a controlled substance from the emergency supply to an individual if

(a) the practitioner of medicine has directed the agent or mandatary to administer the controlled substance; or

(b) the agent or mandatary follows written directives provided by the practitioner of medicine with respect to the administration of the controlled substance.

Packaging and Labelling

Receipt of substance from individual

133 A practitioner who receives a controlled substance from an individual for the purposes of destruction must keep the substance in a collection container that is in a secure location to which only persons whom the practitioner has authorized have access and that is marked in a manner that is sufficient to identify the container.

Storage

Authorized access

134 (1) Subject to subsection (2), a practitioner who stores a controlled substance must ensure that

(a) they store the controlled substance in a secure location in the place where they practise; and

(b) only persons whom the practitioner has authorized have access to that secure location.

Emergency supply

(2) A practitioner of medicine who stores an emergency supply need only ensure that

(a) they take all reasonable measures to ensure that the place of storage is secure; and

(b) only the practitioner of medicine and their agent or mandatary have access to that secure place.

Delivery, Sending and Transportation

Authorization

135 A practitioner may deliver, send or transport a controlled substance.

Requirements during transportation

136 A practitioner who delivers, sends or transports a controlled substance to another person may only do so if they

(a) ensure that, if the controlled substance is being delivered, sent or transported to a licensed dealer specialized in destruction, the substance is placed in a container that is sealed in such a manner that it cannot be opened without breaking the seal and is marked in a manner that is sufficient to identify the container;

(b) take all reasonable measures to ensure the security of the controlled substance while it is being delivered, sent or transported; and

(c) use a method of delivery, sending or transportation that ensures the tracking of the controlled substance until the consignee receives it.

Security

Protective measures

137 A practitioner must take all reasonable measures to ensure the security of any controlled substance in their possession.

Loss or theft — agent or mandatary

138 (1) If an agent or mandatary of a practitioner becomes aware of a loss or theft of a controlled substance, the agent or mandatary must notify the practitioner immediately.

Written report

(2) If a practitioner becomes aware of a loss or theft of a controlled substance, or is notified by an agent or mandatary of such a loss or theft, the practitioner must provide a written report to the Minister within 10 days after the day on which they become aware of the loss or theft or are notified.

Partial protection against self-incrimination

(3) The report, or any evidence derived from it, is not to be used or received to incriminate the practitioner or their agent or mandatary in any criminal proceeding against them other than a prosecution under section 132, 136 or 137 of the *Criminal Code*.

Destruction of Controlled Substances

Conditions

139 (1) The destruction of a controlled substance may be carried out by a practitioner only if the following conditions are met:

(a) the destruction is witnessed by another person among the following:

(i) a pharmacist, pharmacy technician or intern,

(ii) a practitioner, or

(iii) any other health professional;

(b) the destruction is carried out in accordance with a method that complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction; and

(c) immediately following the destruction, the person who carried out the destruction and the witness sign and date a joint declaration attesting that the controlled substance was destroyed, to which each signatory must add their name in printed letters.

Exception — open ampule

(2) A practitioner may, without a witness, destroy the remainder of a controlled substance that is contained in an open ampule and that will not be administered.

Substance returned by individual

(3) A practitioner must, if the destruction of a controlled substance previously returned by an individual for the purposes of destruction was not carried out, sell or provide the substance to a licensed dealer specialized in destruction.

Documents

Application

Scope

140 The requirements set out in sections 141 to 152 apply to a practitioner with respect to the following controlled substances:

(a) if the practitioner is not practising in a hospital, a narcotic, controlled drug or targeted substance; and

(b) a restricted drug.

Information

Substances received

141 A practitioner who receives a controlled substance, other than one that has been previously returned by an individual for the purposes of destruction, must record the following information:

(a) with respect to the person from whom the controlled substance is received, their name and, if applicable, title, as well as their municipal address;

(b) the date of receipt;

(c) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(d) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any.

Substances sold — persons other than individuals

142 A practitioner who sells or provides a controlled substance to a person, other than an individual referred to in section 143, must record

(a) the practitioner's name;

(b) with respect to the person, their name and, if applicable, title, as well as their municipal address;

(c) the date of the sale or provision;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(e) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name,

(ii) subject to subparagraph (iv), its form, strength and quantity,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers.

Substances prescribed, administered or sold — individuals

143 (1) A practitioner who conducts the following activities must record the information set out in subsection (2):

(a) prescribe or administer a controlled substance to an individual or an animal; or

(b) sell or provide a controlled substance to an individual for their own use, for the use of another individual or for an animal.

Information

(2) The information that must be recorded is the following:

(a) the practitioner's name;

(b) the name of the individual who is named in the prescription or who is responsible for the animal identified in the prescription and, if applicable, the name of the animal;

(c) in the case of an administration, sale or provision of a restricted drug to an individual, their name;

(d) the date of the prescription, administration, sale or provision;

(e) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity;

(f) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity,

(iii) its drug identification number, if any, and

(iv) if the finished product that is sold or provided, other than one containing a restricted drug, is intended for administration by the individual to themselves or the animal, and if the dose exceeds the following, a statement to that effect:

(A) in the case of a finished product containing a controlled drug or narcotic, three times the maximum daily dosage recommended by the producer of the product or, if the producer has not recommended a maximum daily dosage, three times the generally recognized maximum daily therapeutic dosage for that product, or

(B) in the case of a finished product containing a targeted substance, five times the usual daily dose for the product.

Emergency supply

144 A practitioner of medicine who is responsible for an emergency supply must record the following information:

(a) the name of their agent or mandatary administering the controlled substance;

(b) the place where the emergency supply is stored;

(c) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity;

(d) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any;

(e) the date of all activities related to that emergency supply; and

(f) if a controlled substance was administered to an individual, the following information:

(i) the name of the individual,

(ii) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity, and

(iii) in the case of a finished product,

(A) its name or, if applicable, brand name,

(B) its form, strength and quantity, and

(C) its drug identification number, if any.

Written orders

145 A practitioner who receives a written order must record the following information:

(a) their name; and

(b) the date of the order and the date on which it was received.

Transportation

146 A practitioner who delivers, sends or transports a controlled substance must record the following information:

(a) their name and the name and municipal address of the place where they practise;

(b) if an agent or mandatary of the practitioner delivers, sends or transports the controlled substance, their name;

(c) if the controlled substance is delivered, sent or transported to another person, the following information with respect to that person:

(i) if they are an individual who is named in a prescription or who is responsible for an animal identified in a prescription, their name and, if applicable, the name of the animal,

(ii) if they are a consignee of a restricted drug, their name, or

(iii) in any other case, their name and, if applicable title;

(d) the municipal address of the place where the controlled substance is delivered, sent or transported;

(e) the date of the delivery, sending or transportation;

(f) in the case of a controlled substance set out in any of Schedules 1 to 4, its name, form and quantity; and

(g) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name,

(ii) subject to subparagraph (iv), its form, strength and quantity,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers.

Destruction

147 A practitioner who destroys a controlled substance must record the following information:

(a) their name;

(b) the name of the witness to the destruction;

(c) the municipal address of the place of destruction;

(d) the date of destruction;

(e) the method of destruction;

(f) in the case of a controlled substance set out in any of Schedules 1 to 4, its name and quantity; and

(g) in the case of a finished product,

(i) subject to subparagraph (iii), its name or, if applicable, brand name,

(ii) subject to subparagraph (iii), its quantity, and

(iii) if the finished product has been previously returned by an individual for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers.

Recording Information and Retention and Provision of Documents

Method of recording

148 A practitioner who records any information under these Regulations must do so using a method that permits an audit of it to be made at any time.

Documents to retain

149 A practitioner who is responsible for the operations of a place where information was recorded under these Regulations or, if information was recorded at a place where operations have ceased, the person who was responsible for those operations on the date those operations ceased must ensure that

(a) any document containing the information that they are required to record under these Regulations is kept for two years after the day on which the last record is recorded in the document;

(b) every written order and prescription is kept, in sequence as to date and number, for two years after the day on which it is received or issued respectively; and

(c) every declaration, report and letter of authorization is kept for two years after the day on which it is provided or received.

Place

150 The documents must be accessible

(a) at the place where the information was recorded; or

(b) if operations have ceased at that place, at a place in Canada.

Quality of documents

151 The documents must be complete and readily retrievable and the information in them must be legible and indelible.

Providing documents

152 A practitioner who is responsible for the operations of the place where the information was recorded or, if operations have ceased at a place where information was recorded, the person who was responsible for those operations on the date those operations ceased must provide any documents that the Minister requests in the time and manner that the Minister specifies.

Prescribed Practitioners

Additional conditions

153 In addition to meeting any other requirements set out in these Regulations, the following practitioners who, in accordance with these Regulations and subject to section 154, conduct any activity with respect to a controlled substance, other than a restricted drug, may only do so if they are authorized by the provincial professional regulatory authority to conduct that activity:

(a) a midwife;

(b) a podiatrist; and

(c) a nurse practitioner.

Midwife and podiatrist

154 A midwife or podiatrist must not possess or conduct any activity with respect to the following controlled substances:

(a) a narcotic set out in subitems 1(1) or (10), 2(1), 5(4) or 10(1) of Schedule 1; or

(b) a controlled drug set out in item 1 of Part 1 of Schedule 2, items 9 and 10 of Part 2 of that Schedule, or item 1 of Part 3 of that Schedule.

Hospitals

Application and General Conditions for Activities

Application

155 For the purposes of sections 156 to 188, the terms *pharmacist*, *pharmacy technician*, *intern* and *health professional*, as defined in subsection 1(1), and *practitioner*, as defined in subsection 2(1) of the Act, are to be read as only including those who are practising in a hospital, except as otherwise provided.

Person in charge

156 A person in charge of a hospital may permit another person to conduct an activity with respect to a controlled substance if

(a) in the case that the other person is a health professional, they are authorized by the provincial professional regulatory authority to conduct that activity; and

(b) the other person conducts that activity as part of their duties and functions.

Orders placed on behalf of hospital

157 A person in charge of a hospital may only permit the following persons to order a controlled substance, other than a restricted drug, on the hospital's behalf:

(a) a pharmacist; or

(b) a practitioner.

Sale of Controlled Substances

Sale to licensed dealer

158 (1) A hospital may sell or provide a controlled substance, other than a restricted drug, to a licensed dealer if

(a) in the case of a controlled substance previously returned by an individual for the purposes of destruction,

(i) the licensed dealer is specialized in destruction, and

(ii) the hospital first receives from that licensed dealer specialized in destruction a written order that is signed and dated and that contains the information set out in subsection (3); and

(b) in the case of any other controlled substance,

(i) one of the following conditions is met:

(A) the licensed dealer is the one that sold or provided that controlled substance to the hospital, or

(B) the hospital sells or provides the controlled substance for the purposes of testing or destruction, and

(ii) the hospital first receives from the licensed dealer a written order that is signed and dated and that contains the information set out in subsection (3).

Restricted drugs

(2) A hospital may sell or provide a restricted drug to a licensed dealer if

(a) the restricted drug was previously returned by an individual for the purposes of destruction;

(b) the licensed dealer is specialized in destruction; and

(c) the hospital first receives from that licensed dealer specialized in destruction a written order that is signed and dated and that contains the information set out in subsection (3).

Written orders

(3) The information that must be contained in the written order is the following:

(a) with respect to the licensed dealer, their name and, if applicable, title, as well as their municipal address;

(b) with respect to the hospital, its name and municipal address;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity;

(e) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name,

(ii) subject to subparagraph (iv), its form, strength and quantity,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers; and

(f) in the case of a controlled substance sold or provided for the purposes of destruction, a statement to that effect.

Sale to pharmacist

159 (1) A hospital may sell or provide a controlled substance, other than a restricted drug, to a pharmacist, other than one who is practising in a hospital, if

(a) the sale or provision is in the case of an emergency; and

(b) the hospital first receives from the pharmacist either a written order that is signed and dated and that contains the following information or a verbal order:

(i) with respect to the pharmacist, their name and the name and municipal address of the place where they practise,

(ii) with respect to the hospital, its name and municipal address,

(iii) the date of the order,

(iv) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity,

(v) in the case of a finished product,

(A) its name or, if applicable, brand name,

(B) its form, strength and quantity, and

(C) its drug identification number, if any, and

(vi) a declaration from the pharmacist that they require the controlled substance for emergency purposes.

Exception — prohibition

(2) A hospital must not sell or provide to the pharmacist a controlled substance that is the subject of a prohibition on the pharmacist's professional practice imposed by the provincial professional regulatory authority.

Sale to practitioner

160 (1) A hospital may sell or provide a controlled substance, other than a restricted drug, to a practitioner, other than one who is practising in a hospital, if

(a) the sale or provision is in the case of an emergency; and

(b) the hospital first receives from the practitioner either a written order that is signed and dated and that contains the following information or a verbal order:

(i) with respect to the practitioner, their name and the name and municipal address of the place where they practise,

(ii) with respect to the hospital, its name and municipal address,

(iii) the date of the order,

(iv) in the case of a controlled substance set out any of Schedules 1 to 3, its name, form and quantity,

(v) in the case of a finished product,

(A) its name or, if applicable, brand name,

(B) its form, strength and quantity, and

(C) its drug identification number, if any, and

(vi) a declaration from the practitioner that they require the controlled substance for emergency purposes.

Exception — prohibition

(2) A hospital must not sell or provide to the practitioner a controlled substance that is the subject of a prohibition on the practitioner's professional practice imposed by the provincial professional regulatory authority.

Sale to another hospital

161 (1) Subject to subsection (2), a hospital may, in the case of an emergency, sell or provide a controlled substance, other than a restricted drug, to another hospital if the hospital first receives from the other hospital a written order that is signed and dated by a person permitted to place an order on the other hospital's behalf and that contains the following information or a verbal order from such a person:

(a) with respect to the other hospital placing the order, its name and municipal address, as well as the name and title of the person placing the order;

(b) with respect to the hospital selling or providing the controlled substance, its name and municipal address;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity;

(e) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any; and

(f) a declaration from the person placing the order that the other hospital requires the controlled substance for emergency purposes.

No emergency

(2) A hospital may, in circumstances other than an emergency, sell or provide a controlled substance, other than a restricted drug, to another hospital if the hospital is ceasing its operations and if the hospital first receives from the other hospital a written order that is signed and dated by a person permitted to place an order on the other hospital's behalf and that contains the following information:

(a) with respect to the other hospital placing the order, its name and municipal address, as well as the name and title of the person placing the order;

(b) with respect to the hospital selling or providing the controlled substance, its name and municipal address;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any.

Sale to Minister

162 A hospital may sell or provide a controlled substance to the Minister if the hospital first receives from the Minister a written order that is signed and dated on the Minister's behalf and that contains the following information:

(a) with respect to the individual signing the order, their name and, if applicable, title, as well as the municipal address of the place where the controlled substance is to be delivered, sent or transported;

(b) with respect to the hospital, its name and municipal address;

(c) the date of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any.

Sale to individual

163 A hospital may sell or provide a controlled substance, other than a restricted drug, to an individual if

(a) the sale or provision is for the individual's own use, for the use of another individual or for an animal; and

(b) a practitioner first issues a written or verbal prescription for the individual for whom, or the animal for which, the controlled substance is sold or provided.

Administration of Controlled Substances

Condition

164 A hospital may administer a controlled substance, other than a restricted drug, to an individual or animal if a practitioner first issues a written or verbal prescription.

Compounding of Finished Products

Orders and prescriptions

165 (1) A hospital may compound a finished product, other than one containing a restricted drug, if it is for the purpose of fulfilling a prescription and,

(a) if the finished product is compounded at the request of a practitioner, that practitioner first issues a written or verbal prescription; or

(b) if the finished product is compounded at the request of one of the following persons, in the case of an emergency, the hospital first receives from that person either a written order that is signed and dated and that contains the information set out in subsection (2) or a verbal order:

(i) a pharmacist who is not practising in that hospital or another hospital,

(ii) a practitioner who is not practising in that hospital or another hospital, or

(iii) another hospital, if the order is placed by a person permitted to place an order on its behalf.

Written orders

(2) The information that must be contained in the written order is the following:

(a) with respect to the person placing the order,

(i) if they are a pharmacist, their name and the name and municipal address of the place where they practise,

(ii) if they are a practitioner, their name and the name and municipal address of the place where they practise, and

(iii) if it is another hospital, its name and municipal address, as well as the name of the person permitted to place the order on its behalf;

(b) with respect to the hospital receiving the order, its name and municipal address;

(c) the date of the order;

(d) with respect to the finished product,

(i) its name, and

(ii) its form, strength and quantity; and

(e) a declaration that they require the finished product for emergency purposes or, in the case of another hospital, a declaration from the person placing the order that the other hospital requires the finished product for emergency purposes.

Substitution of Controlled Substances

Sale and compounding

166 A hospital that sells or provides a controlled substance or that compounds a finished product may, before the sale, provision or compounding, substitute a controlled substance for another controlled substance identified in a prescription, if it is authorized to do so under the laws of the province where the sale, provision or compounding takes place.

Verification of Identity

Orders

167 A hospital that receives an order from a person for a controlled substance must verify the person's name and, if applicable, their title as well as their signature if it is not known to the hospital.

Packaging and Labelling

Receipt of substance from individual

168 A hospital that receives a controlled substance from an individual for the purposes of destruction must keep the substance in a collection container that is in a secure location to which only persons whom it has authorized have access and that is marked in a manner that is sufficient to identify the container.

Storage

Authorized access

169 A hospital that stores a controlled substance must ensure that

(a) the controlled substance is stored in a secure location in the hospital; and

(b) only persons whom it has authorized have access to that secure location.

Delivery, Sending and Transportation

Authorization

170 A hospital may deliver, send or transport a controlled substance.

Requirements during transportation

171 A hospital that delivers, sends or transports a controlled substance to another person may only do so if it

(a) ensures that, if the controlled substance is being delivered, sent or transported to a licensed dealer specialized in destruction, the substance is placed in a container that is sealed in such a manner that it cannot be opened without breaking the seal and is marked in a manner that is sufficient to identify the container;

(b) takes all reasonable measures to ensure the security of the controlled substance while it is being delivered, sent or transported; and

(c) uses a method of delivery, sending or transportation that ensures the tracking of the controlled substance until the consignee receives it.

Security

Protective measures

172 A hospital must take all reasonable measures to ensure the security of any controlled substance in its possession.

Loss or theft — agent or mandatary

173 (1) If an agent or mandatary of a hospital becomes aware of a loss or theft of a controlled substance, the agent or mandatary must notify the hospital immediately.

Written report

(2) If a hospital becomes aware of a loss or theft of a controlled substance, or is notified by an agent or mandatary of such a loss or theft, the hospital must provide a written report to the Minister within 10 days after the day on which it becomes aware of the loss or theft or is notified.

Partial protection against self-incrimination

(3) The report, or any evidence derived from it, is not to be used or received to incriminate the hospital or its agent or mandatary in any criminal proceeding against them other than a prosecution under section 132, 136 or 137 of the *Criminal Code*.

Destruction of Controlled Substances

Conditions

174 (1) The destruction of a controlled substance in a hospital may only be carried out, subject to subsection (2), by the person in charge of the hospital, a pharmacist, a pharmacy technician or a practitioner and if the following conditions are met:

(a) the destruction is witnessed by another person among the following:

(i) a pharmacist, pharmacy technician or intern,

(ii) a practitioner,

(iii) any other health professional, or

(iv) the person in charge of the hospital;

(b) the destruction is carried out in accordance with a method that complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction; and

(c) immediately following the destruction, the person who carried out the destruction and the witness sign and date a joint declaration attesting that the controlled substance was destroyed, to

which each signatory must add their name in printed letters.

Exception — open ampule

(2) A health professional may, without a witness, destroy the remainder of a controlled substance, other than a restricted drug, that is contained in an open ampule and that will not be administered.

Substance returned by individual

(3) A hospital must, if the destruction of a controlled substance previously returned by an individual for the purposes of destruction was not carried out, sell or provide the substance to a licensed dealer specialized in destruction.

Documents

Information

Substances received

175 A hospital that receives a controlled substance, other than one that has been previously returned by an individual for the purposes of destruction, must record the following information:

(a) the name of the person receiving the controlled substance;

(b) with respect to the person from whom the controlled substance is received, their name and, if applicable, title, as well as their municipal address;

(c) the date of receipt;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any.

Substances sold — persons other than individuals

176 A hospital that sells or provides a controlled substance to a person, other than an individual referred to in section 177, must record the following information:

(a) the name of the person selling or providing the controlled substance;

(b) with respect to the person to whom the controlled substance is sold or provided, their name and, if applicable, title, as well as their municipal address;

(c) the date of the sale or provision;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity;

(e) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name,

(ii) subject to subparagraph (iv), its form, strength and quantity,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers; and

(f) if applicable, the reason for the emergency sale or provision.

Substances sold or administered — individuals

177 A hospital that sells or provides a controlled substance to an individual for their own use, for the use of another individual or for an animal, or that administers a controlled substance to an individual or an animal, must record the following information:

(a) the name of the person selling, providing or administering the controlled substance;

(b) the name of the individual who is named in the prescription or who is responsible for the animal identified in the prescription and, if applicable, the name of the animal;

(c) the date of the sale, provision or administration;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any.

Finished products compounded

178 A hospital that compounds a finished product must record the following information:

(a) the name of the person compounding the finished product;

(b) the name of the individual who is named in the prescription or who is responsible for the animal identified in the prescription and, if applicable, the name of the animal;

(c) the name of the practitioner who issued the prescription, as well as the name and municipal address of the place where they practise;

(d) the number assigned to the prescription;

(e) the date of compounding; and

(f) with respect to the finished product,

(i) its name, and

(ii) its form, strength and quantity.

Controlled substance substitutions

179 A hospital that substitutes a controlled substance for another controlled substance identified in a prescription must record the following information:

(a) the name of the person who carries out the substitution;

(b) the number assigned to the original prescription;

(c) the date of the substitution;

(d) the name of the controlled substance identified in the prescription; and

(e) the name of the substitute controlled substance.

Written orders

180 A hospital that receives a written order for a controlled substance must record the following information:

(a) the name of the person receiving the order; and

(b) the date of the order and the date on which it was received.

Verbal orders

181 A hospital that receives a verbal order for a controlled substance must record the following information:

(a) the name of the person receiving the order;

(b) with respect to the person placing the order,

(i) their name, municipal address and, in the case of another hospital, the name of the person permitted to place the order on its behalf, and

(ii) a declaration that they require the controlled substance for emergency purposes or, in the case of another hospital, a declaration from the person placing the order that the other hospital requires the controlled substance for emergency purposes;

(c) the date of receipt of the order;

(d) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(e) in the case of a finished product,

(i) its name or, if applicable, brand name,

(ii) its form, strength and quantity, and

(iii) its drug identification number, if any.

Transportation

182 A hospital that delivers, sends or transports a controlled substance must record the following information:

(a) its name and municipal address;

(b) with respect to the agent or mandatary of the hospital delivering, sending or transporting the controlled substance, their name;

(c) if the controlled substance is delivered, sent or transported to another person, the following information with respect to that person:

(i) if it is not a person referred to in subparagraph (ii), their name and, if applicable, title, or

(ii) if they are an individual who is named in a prescription or who is responsible for an animal identified in a prescription, their name and, if applicable, the name of the animal;

(d) the municipal address of the place where the controlled substance will be delivered, sent or transported;

(e) the date of the delivery, sending or transportation;

(f) the means of transportation used;

(g) in the case of a controlled substance set out in any of Schedules 1 to 3, its name, form and quantity; and

(h) in the case of a finished product,

(i) subject to subparagraph (iv), its name or, if applicable, brand name,

(ii) subject to subparagraph (iv), its form, strength and quantity,

(iii) subject to subparagraph (iv), its drug identification number, if any, and

(iv) if the finished product has been previously returned by an individual for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers.

Destruction

183 A person who destroys a controlled substance in a hospital must record the following information:

(a) their name;

(b) the name of the witness to the destruction;

(c) the municipal address of the hospital;

(d) the date of destruction;

(e) the method of destruction;

(f) in the case of a controlled substance set out in any of Schedules 1 to 3, its name and quantity; and

(g) in the case of a finished product,

(i) subject to subparagraph (iii), its name or, if applicable, brand name,

(ii) subject to subparagraph (iii), its quantity, and

(iii) if the finished product has been previously returned by an individual for the purposes of destruction, only the identifier marked on the collection container of the finished product and the number of collection containers.

Recording Information and Retention and Provision of Documents

Method of recording

184 Any person who records any information under sections 175 to 183 must do so using a method that permits an audit of it to be made at any time.

Documents to retain

185 A hospital or, if a hospital ceases its operations, the person who was responsible for those operations on the date those operations ceased must ensure that

(a) any document containing the information that is required to be recorded under sections 175 to 183 is kept for two years after the day on which the last record is recorded in the document;

(b) every written order and prescription is kept, in sequence as to date and number, for two years after the day on which it is received or issued respectively; and

(c) every declaration and report is kept for two years after the day on which it is provided or received.

Place

186 The documents must be accessible

(a) at the hospital where the information was recorded; or

(b) if that hospital has ceased its operations, at a place in Canada.

Quality of documents

187 The documents must be complete and readily retrievable and the information in them must be legible and indelible.

Providing documents

188 A hospital or, if a hospital has ceased its operations, the person who was responsible for those operations on the date those operations ceased, must provide any documents that the Minister requests in the time and manner that the Minister specifies.

Minister

Authorizations and Conditions Applicable to Activities

Sale of Controlled Substances

Sale to practitioner

189 (1) The Minister may sell or provide a controlled substance to a practitioner that the Minister has named in a letter of authorization.

Exception — prohibition

(2) The Minister must not sell or provide to the practitioner a controlled substance that is the subject of a prohibition on the practitioner's professional practice imposed by the provincial professional regulatory authority.

Sale to exempted person

190 The Minister may sell or provide a controlled substance to a person that the Minister has exempted under subsection 56(1) of the Act with respect to that substance.

Delivery, Sending and Transportation

Authorization

191 The Minister may deliver, send or transport a controlled substance.

Import and Export

Import

192 The Minister may import a controlled substance that is intended to be sold or provided to one of the following persons:

(a) a practitioner named in a letter of authorization; or

(b) a person exempted under subsection 56(1) of the Act with respect to that substance.

Export

193 The Minister may export a controlled substance.

Provision of Information to Third Parties

Provincial government or regulatory authority — entitled persons

194 (1) The Minister may provide in writing any factual information that has been obtained under the Act or these Regulations about a pharmacist, pharmacy technician, practitioner or any other health professional to any relevant provincial government or to any provincial professional regulatory authority of a province in which the person is or was entitled by that authority to practise their profession, if

(a) the government or authority submits to the Minister a written request that sets out the person's name and municipal address, a description of the information being requested and a statement that the information is required for the purpose of assisting a lawful investigation by the government or authority;

(b) the Minister has reasonable grounds to believe that the person has

(i) contravened a rule of conduct established by the authority,

(ii) been convicted of a designated substance offence, or

(iii) contravened these Regulations; or

(c) the Minister has reasonable grounds to believe that the provision of the information is necessary to assist the government or authority in monitoring the person's professional conduct for compliance with the laws of the province for the purpose of protecting public health or safety.

Provincial government or regulatory authority — persons not entitled

(2) The Minister may provide in writing any factual information that has been obtained under the Act or these Regulations about a pharmacist, pharmacy technician, practitioner or any other health professional to any relevant provincial government or any provincial professional regulatory authority of a province in which the person is not entitled by that authority to practise their profession, if the government or authority submits to the Minister

(a) a written request that sets out the person's name and municipal address and a description of the information being requested; and

(b) a document that shows that

(i) the person has applied to that authority to practise in that province, or

(ii) the government or authority has reasonable grounds to believe that the person is practising in that province without being authorized to do so.

Customs officer

195 The Minister may, for the purpose of verifying whether an importation or exportation of a controlled substance complies with these Regulations, provide the following to a customs officer:

(a) information provided in the permit application under section 34, 42, 205 or 213;

(b) information listed on the permit under subsection 35(1), 43(1), 206(1) or 214(1);

(c) information provided in the declaration under section 39, 47, 210 or 218; or

(d) information concerning the suspension or revocation of an import or export permit.

International Narcotics Control Board

196 The Minister may provide to the International Narcotics Control Board any information that is obtained under the Act or these Regulations if the provision would allow Canada to respect its international obligations in relation to controlled substances.

Competent authorities

197 The Minister may, for the purposes of the administration or enforcement of the Act or these Regulations or if it would allow Canada to respect its international obligations in relation to controlled substances, provide to a competent authority

(a) information obtained from a licensed dealer that has applied for or that holds an import or export permit;

(b) information relating to

(i) an import or export permit, or

(ii) an activity specified on a dealer's licence held by a licensed dealer that has applied for or that holds an import or export permit;

(c) any document that the holder or former holder of an import or export permit is required to retain, including any document that relates to the dealer's licence that the dealer holds or held; and

(d) a copy of any import or export permit.

Temporary Scheduling

Restricted drugs

198 (1) The Minister may, by order, add to Part 3 of Schedule 4 to these Regulations any item or portion of an item listed in Schedule V to the Act.

Deletion

(2) The Minister may, by order, delete any item or portion of an item from Part 3 of Schedule 4.

Deletion — Schedule V to Act

(3) An item or portion of an item listed in Part 3 of Schedule 4 to these Regulations is deemed to be deleted on the day on which the equivalent item or portion of an item is no longer listed in Schedule V to the Act.

Government Laboratories

Production

Authorization

199 A government laboratory may produce a controlled substance.

Sale of Controlled Substances

Sale to licensed dealer

200 A government laboratory may sell or provide a controlled substance to a licensed dealer.

Sale to Minister

201 A government laboratory may sell or provide a controlled substance to the Minister.

Sale to another government laboratory

202 A government laboratory may sell or provide a controlled substance to another government laboratory.

Delivery, Sending and Transportation

Authorization

203 A government laboratory may deliver, send or transport a controlled substance.

Import and Export

Authorization

Condition

204 A government laboratory may import or export a controlled substance if it does so in accordance with an import or export permit issued under these Regulations.

Import Permit

Application

205 (1) A government laboratory must submit to the Minister, before each importation of a controlled substance, an application for an import permit that contains the following information:

(a) the government laboratory's name and municipal address;

(b) the name and municipal address of the proposed customs broker for the government laboratory, if any;

(c) the name of the customs office where the importation is anticipated and the proposed date of importation;

(d) the name and municipal address, in the country of export, of the exporter from whom the controlled substance is being obtained;

(e) the name of the carrier that is proposed to transport the controlled substance to the customs office where the importation is anticipated;

(f) each proposed mode of transportation and any proposed country of transit or transhipment;

(g) in the case of a controlled substance set out in any of Schedules 1 to 4,

(i) its name,

(ii) its CAS registry number, if any,

(iii) if it is a salt, the name of the salt,

(iv) its form,

(v) its purity and anhydrous content, and

(vi) its quantity; and

(h) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Signature and attestation

(2) The application must

(a) be signed and dated by the person in charge of the government laboratory; and

(b) include an attestation by that person that, to the best of their knowledge,

(i) the importation does not contravene the laws of the country of exportation or any country of transit or transhipment, and

(ii) all of the information and documents submitted in support of the application are correct and complete.

Additional information and documents

(3) The government laboratory must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Issuance

206 (1) Subject to section 208, on completion of the review of the import permit application, the Minister must issue to the government laboratory an import permit that contains

(a) the permit number;

(b) the information set out in subsection 205(1);

(c) the effective date of the permit;

(d) the expiry date of the permit, which must be not later than 180 days after its effective date; and

(e) any terms and conditions that the Minister has reasonable grounds to believe are necessary to

(i) ensure that an international obligation is respected, or

(ii) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Permit integrity

(2) A person must not alter or deface in any manner an import permit.

Validity

207 An import permit is valid until the earliest of

(a) the expiry date set out in the permit,

(b) the date of the suspension or revocation of the permit under section 211 or 212, and

(c) the date of the expiry, suspension or revocation of the export authorization that applies to the controlled substance to be imported and that is issued by the competent authority in the country of export.

Refusal

208 (1) The Minister must refuse to issue an import permit if

(a) the Minister has reasonable grounds to believe that the importation would contravene an international obligation;

(b) the government laboratory has not provided the Minister with the information or documents required under subsection 205(3) or before the date specified in the written request referred to in that subsection, or the information or documents that it has provided before that date are not sufficient to complete the review of the permit application;

(c) the Minister has reasonable grounds to believe that the government laboratory has submitted false or misleading information or false or falsified documents in or in support of the permit application;

(d) the Minister has reasonable grounds to believe that the importation would contravene the laws of the country of export or any country of transit or transhipment; or

(e) the Minister has reasonable grounds to believe that the issuance of the permit would likely create a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Prior notice

(2) Before refusing to issue an import permit, the Minister must

(a) provide the government laboratory with a prior written notice that sets out the Minister's reasons and gives the government laboratory an opportunity to be heard; and

(b) consider the government laboratory's submissions, if applicable.

Providing copy of permit

209 The holder of an import permit must provide a copy of the permit to the customs office at the time of importation.

Declaration

210 The holder of an import permit must provide the Minister, within 15 days after the day of release of the controlled substance specified in the permit in accordance with the *Customs Act*, with a declaration that contains the following information:

(a) the permit holder's name;

(b) the number of the import permit;

(c) the name of the customs office from which the controlled substance was released and the date of the release;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4,

(i) its name,

(ii) if it is a salt, the name of the salt,

(iii) its form, and

(iv) its quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Suspension

211 (1) Subject to subsection (2), the Minister must immediately suspend an import permit if

(a) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use; or

(b) the Minister has reasonable grounds to believe that the importation would contravene the laws of the country of export or any country of transit or transhipment.

Notice

(2) The suspension takes effect as soon as the Minister provides the government laboratory with a written notice that

(a) sets out the reasons for the suspension;

(b) gives the government laboratory an opportunity to be heard; and

(c) if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.

Reinstatement of permit

(3) The Minister must reinstate the import permit if the Minister has reasonable grounds to believe that the suspension is no longer necessary.

Revocation

212 (1) The Minister must revoke an import permit if

(a) the government laboratory requests the Minister to do so or informs the Minister of the loss or theft of the permit or the actual or potential unauthorized use of the permit;

(b) the government laboratory does not carry out the corrective measures specified by the Minister under paragraph 211(2)(c) by the specified date; or

(c) the Minister has reasonable grounds to believe that the government laboratory submitted misleading information or falsified documents in or in support of the application for the permit.

Prior notice

(2) Before revoking an import permit, the Minister must

(a) provide the government laboratory with a prior written notice that sets out the Minister's reasons and gives the government laboratory an opportunity to be heard; and

(b) consider the government laboratory's submissions, if applicable.

Export Permit

Application

213 (1) A government laboratory must submit to the Minister, before each exportation of a controlled substance, an application for an export permit that contains the following information and document:

(a) the government laboratory's name and municipal address;

(b) the name and municipal address of the proposed customs broker for the government laboratory, if any;

(c) the name of the customs office where the exportation is anticipated and the proposed date of exportation;

(d) the name and municipal address of the importer in the country of final destination;

(e) the name of the carrier that is proposed to transport the controlled substance from the customs office where the exportation is anticipated;

(f) each proposed mode of transportation and any proposed country of transit or transhipment;

(g) in the case of a controlled substance set out in any of Schedules 1 to 4,

(i) its name,

(ii) its CAS registry number, if any,

(iii) if it is a salt, the name of the salt,

(iv) its form,

(v) its purity and anhydrous content, and

(vi) its quantity;

(h) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any; and

(i) a copy of the import authorization issued by the competent authority in the country of final destination that sets out the name of the importer and the municipal address of their site in that country.

Signature and attestation

(2) The application must

(a) be signed and dated by the person in charge of the government laboratory; and

(b) include an attestation by that person that, to the best of their knowledge,

(i) the exportation does not contravene the laws of the country of final destination or any country of transit or transhipment, and

(ii) all of the information and documents submitted in support of the application are correct and complete.

Additional information and documents

(3) The government laboratory must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Issuance

214 (1) Subject to section 216, on completion of the review of the export permit application, the Minister must issue to the government laboratory an export permit that contains

(a) the permit number;

(b) the information set out in paragraphs 213(1)(a) to (h) and the number of the import authorization referred to in paragraph 213(1)(i);

(c) the effective date of the permit;

(d) the expiry date of the permit, being the earliest of

(i) a date specified by the Minister that is not more than 180 days after its effective date, and

(ii) the expiry date of the import authorization issued by the competent authority in the country of final destination; and

(e) any terms and conditions that the Minister has reasonable grounds to believe are necessary to

(i) ensure that an international obligation is respected, or

(ii) reduce a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Permit integrity

(2) A person must not alter or deface in any manner an export permit.

Validity

215 An export permit is valid until the earliest of

(a) the expiry date set out in the permit,

(b) the date of the suspension or revocation of the permit under section 219 or 220, and

(c) the date of the expiry, suspension or revocation of the import authorization that applies to the controlled substance to be exported and that is issued by the competent authority in the country

of final destination.

Refusal

216 (1) The Minister must refuse to issue an export permit if

(a) the Minister has reasonable grounds to believe that the exportation would contravene an international obligation;

(b) the government laboratory has not provided the Minister with the information or documents required under subsection 213(3) or before the date specified in the written request referred to in that subsection, or the information or documents that it has provided before that date are not sufficient to complete the review of the permit application;

(c) the Minister has reasonable grounds to believe that the government laboratory has submitted false or misleading information or false or falsified documents in or in support of the permit application;

(d) the Minister has reasonable grounds to believe that the exportation would not be in conformity with the import authorization issued by the competent authority of the country of final destination;

(e) the Minister has reasonable grounds to believe that the exportation would contravene the laws of the country of final destination or any country of transit or transhipment; or

(g) the Minister has reasonable grounds to believe that the issuance of the permit would likely create a risk to public health or safety, including the risk that a controlled substance could be diverted to an illicit market or use.

Prior notice

(2) Before refusing to issue an export permit, the Minister must

(a) provide the government laboratory with a prior written notice that sets out the Minister's reasons and gives the government laboratory an opportunity to be heard; and

(b) consider the government laboratory's submissions, if applicable.

Providing copy of permit

217 The holder of an export permit must provide a copy of the permit to the customs office at the time of exportation.

Declaration

218 The holder of an export permit must provide the Minister, within 15 days after the day of export of the controlled substance specified in the permit, with a declaration that contains the following information:

(a) the permit holder's name;

(b) the number of the export permit;

(c) the name of the customs office from which the controlled substance was exported and the date of export;

(d) in the case of a controlled substance set out in any of Schedules 1 to 4,

(i) its name,

(ii) if it is a salt, the name of the salt,

(iii) its form, and

(iv) its quantity; and

(e) in the case of a mixture or finished product,

(i) its name or, if applicable, brand name, as well as the name of the controlled substance it contains,

(ii) its form, its strength, the number of containers and, if applicable, the number of units per container, and

(iii) its drug identification number, if any.

Suspension

219 (1) Subject to subsection (2), the Minister must immediately suspend an export permit if

(a) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health or safety, including to prevent a controlled substance from being diverted to an illicit market or use; or

(b) the Minister has reasonable grounds to believe that the exportation would contravene the laws of the country of final destination or any country of transit or transhipment.

Notice

(2) The suspension takes effect as soon as the Minister provides the government laboratory with a written notice that

(a) sets out the reasons for the suspension;

(b) gives the government laboratory an opportunity to be heard; and

(c) if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.

Reinstatement of permit

(3) The Minister must reinstate the export permit if the Minister has reasonable grounds to believe that the suspension is no longer necessary.

Revocation

220 (1) The Minister must revoke an export permit if

(a) the government laboratory requests the Minister to do so or informs the Minister of the loss or theft of the permit or the actual or potential unauthorized use of the permit;

(b) the government laboratory does not carry out the corrective measures specified by the Minister under paragraph 219(2)(c) by the specified date; or

(c) the Minister has reasonable grounds to believe that the government laboratory submitted misleading information or falsified documents in or in support of the application for the permit.

Prior notice

(2) Before revoking an export permit, the Minister must

(a) provide the government laboratory with a prior written notice that sets out the Minister's reasons and gives the government laboratory an opportunity to be heard; and

(b) consider the government laboratory's submissions, if applicable.

Particular Persons

Sale of Controlled Substances

Authorization

221 A particular person may sell or provide a controlled substance to a licensed dealer, pharmacist or police force for the purposes of destruction.

Delivery, Sending and Transportation

Authorization

222 A particular person may deliver, send or transport a controlled substance to a licensed dealer, pharmacist or police force for the purposes of destruction.

Individuals

Transportation and provision

223 An individual who has obtained, in accordance with the provisions of the Act and its regulations, a controlled substance identified in a prescription for another individual named in that prescription may deliver, transport, sell or provide the substance to that individual.

Return for destruction

224 An individual who has reasonable grounds to believe that a controlled substance in their possession was obtained in accordance with the provisions of the Act and its regulations may, for the purposes of destruction, deliver, transport, sell or provide the substance directly to one of the following persons:

(a) a pharmacist or pharmacy technician, other than one who is practising in a hospital;

(b) a practitioner, other than one who is practising in a hospital;

(c) a hospital; or

(d) a particular person.

Import

225 On entering Canada, an individual may import a substance containing a controlled substance set out in any of Schedules 1 to 3 that is in their actual possession or that forms part of their baggage if

(a) the individual is importing the substance

(i) for their own use,

(ii) for the use and on the behalf of an accompanying individual, or

(iii) for administration to an animal for which the individual is responsible and that is accompanying the individual;

(b) the substance is declared to a customs officer at the port of entry into Canada;

(c) the substance, except a finished product referred to in subsection 98(2) that contains low-dose codeine phosphate, is in a container obtained from a health care provider and that container carries a label on which the following information appears:

(i) the name of the individual for whom, or the animal for which, the substance was lawfully obtained,

(ii) the name of the health care provider who authorized the substance to be obtained,

(iii) with respect to the substance,

(A) its name or, if applicable, brand name,

(B) its form, strength and quantity, and

(C) its drug identification number, if any, and

(iv) the daily dose of the substance authorized by the health care provider; and

(d) the imported quantity of the substance does not exceed a 90-day supply required to treat a condition, based on the daily dose shown on the label.

Export

226 On departing Canada, an individual may export a substance containing a controlled substance set out in any of Schedules 1 to 3 that is in their actual possession or that forms part of their baggage if

(a) the individual is exporting the substance

(i) for their own use,

(ii) for the use and on the behalf of an accompanying individual, or

(iii) for administration to an animal for which the individual is responsible and that is accompanying the individual;

(b) the substance, except a finished product referred to in subsection 98(2) that contains low-dose codeine phosphate, is in a container obtained from a health care provider and that container carries a label on which the following information appears:

(i) the name of the individual for whom, or the animal for which, the substance was lawfully obtained,

(ii) the name of the health care provider who authorized the substance to be obtained,

(iii) with respect to the substance,

(A) its name or, if applicable, brand name,

(B) its form, strength and quantity, and

(C) its drug identification number, if any, and

(iv) the daily dose of the substance authorized by the health care provider; and

(c) the exported quantity of the substance does not exceed a 90-day supply required to treat a condition, based on the daily dose shown on the label.

Test Kits

Application

227 Only sections 1, 7 to 33 and 228 to 234 apply to a test kit.

Requirement to obtain registration number

228 The following persons are required to obtain a registration number for a test kit:

(a) a person that intends to produce a test kit; and

(b) a person for whom another person, in accordance with a custom order, intends to produce a test kit.

Application for registration number

229 (1) An application to obtain a registration number for a test kit must be submitted to the Minister and contain the following information with respect to the test kit:

(a) its brand name;

(b) a detailed description of its design and construction;

(c) with respect to the controlled substance set out in any of Schedules 1 to 4 and any other substance it contains, their names, forms and quantities;

(d) a description of its proposed use; and

(e) its directions for use.

Signature and attestation

(2) The application must

(a) be signed and dated by the person authorized by the applicant for that purpose; and

(b) include an attestation by that person that all of the information submitted in support of the application is correct and complete to the best of their knowledge.

Additional information and documents

(3) The applicant must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the Minister determines is necessary to complete the review of the application.

Issuance of registration number

230 (1) Subject to section 231, on completion of the review of the application for a registration number, the Minister must issue to the applicant a document that sets out a registration number for the test kit, preceded by the letters "TK", if the Minister determines that the test kit will only be used for a medical, laboratory, industrial, educational, law administration or enforcement, or research purpose.

Registration number integrity

(2) A person must not alter or deface in any manner the document that sets out the registration number.

Refusal to issue registration number

231 (1) The Minister must refuse to issue a registration number for a test kit if the Minister has reasonable grounds to believe that

(a) the test kit poses a risk to public health or safety, including the risk that the controlled substance in the test kit could be diverted to an illicit market or use, because

(i) the total amount of the controlled substance is too high, or

(ii) the adulterating or denaturing agent in the test kit is not likely to prevent or deter the consumption of the controlled substance in the test kit by an individual or animal or the administration of that substance to an individual or animal; or

(b) the test kit will be used for a purpose other than one referred to in subsection 230(1).

Prior notice

(2) Before refusing to issue a registration number, the Minister must

(a) provide the applicant with a prior written notice that sets out the Minister's reasons and gives the applicant an opportunity to be heard; and

(b) consider the applicant's submissions, if applicable.

Notice to Minister

232 A person must inform the Minister in writing of any of the following facts within 30 days after their occurrence:

(a) the person has ceased to conduct all activities authorized under section 234 with respect to the test kit;

(b) the person has transferred the production of the test kit to another person;

(c) the person has increased the quantity of the controlled substance in the test kit;

(d) the person has changed the brand name of the test kit;

(e) the person has altered in any manner the adulterating or denaturing agent in the test kit or changed the quantity of either agent in it; or

(f) the person has substituted the adulterating or denaturing agent with another one.

Cancellation of registration number

233 (1) The Minister must cancel the registration number of a test kit if

(a) the Minister receives a notice from the person to whom the document that sets out the registration number was issued, stating that production of the test kit has ceased; or

(b) the Minister has reasonable grounds to believe that one of the circumstances referred to in paragraph 231(1)(a) or (b) exists.

Prior notice

(2) Before cancelling a registration number, the Minister must

(a) provide the person to whom the document that sets out the registration number was issued with a prior written notice that sets out the Minister's reasons and gives the applicant an opportunity to be heard; and

(b) consider the person's submissions, if applicable.

Effect of cancellation

(3) The following rules apply when the registration number of a test kit is cancelled:

(a) in the case of a test kit produced before a cancellation under paragraph (1)(a),

(i) the activities set out in section 234 remain authorized, and

(ii) the registration number must remain on the label of the test kit; and

(b) in the case of a test kit produced either before or after a cancellation under paragraph (1)(b), the registration number must not be displayed on its label.

Authorized activities

234 (1) Any person, other than a person referred to in subsection (2), may possess, sell, provide, transport, send, deliver, import or export a test kit if the following conditions are met:

(a) subject to subparagraph 233(3)(a)(i), the registration number of the test kit has not been cancelled under subsection 233(1);

(b) the test kit will be used for a medical, laboratory, industrial, educational, law administration or enforcement, or research purpose; and

(c) the test kit carries a label on which the following information appears:

(i) the registration number of the test kit, and

(ii) in the case of a test kit that is not subject to the labelling requirements set out in the *Medical Devices Regulations*,

(A) the name and municipal address of the person that produced the test kit or, if the test kit is produced in accordance with a custom order, of the other person for whom the test kit was produced, and

(B) its brand name.

Member of police force

(2) A person referred to in section 2 may possess a test kit.

Miscellaneous Provisions

Advertising

Restrictions

235 A person that advertises a controlled substance may only do so if

(a) the substance is not a restricted drug;

(b) the advertisement is directed to a person that is not part of the general public; and

(c) in the case of a written advertisement,

(i) the advertisement appears in a document distributed to, or in a trade publication for,

(A) a licensed dealer,

(B) a pharmacist, pharmacy technician or practitioner, or

(C) a hospital, and

(ii) the advertisement contains, in a conspicuous place, a legible and intelligible statement that the substance is a controlled substance.

Notification of an Application for an Order of Restoration

Written notification

236 (1) For the purposes of subsection 24(1) of the Act, the prior notification of an application for an order of restoration given to the Attorney General must be made in writing and provided by registered mail at least 15 days before the date on which the application is to be made to a justice.

Content of notification

(2) The prior notification must specify

(a) the name of the justice to whom the application is to be made;

(b) the time and place at which the application is to be heard;

(c) details concerning the controlled substance or other thing in respect of which the application is to be made; and

(d) the evidence on which the applicant intends to rely to establish that the applicant is entitled to possession of the controlled substance or other thing referred to in paragraph (c).

Repeals

237 Parts G and J of the *Food and Drug Regulations* [1] are repealed.

238 The following regulations are repealed:

(a) the *Narcotic Control Regulations* [2];

(b) the *Regulations Exempting Certain Precursors and Controlled Substances from the Application of the Controlled Drugs and Substances Act* [3];

(c) the *Benzodiazepines and Other Targeted Substances Regulations* [4]; and

(d) the *New Classes of Practitioners Regulations* [5].

Coming into Force

October 1, 2026

239 These Regulations come into force on October 1, 2026.

SCHEDULE 1

(Subsection 1(1), paragraphs 5(1)(a), 11(1)(f), 12(1)(c) and (i), 34(1)(h), 39(d), 42(1)(h), 47(d), 56(d), 57(1)(d), 58(1)(d), 59(d), 61(d), 62(d) and 69(1)(d), subparagraph 72(e)(iv), paragraphs 73(1)(g), 75(d), 76(d), 77(a), 78(b), 80(g), 81(d), 82(d), 83(b), 84(e), 85(1)(a), 92(3)(d), 93(1)(d) and (2)(e), 94(1)(d),

95(d), 97(d), 111(d), 112(d), 117(d), 120(g), 121(f), 128(2)(d), 129(d), 141(c), 142(d), 143(2)(e) and 144(c), subparagraph 144(f)(ii), paragraphs 146(f), 147(f), 154(a) and 158(3)(d), subparagraphs 159(1)(b)(iv) and 160(1)(b)(iv), paragraphs 161(1)(d) and (2)(d), 162(d), 175(d), 176(d), 177(d), 181(d), 182(g), 183(f), 205(1)(g), 210(d), 213(1)(g) and 218(d), sections 225 and 226 and paragraph 229(1)(c))

Narcotics

Item	Name

1	Opium Poppy (*Papaver somniferum*), its preparations, derivatives, alkaloids and salts, including (1) Opium (2) Codeine (methylmorphine) (3) Morphine (7,8-didehydro-4,5-epoxy-17-methylmorphinan-3,6-diol) (4) Thebaine (paramorphine) and the salts, derivatives and salts of derivatives of the substances set out in subitems (1) to (4), including (5) Acetorphine (acetyletorphine) (6) Acetyldihydrocodeine (4,5-epoxy-3-methoxy-17-methylmorphinan-6-ol acetate) (7) Benzylmorphine (7,8-didehydro-4,5-epoxy-17-methyl-3-(phenylmethoxy) morphinan-6-ol) (8) Codoxime (dihydrocodeinone O-(carboxymethyl)oxime) (9) Desomorphine (dihydrodeoxymorphine) (10) Diacetylmorphine (heroin) (11) Dihydrocodeine (4,5-epoxy-3-methoxy-17-methylmorphinan-6-ol) (12) Dihydromorphine (4,5-epoxy-17-methylmorphinan-3,6-diol) (13) Ethylmorphine (7,8-didehydro-4,5-epoxy-3-ethoxy-17-methylmorphinan-6-ol) (14) Etorphine (tetrahydro-7alpha-(1-hydroxy-1-methylbutyl)-6,14-endo-ethenooripavine) (15) Hydrocodone (dihydrocodeinone) (16) Hydromorphinol (dihydro-14-hydroxymorphine) (17) Hydromorphone (dihydromorphinone) (18) Methyldesorphine (delta-6-deoxy-6-methylmorphine) (19) Methyldihydromorphine (dihydro-6-methylmorphine) (20) Metopon (dihydromethylmorphinone) (21) Morphine-N-oxide (morphine oxide) (22) Myrophine (benzylmorphine myristate) (23) Nalorphine (N-allylnormorphine) (24) Nicocodine (6-nicotinylcodeine) (25) Nicomorphine (dinicotinylmorphine) (26) Norcodeine (N-desmethylcodeine) (27) Normorphine (N-desmethylmorphine) (28) Oxycodone (dihydrohydroxycodeinone) (29) Oxymorphone (dihydrohydroxymorphinone) (30) Pholcodine (3-[2-(4-morpholinyl)ethyl]morphine) (31) Thebacon (acetyldihydrocodeinone) but not including (32) Apomorphine (5,6,6a,7-tetrahydro-6-methyl-4H-dibenzo[de,g]quinoline-10,11-diol) and its salts

	(33) Cyprenorphine (N-(cyclopropylmethyl)-6,7,8,14-tetrahydro-7alpha-(1-hydroxy-1-methylethyl)-6,14-endo-ethenonororipavine) and its salts (34) Nalmefene (17-(cyclopropylmethyl)-4,5alpha-epoxy-6-methylenemorphinan-3,14-diol) and its salts (35) Naloxone (4,5alpha-epoxy-3,14-dihydroxy-17-(2-propenyl)morphinan-6-one) and its salts (36) Naltrexone (17-(cyclopropylmethyl)-4,5alpha-epoxy-3,14-dihydroxymorphinan-6-one) and its salts (37) Methylnaltrexone (17-(cyclopropylmethyl)-4,5alpha-epoxy-3,14-dihydroxy-17-methyl-6-oxomorphinanium) and its salts (38) Naloxegol (4,5alpha-epoxy-6alpha-(3,6,9,12,15,18,21-heptaoxadocos-1-yloxy)-17-(2-propenyl)morphinan-3,14-diol) and its salts (39) Narcotine (6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-g]isoquinolin-5-yl)-1(3H)-isobenzofuranone) and its salts (40) Papaverine (1-[(3,4-dimethoxyphenyl)methyl]-6,7-dimethoxyisoquinoline) and its salts (41) Poppy seed
2	Coca (*Erythroxylum*), its preparations, derivatives, alkaloids and salts, including (1) Coca leaves (2) Cocaine (benzoylmethylecgonine) (3) Ecgonine (3-hydroxy-2-tropane carboxylic acid) but not including (4) ^{123}I-ioflupane

3	Phenylpiperidines, their intermediates, salts, derivatives and analogues and salts of intermediates, derivatives and analogues, including (1) Allylprodine (3-allyl-1-methyl-4-phenyl-4-piperidinol propionate) (2) Alphameprodine (alpha-3-ethyl-1-methyl-4-phenyl-4-piperidinol propionate) (3) Alphaprodine (alpha-1,3-dimethyl-4-phenyl-4-piperidinol propionate) (4) Anileridine (ethyl 1-[2-(p-aminophenyl)ethyl]-4-phenylpiperidine-4-carboxylate) (5) Betameprodine (beta-3-ethyl-1-methyl-4-phenyl-4-piperidinol propionate) (6) Betaprodine (beta-1,3-dimethyl-4-phenyl-4-piperidinol propionate) (7) Benzethidine (ethyl 1-(2-benzyloxyethyl)-4-phenylpiperidine-4-carboxylate) (8) Diphenoxylate (ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylate) (9) Difenoxin (1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylate) (10) Etoxeridine (ethyl 1-[2-(2-hydroxyethoxy)ethyl]-4-phenylpiperidine-4-carboxylate) (11) Furethidine (ethyl 1-(2-tetrahydrofurfuryloxyethyl)-4-phenylpiperidine-4-carboxylate) (12) Hydroxypethidine (ethyl 4-(m-hydroxyphenyl)-1-methylpiperidine-4-carboxylate) (13) Ketobemidone (1-[4-(m-hydroxyphenyl)-1-methyl-4-piperidyl]-1-propanone) (14) Methylphenylisonipecotonitrile (4-cyano-1-methyl-4-phenylpiperidine) (15) Morpheridine (ethyl 1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylate) (16) Norpethidine (ethyl 4-phenylpiperidine-4-carboxylate) (17) Pethidine (ethyl 1-methyl-4-phenylpiperidine-4-carboxylate) (18) Phenoperidine (ethyl 1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4-carboxylate) (19) Piminodine (ethyl 1-[3-(phenylamino)propyl]-4-phenylpiperidine-4-carboxylate) (20) Properidine (isopropyl 1-methyl-4-phenylpiperidine-4-carboxylate) (21) Trimeperidine (1,2,5-trimethyl-4-phenyl-4-piperidinol propionate) (22) Pethidine Intermediate C (1-methyl-4-phenylpiperidine-4-carboxylate) but not including (23) Carperidine (ethyl 1-(2-carbamylethyl)-4-phenylpiperidine-4-carboxylate) and its salts (24) Oxpheneridine (ethyl 1-(2-hydroxy-2-phenylethyl)-4-phenylpiperidine-4-carboxylate) and its salts
4	Phenazepines, their salts, derivatives and salts of derivatives including (1) Proheptazine (hexahydro-1,3-dimethyl-4-phenyl-1H-azepin-4-ol propionate) but not including (2) Ethoheptazine (ethyl hexahydro-1-methyl-4-phenylazepine-4-carboxylate) and its salts (3) Metethoheptazine (ethyl hexahydro-1,3-dimethyl-4-phenylazepine-4-carboxylate) and its salts (4) Metheptazine (methylhexahydro-1,2-dimethyl-4-phenylazepine-4-carboxylate) and its salts

5	Amidones, their intermediates, salts, derivatives and salts of intermediates and derivatives, including (1) Dimethylaminodiphenylbutanonitrile (4-cyano-2-dimethylamino-4,4-diphenylbutane) (2) Dipipanone (4,4-diphenyl-6-piperidino-3-heptanone) (3) Isomethadone (6-dimethylamino-5-methyl-4,4-diphenyl-3-hexanone) (4) Methadone (6-dimethylamino-4,4-diphenyl-3-heptanone) (5) Normethadone (6-dimethylamino-4,4-diphenyl-3-hexanone) (6) Norpipanone (4,4-diphenyl-6-piperidino-3-hexanone) (7) Phenadoxone (6-morpholino-4,4-diphenyl-3-heptanone)
6	Methadols, their salts, derivatives and salts of derivatives, including (1) Acetylmethadol (6-dimethylamino-4,4-diphenyl-3-heptanol acetate) (2) Alphacetylmethadol (alpha-6-dimethylamino-4,4-diphenyl-3-heptanol acetate) (3) Alphamethadol (alpha-6-dimethylamino-4,4-diphenyl-3-heptanol) (4) Betacetylmethadol (beta-6-dimethylamino-4,4-diphenyl-3-heptanol acetate) (5) Betamethadol (beta-6-dimethylamino-4,4-diphenyl-3-heptanol) (6) Dimepheptanol (6-dimethylamino-4,4-diphenyl-3-heptanol) (7) Noracymethadol (alpha-6-methylamino-4,4-diphenyl-3-heptanol acetate)
7	Phenalkoxams, their salts, derivatives and salts of derivatives, including (1) Dimenoxadol (dimethylaminoethyl 1-ethoxy-1,1-diphenylacetate) (2) Dioxaphetyl butyrate (ethyl 2,2-diphenyl-4-morpholinobutyrate) (3) Dextropropoxyphene ([S-(R*,S*)]-alpha-[2-(dimethylamino)-1-methylethyl]-alpha-phenylbenzeneethanol, propanoate ester)
8	Thiambutenes, their salts, derivatives and salts of derivatives, including (1) Diethylthiambutene (N,N-diethyl-1-methyl-3,3-di-2-thienylallylamine) (2) Dimethylthiambutene (N,N,1-trimethyl-3,3-di-2-thienylallylamine) (3) Ethylmethylthiambutene (N-ethyl-N,1-dimethyl-3,3-di-2-thienylallylamine)
9	Moramides, their intermediates, salts, derivatives and salts of intermediates and derivatives, including (1) Dextromoramide (d-1-(3-methyl-4-morpholino-2,2-diphenylbutyryl)pyrrolidine) (2) Diphenylmorpholinoisovaleric acid (2-methyl-3-morpholino-1,1-diphenylpropionic acid) (3) Levomoramide (l-1-(3-methyl-4-morpholino-2,2-diphenylbutyryl)pyrrolidine) (4) Racemoramide (*d*,*l*-1-(3-methyl-4-morpholino-2,2-diphenylbutyryl)pyrrolidine)

10	Morphinans, their salts, derivatives and salts of derivatives, including (1) Buprenorphine (17-(cyclopropylmethyl)-alpha-(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-alpha-methyl-6,14-ethenomorphinan-7-methanol) (2) Drotebanol (6beta,14-dihydroxy-3,4-dimethoxy-17-methylmorphinan) (3) Levomethorphan (1-3-methoxy-17-methylmorphinan) (4) Levorphanol (1-3-hydroxy-17-methylmorphinan) (5) Levophenacylmorphan (1-3-hydroxy-17-phenacylmorphinan) (6) Norlevorphanol (1-3-hydroxymorphinan) (7) Phenomorphan (3-hydroxy-17-(2-phenylethyl)morphinan) (8) Racemethorphan (*d*,*l*-3-methoxy-17-methylmorphinan) (9) Racemorphan (*d*,*l*-3-hydroxy-N-methylmorphinan) but not including (10) Dextromethorphan (*d*-1,2,3,9,10,10a-hexahydro-6-methoxy-11-methyl-4H-10,4a-iminoethanophenanthren) and its salts (11) Dextrorphan (*d*-1,2,3,9,10,10a-hexahydro-11-methyl-4H-10,4a-iminoethanophenanthren-6-ol) and its salts (12) Levallorphan (*l*-11-allyl-1,2,3,9,10,10a-hexahydro-4H-10,4a-iminoethanophenanthren-6-ol) and its salts (13) Levargorphan (*l*-11-propargyl-1,2,3,9,10,10a-hexahydro-4H-10,4a-iminoethanophenanthren-6-ol) and its salts (14) Butorphanol (*l*-N-cyclobutylmethyl-3,14-dihydroxymorphinan) and its salts (15) Nalbuphine (N-cyclobutylmethyl-4,5-epoxymorphinan-3,6,14-triol) and its salts
11	Benzazocines, their salts, derivatives and salts of derivatives, including (1) Phenazocine (1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-phenethyl-2,6-methano-3-benzazocin-8-ol) (2) Metazocine (1,2,3,4,5,6-hexahydro-3,6,11-trimethyl-2,6-methano-3-benzazocin-8-ol) (3) Pentazocine (1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-2,6-methano-3-benzazocin-8-ol) but not including (4) Cyclazocine (1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-(cyclopropylmethyl)-2,6-methano-3-benzazocin-8-ol) and its salts
12	Ampromides, their salts, derivatives and salts of derivatives, including (1) Diampromide (N-[2-(methylphenethylamino)propyl]propionanilide) (2) Phenampromide (N-((1-methyl-2-piperidino)ethyl)propionanilide) (3) Propiram (N-(1-methyl-2-piperidinoethyl)-N-2-pyridylpropionamide)

13	Benzimidazoles, their salts, derivatives and salts of derivatives, including (1) Clonitazene (2-(p-chlorobenzyl)-1-diethylaminoethyl-5-nitrobenzimidazole) (2) Etonitazene (2-(p-ethoxybenzyl)-1-diethylaminoethyl-5-nitrobenzimidazole) (3) Bezitramide (1-(3-cyano-3,3-diphenylpropyl)-4-(2-oxo-3-propionyl-1-benzimidazolinyl)-piperidine)
14	Phencyclidine (1-(1-phenylcyclohexyl)piperidine), its salts, derivatives and analogues and salts of derivatives and analogues, including (1) Ketamine (2-(2-chlorophenyl)-2-(methylamino)cyclohexanone)
15	Fentanyls, their salts, derivatives and analogues and salts of derivatives and analogues, including (1) Acetyl-alpha-methylfentanyl (N-[1-(alpha-methylphenethyl)-4-piperidyl]acetanilide) (2) Alfentanil (N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidyl]propionanilide) (3) Carfentanil (methyl 4-[(1-oxopropyl)phenylamino]-1-(2-phenethyl)-4-piperidinecarboxylate) (4) p-Fluorofentanyl (4'-fluoro-N-(1-phenethyl-4-piperidyl)propionanilide) (5) Fentanyl (N-(1-phenethyl-4-piperidyl)propionanilide) (6) beta-Hydroxyfentanyl (N-[1-(beta-hydroxyphenethyl)-4-piperidyl]propionanilide) (7) beta-Hydroxy-3-methylfentanyl (N-[1-(beta-hydroxyphenethyl)-3-methyl-4-piperidyl]propionanilide) (8) alpha-Methylfentanyl (N-[1-(alpha-methylphenethyl)-4-piperidyl]propionanilide) (9) alpha-Methylthiofentanyl (N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]propionanilide) (10) 3-Methylfentanyl (N-(3-methyl-1-phenethyl-4-piperidyl)propionanilide) (11) 3-Methylthiofentanyl (N-[3-methyl-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide) (12) Remifentanil (dimethyl 4-carboxy-4-(N-phenylpropionamido)-1-piperidinepropionate) (13) Sufentanil (N-[4-(methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide) (14) Thiofentanyl (N-[1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide) (15) 4-Anilino-N-phenethylpiperidine (ANPP) (N-phenyl-1-(2-phenylethyl)piperidine-4-amine), its derivatives and analogues and salts of derivatives and analogues
16	Tilidine (ethyl-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate), its salts, derivatives and salts of derivatives

17	Synthetic cannabinoid receptor type 1 agonists, their salts, derivatives, isomers and salts of derivatives and isomers, including those that fall within the following core chemical structure classes, with the exception of any substance that is identical to any phytocannabinoid and of ((3S)-2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl)-1-naphthalenyl-methanone (WIN 55,212-3) and its salts: (1) Any substance that has a 2-(cyclohexyl)phenol structure with substitution at the 1-position of the benzene ring by a hydroxy, ether or ester group and further substituted at the 5-position of the benzene ring, whether or not further substituted on the benzene ring to any extent, and substituted at the 3'-position of the cyclohexyl ring by an alkyl, carbonyl, hydroxyl, ether or ester, and whether or not further substituted on the cyclohexyl ring to any extent, including (i) Nabilone ((±)-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one) (ii) Parahexyl (3-hexyl-6,6,9-trimethyl-7,8,9,10-tetrahydro-6H-dibenzo[b,d]pyran-1-ol) (iii) 3-(1,2-dimethylheptyl)-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran-1-ol (DMHP) (iv) 5-(1,1-dimethylheptyl)-2-(5-hydroxy-2-(3-hydroxypropyl)cyclohexyl)phenol (CP 55,940) (v) 5-(1,1-dimethylheptyl)-2-(3-hydroxycyclohexyl)phenol (CP 47,497) (2) Any substance that has a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent, including (i) 1-pentyl-3-(1-naphthoyl)indole (JWH-018) (ii) 1-butyl-3-(1-naphthoyl)indole (JWH-073) (iii) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122) (iv) 1-hexyl-3-(1-naphthoyl)indole (JWH-019) (v) 1-(4-pentenyl)-3-(1-naphthoyl)indole (JWH-022) (vi) 1-butyl-3-(4-methoxy-1-naphthoyl)indole (JWH-080) (vii) 1-pentyl-3-(4-methoxy-1-naphthoyl)indole (JWH-081) (viii) 1-(2-morpholin-4-ylethyl)-3-(1-naphthoyl)indole (JWH-200) (ix) 1-pentyl-3-(4-ethyl-1-naphthoyl)indole (JWH-210) (x) 1-pentyl-3-(2-methoxy-1-naphthoyl)indole (JWH-267) (xi) 1-[(N-methylpiperidin-2-yl)methyl]-3-(1-naphthoyl)indole (AM-1220) (xii) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM-2201) (xiii) 1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl)indole (MAM-2201) (xiv) 1-(5-fluoropentyl)-3-(4-ethyl-1-naphthoyl)indole (EAM-2201) (xv) ((3R)-2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1, 4-benzoxazin-6-yl)-1-naphthalenyl-methanone (WIN 55,212-2) (3) Any substance that has a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted on the pyrrole ring to any extent and whether or not substituted on the naphthyl ring to any extent, including (i) 1-pentyl-5-(2-fluorophenyl)-3-(1-naphthoyl)pyrrole (JWH-307)

	(4) Any substance that has a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent, including (i) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250) (ii) 1-pentyl-3-(2-methylphenylacetyl)indole (JWH-251) (iii) 1-pentyl-3-(3-methoxyphenylacetyl)indole (JWH-302) (5) Any substance that has a 3-benzoylindole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent, including (i) 1-(1-methylpiperidin-2-ylmethyl)-3-(2-iodobenzoyl)indole (AM-2233) (6) Any substance that has a 3-methanone(cyclopropyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent and whether or not substituted on the cyclopropyl ring to any extent, including (i) (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)-methanone (UR-144) (ii) (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)-methanone (5F-UR-144) (iii) (1-(2-(4-morpholinyl)ethyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)-methanone (A-796,260) (7) Any substance that has a quinolin-8-yl 1H-indole-3-carboxylate structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent and whether or not substituted on the quinolin-8-yl ring to any extent, including (i) 1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (PB-22) (ii) 1-(5-fluoropentyl)-8-quinolinylester-1H-indole-3-carboxylicacid (5F-PB-22) (8) Any substance that has a 3-carboxamideindazole structure with substitution at the nitrogen atom of the indazole ring, whether or not further substituted on the indazole ring to any extent and whether or not substituted at the carboxamide group to any extent, including (i) N-(adamantan-1-yl)-1-pentyl-1H-indazole-3-carboxamide (AKB48) (ii) N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5F-AKB48) (iii) N-(1-(aminocarbonyl)-2-methylpropyl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA) (iv) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA) (9) Any substance that has a 3-carboxamideindole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent and whether or not substituted at the carboxamide group to any extent, including (i) N-(adamantan-1-yl)-1-fluoropentylindole-3-carboxamide (STS-135) (ii) N-(adamantan-1-yl)-1-pentylindole-3-carboxamide (APICA)
18	Tapentadol (3-[(1R,2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl]-phenol), its salts, derivatives and isomers and salts of derivatives and isomers

19	Tramadol (2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol), its salts, isomers and salts of isomers and the following derivatives of tramadol and the salts, isomers and salts of isomers of those derivatives: (1) *O*-desmethyltramadol (3-[2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]-phenol) (2) *N*,*O*-didesmethyltramadol (3-[1-hydroxy-2-[(methylamino)methyl]cyclohexyl]-phenol)
20	AP-237 (1-(4-cinnamylpiperazin-1-yl)butan-1-one), its salts, derivatives and analogues and salts of derivatives and analogues, including: (1) 2-methyl-AP-237 (1-(4-cinnamyl-2-methylpiperazin-1-yl)butan-1-one) (2) *para*-methyl-AP-237 ((*E*)-1-(4-(3-(*p*-tolyl)allyl)piperazin-1-yl)butan-1-one) (3) AP-238 (1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one)
21	Piritramide (1-(3-cyano-3,3-diphenylpropyl)-4-(1-piperidino)piperidine-4-carboxylic acid amide), its salts, derivatives and salts of derivatives

SCHEDULE 2

(Subsection 1(1), section 3, paragraphs 5(1)(b), 11(1)(f), 12(1)(c) and (i), 34(1)(h), 39(d), 42(1)(h), 47(d), 56(d), 57(1)(d), 58(1)(d), 59(d), 61(d), 62(d) and 69(1)(d), subparagraph 72(e)(iv), paragraphs 73(1)(g), 75(d), 76(d), 77(a), 78(b), 80(g), 81(d), 82(d), 83(b), 84(e), 85(1)(a), 92(3)(d), 93(1)(d) and (2)(e), 94(1)(d), 95(d), 97(d), 111(d), 112(d), 117(d), 120(g), 121(f), 128(2)(d), 129(d), 141(c), 142(d), 143(2)(e) and 144(c), subparagraph 144(f)(ii), paragraphs 146(f), 147(f), 154(b) and 158(3)(d), subparagraphs 159(1)(b)(iv) and 160(1)(b)(iv), paragraphs 161(1)(d) and (2)(d), 162(d), 175(d), 176(d), 177(d), 181(d), 182(g), 183(f), 205(1)(g), 210(d), 213(1)(g) and 218(d), sections 225 and 226 and paragraph 229(1)(c))

Controlled Drugs

PART 1

Item	Name
1	Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, excluding those substances set out in item 1 of Part 1 of Schedule 4 but including (1) Amphetamine (alpha-methylbenzeneethanamine) (2) Methamphetamine (N,alpha-dimethylbenzeneethanamine) (3) Benzphetamine (N-benzyl-N,alpha-dimethylbenzeneethanamine)

2	Methylphenidate (methyl 2-phenyl-2-(piperidin-2-yl)acetate), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, including (1) Ethylphenidate (ethyl 2-phenyl-2-(piperidin-2-yl)acetate) (2) Isopropylphenidate (isopropyl 2-phenyl-2-(piperidin-2-yl)acetate) (3) Propylphenidate (propyl 2-phenyl-2-(piperidin-2-yl)acetate) (4) 3,4-Dichloromethylphenidate (methyl 2-(3,4-dichlorophenyl)-2-(piperidin-2-yl)acetate) (5) 4-Methylmethylphenidate (methyl 2-(4-methylphenyl)-2-(piperidin-2-yl)acetate) (6) 4-Fluoromethylphenidate (methyl 2-(4-fluorophenyl)-2-(piperidin-2-yl)acetate) (7) Methylnaphthidate (methyl 2-(naphthalen-2-yl)-2-(piperidin-2-yl)acetate) (8) Ethylnaphthidate (ethyl 2-(naphthalen-2-yl)-2-(piperidin-2-yl)acetate)
3	Methaqualone (2-methyl-3-(2-methylphenyl)-4(3H)-quinazolinone) and its salts
4	4-hydroxybutanoic acid (GHB) and its salts
5	Aminorex (5-phenyl-4,5-dihydro-1,3-oxazol-2-amine), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, including (1) 4-Methylaminorex (4-methyl-5-phenyl-4,5-dihydro-1,3-oxazol-2-amine) (2) 4,4'-Dimethylaminorex (4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine)
6	Fenetylline (*d,l*-3,7-dihydro-1,3-dimethyl-7-(2-[(1-methyl-2-phenethyl)amino]ethyl)-1H-purine-2,6-dione) and its salts
7	Lefetamine ((-)-N,N-dimethyl-alpha-phenylbenzeneethanamine), its salts, derivatives and isomers and salts of derivatives and isomers
8	Mecloqualone (2-methyl-3-(2-chlorophenyl)-4(3H)-quinazolinone) and its salts
9	Mesocarb (3-(alpha-methylphenethyl)-N-(phenylcarbamoyl)sydnone imine) and its salts
10	Zipeprol (4-(2-methoxy-2-phenylethyl)-alpha-(methoxyphenylmethyl)-1-piperazineethanol) and its salts
11	Amineptine (7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid) and its salts

PART 2

Item	Name

1	Barbiturates, their salts and derivatives, excluding the substances set out in items 6 and 7 of Part 1 as well as barbituric acid (2,4,6(1H,3H,5H)-pyrimidinetrione) and its salts and 1,3-dimethylbarbituric acid (1,3-dimethyl-2,4,6(1H,3H,5H)-pyrimidinetrione) and its salts, but including (1) Allobarbital (5,5-diallylbarbituric acid) (2) Alphenal (5-allyl-5-phenylbarbituric acid) (3) Amobarbital (5-ethyl-5-(3-methylbutyl)barbituric acid) (4) Aprobarbital (5-allyl-5-isopropylbarbituric acid) (5) Barbital (5,5-diethylbarbituric acid) (6) Butabarbital (5-sec-butyl-5-ethylbarbituric acid) (7) Butalbital (5-allyl-5-isobutylbarbituric acid) (8) Butallylonal (5-(2-bromoallyl)-5-sec-butylbarbituric acid) (9) Butethal (5-butyl-5-ethylbarbituric acid) (10) Cyclobarbital (5-(1-cyclohexen-1-yl)-5-ethylbarbituric acid) (11) Cyclopal (5-allyl-5-(2-cyclopenten-1-yl)barbituric acid) (12) Heptabarbital (5-(1-cyclohepten-1-yl)-5-ethylbarbituric acid) (13) Hexethal (5-ethyl-5-hexylbarbituric acid) (14) Hexobarbital (5-(1-cyclohexen-1-yl)-1,5-dimethylbarbituric acid) (15) Mephobarbital (5-ethyl-1-methyl-5-phenylbarbituric acid) (16) Methabarbital (5,5-diethyl-1-methylbarbituric acid) (17) Propallylonal (5-(2-bromoallyl)-5-isopropyl-barbituric acid) (18) Pentobarbital (5-ethyl-5-(1-methylbutyl)barbituric acid) (19) Phenobarbital (5-ethyl-5-phenylbarbituric acid) (20) Probarbital (5-ethyl-5-isopropylbarbituric acid) (21) Phenylmethylbarbituric Acid (5-methyl-5-phenylbarbituric acid) (22) Secobarbital (5-allyl-5-(1-methylbutyl)barbituric acid) (23) Sigmodal (5-(2-bromoallyl)-5-(1-methylbutyl) barbituric acid) (24) Talbutal (5-allyl-5-sec-butylbarbituric acid) (25) Vinbarbital (5-ethyl-5-(1-methyl-1-butenyl)barbituric acid) (26) Vinylbital (5-(1-methylbutyl)-5-vinylbarbituric acid)
2	Thiobarbiturates, their salts and derivatives, including (1) Thialbarbital (5-allyl-5-(2-cyclohexen-1-yl)-2-thiobarbituric acid) (2) Thiamylal (5-allyl-5-(1-methylbutyl)-2-thiobarbituric acid) (3) Thiobarbituric Acid (2-thiobarbituric acid) (4) Thiopental (5-ethyl-5-(1-methylbutyl)-2-thiobarbituric acid)
3	Chlorphentermine (1-(p-chlorophenyl)-2-methyl-2-aminopropane) and its salts

4	Diethylpropion (2-(diethylamino)propiophenone) and its salts
5	Phentermine (alpha,alpha-dimethylbenzeneethanamine) and its salts
6	Butorphanol (*l*-N-cyclobutylmethyl-3,14-dihydroxymorphinan) and its salts
7	Nalbuphine (N-cyclobutylmethyl-4,5-epoxy-morphinan-3,6,14-triol) and its salts
8	Pyrovalerone (4'-methyl-2-(1-pyrrolidinyl)valerophenone) and its salts
9	Phendimetrazine (d-3,4-dimethyl-2-phenylmorpholine) and its salts
10	Phenmetrazine (3-methyl-2-phenylmorpholine) and its salts
11	Glutethimide (2-ethyl-2-phenylglutarimide)
12	Pemoline (2-amino-5-phenyl-oxazolin-4-one) and its salts

PART 3

Item	Name

1	Anabolic steroids and their derivatives, including (1) Androisoxazole (17beta-hydroxy-17alpha-methylandrostano[3,2-c]isoxazole) (2) Androstanolone (17beta-hydroxy-5alpha-androstan-3-one) (3) Androstenediol (androst-5-ene-3beta,17beta-diol) (4) Bolandiol (estr-4-ene-3beta,17beta-diol) (5) Bolasterone (17beta-hydroxy-7alpha,17-dimethylandrost-4-en-3-one) (6) Bolazine (17beta-hydroxy-2alpha-methyl-5alpha-androstan-3-one azine) (7) Boldenone (17beta-hydroxyandrosta-1,4-dien-3-one) (8) Bolenol (19-nor-17alpha-pregn-5-en-17-ol) (9) Calusterone (17beta-hydroxy-7beta,17-dimethylandrost-4-en-3-one) (10) Clostebol (4-chloro-17beta-hydroxyandrost-4-en-3-one) (11) Drostanolone (17beta-hydroxy-2alpha-methyl-5alpha-androstan-3-one) (12) Enestebol (4,17beta-dihydroxy-17-methylandrosta-1,4-dien-3-one) (13) Epitiostanol (2alpha,3alpha-epithio-5alpha-androstan-17beta-ol) (14) Ethylestrenol (19-nor-17alpha-pregn-4-en-17-ol) (15) Fluoxymesterone (9-fluoro-11beta,17beta-dihydroxy-17-methylandrost-4-en-3-one) (16) Formebolone (11alpha,17beta-dihydroxy-17-methyl-3-oxoandrosta-1,4-di-en-2-carboxaldehyde) (17) Furazabol (17-methyl-5alpha-androstano[2,3-c]furazan-17beta-ol) (18) Mebolazine (17beta-hydroxy-2alpha,17-dimethyl-5alpha-androstan-3-one azine) (19) Mesabolone (17beta-[(1-methoxycyclohexyl)oxy]-5alpha-androst-1-en-3-one) (20) Mesterolone (17beta-hydroxy-1alpha-methyl-5alpha-androstan-3-one) (21) Metandienone (17beta-hydroxy-17-methylandrosta-1,4-dien-3-one) (22) Metenolone (17beta-hydroxy-1-methyl-5alpha-androst-1-en-3-one) (23) Methandriol (17alpha-methylandrost-5-ene-3beta,17beta-diol) (24) Methyltestosterone (17beta-hydroxy-17-methylandrost-4-en-3-one) (25) Metribolone (17beta-hydroxy-17-methylestra-4,9,11-trien-3-one) (26) Mibolerone (17beta-hydroxy-7alpha,17-dimethylestr-4-en-3-one) (27) Nandrolone (17beta-hydroxyestr-4-en-3-one) (28) Norboletone (13-ethyl-17beta-hydroxy-18,19-dinorpregn-4-en-3-one) (29) Norclostebol (4-chloro-17beta-hydroxyestr-4-en-3-one) (30) Norethandrolone (17alpha-ethyl-17beta-hydroxyestr-4-en-3-one) (31) Oxabolone (4,17beta-dihydroxyestr-4-en-3-one) (32) Oxandrolone (17beta-hydroxy-17-methyl-2-oxa-5alpha-androstan-3-one) (33) Oxymesterone (4,17beta-dihydroxy-17-methylandrost-4-en-3-one) (34) Oxymetholone (17beta-hydroxy-2-(hydroxymethylene)-17-methyl-5alpha-androstan-3-one) (35) Prasterone (3beta-hydroxyandrost-5-en-17-one)

	(36) Quinbolone (17beta-(1-cyclopenten-1-yloxy)androsta-1,4-dien-3-one) (37) Stanozolol (17beta-hydroxy-17-methyl-5alpha-androstano[3,2-c]pyrazole) (38) Stenbolone (17beta-hydroxy-2-methyl-5alpha-androst-1-en-3-one) (39) Testosterone (17beta-hydroxyandrost-4-en-3-one) (40) Tibolone ((7alpha,17alpha)-17-hydroxy-7-methyl-19-norpregn-5(10)en-20-yn-3-one) (41) Tiomesterone (1alpha,7alpha-bis(acetylthio)-17beta-hydroxy-17-methylandrost-4-en-3-one) (42) Trenbolone (17beta-hydroxyestra-4,9,11-trien-3-one)
2	Zeranol (3,4,5,6,7,8,9,10,11,12-decahydro-7,14,16-trihydroxy-3-methyl-1H-2-benzoxacyclotetradecin-1-one)

SCHEDULE 3

(Subsection 1(1), paragraphs 5(1)(c), 11(1)(f), 12(1)(c) and (i), 34(1)(h), 39(d), 42(1)(h), 47(d), 56(d), 57(1)(d), 58(1)(d), 59(d), 61(d), 62(d) and 69(1)(d), subparagraph 72(e)(iv), paragraphs 73(1)(g), 75(d), 76(d), 77(a), 78(b), 80(g), 81(d), 82(d), 83(b), 84(e), 85(1)(a), 92(3)(d), 93(1)(d) and (2)(e), 94(1)(d), 95(d), 97(d), 111(d), 112(d), 117(d), 120(g), 121(f), 128(2)(d), 129(d), 141(c), 142(d), 143(2)(e) and 144(c), subparagraph 144(f)(ii), paragraphs 146(f), 147(f) and 158(3)(d), subparagraphs 159(1)(b)(iv) and 160(1)(b)(iv), paragraphs 161(1)(d) and (2)(d), 162(d), 175(d), 176(d), 177(d), 181(d), 182(g), 183(f), 205(1)(g), 210(d), 213(1)(g) and 218(d), sections 225 and 226 and paragraph 229(1)(c))

Targeted Substances

PART 1

Item	Name
1	Flunitrazepam (5-(o-fluorophenyl)-1,3-dihydro-1-methyl-7-nitro-2H-1,4-benzodiazepin-2-one) and any of its salts or derivatives

PART 2

Item	Name

1	Benzodiazepines, their salts and derivatives, including (1) Alprazolam (8-chloro-1-methyl-6-phenyl-4H-s-triazolo[4,3-a][1,4]benzodiazepine) (2) Bromazepam (7-bromo-1,3-dihydro-5-(2-pyridyl)-2H-1,4-benzodiazepin-2-one) (3) Brotizolam (2-bromo-4-(o-chlorophenyl)-9-methyl-6H-thieno[3,2-f]-s-triazolo[4,3-a][1,4]diazepine) (4) Camazepam (7-chloro-1,3-dihydro-3-(N,N-dimethylcarbamoyl)-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one) (5) Chlordiazepoxide (7-chloro-2-(methylamino)-5-phenyl-3H-1,4-benzodiazepine-4-oxide) (6) Clobazam (7-chloro-1-methyl-5-phenyl-1H-1,5-benzodiazepine-2,4(3H,5H)-dione) (7) Clonazepam (5-(o-chlorophenyl)-1,3-dihydro-7-nitro-2H-1,4-benzodiazepin-2-one) (8) Clorazepate (7-chloro-2,3-dihydro-2,2-dihydroxy-5-phenyl-1H-1,4-benzodiazepine-3-carboxylic acid) (9) Cloxazolam (10-chloro-11b-(o-chlorophenyl)-2,-3,7,11b-tetrahydrooxazolo [3,2-d] [1,4]benzodiazepin-6[5H]-one) (10) Delorazepam (7-chloro-5-(o-chlorophenyl)-1,3-dihydro-2H-1,-4-benzodiazepin-2-one) (11) Diazepam (7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one) (12) Estazolam (8-chloro-6-phenyl-4H-s-triazolo[4,3-a][1,4]benzodiazepine) (13) Ethyl Loflazepate (ethyl 7-chloro-5-(o-fluorophenyl)-2,3-dihydro-2-oxo-1H-1,4-benzodiazepine-3-carboxylate) (14) Fludiazepam (7-chloro-5-(o-fluorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepin-2-one) (15) Flurazepam (7-chloro-1-[2-(diethylamino)ethyl]-5-(o-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one) (16) Halazepam (7-chloro-1,3-dihydro-5-phenyl-1-(2,2,-2-trifluoroethyl)-2H-1,4-benzodiazepin-2-one) (17) Haloxazolam (10-bromo-11b-(o-fluorophenyl)-2,3,7,11b-tetrahydrooxazolo[3,2-d] [1,4]benzodiazepin-6(5H)-one) (18) Ketazolam (11-chloro-8,12b-dihydro-2,8-dimethyl-12b-phenyl-4H-[1,3]-oxazino-[3,2-d] [1,4]benzodiazepine-4,7(6H)-dione) (19) Loprazolam (6-(o-chlorophenyl)-2,4-dihydro-2-[(4-methyl-1-piperazinyl)methylene]-8-nitro-1H-imidazo[1,2-a][1,4]-benzodiazepin-1-one) (20) Lorazepam (7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-2H-1,4-benzodiazepin-2-one) (21) Lormetazepam (7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-1-methyl-2H-1,4-benzodiazepin-2-one) (22) Medazepam (7-chloro-2,3-dihydro-1-methyl-5-phenyl-1H-1,4-benzodiazepine) (23) Midazolam (8-chloro-6-(o-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine) (24) Nimetazepam (1,3-dihydro-1-methyl-7-nitro-5-phenyl-2H-1,4-benzodiazepin-2-one) (25) Nitrazepam (1,3-dihydro-7-nitro-5-phenyl-2H-1,4-benzodiazepin-2-one) (26) Nordazepam (7-chloro-1,3-dihydro-5-phenyl-2H-1,4-benzodiazepin-2-one) (27) Oxazepam (7-chloro-1,3-dihydro-3-hydroxy-5-phenyl-2H-1,4-benzodiazepin-2-one) (28) Oxazolam (10-chloro-2,3,7,11b-tetrahydro-2-methyl-11b-phenyloxazolo[3,2-d][1,4]benzodiazepin-6(5H)-one)

	(29) Pinazepam (7-chloro-1,3-dihydro-5-phenyl-1-(2-propynyl)-2H-1,4-benzodiazepin-2-one) (30) Prazepam (7-chloro-1-(cyclopropylmethyl)-1,3-dihydro-5-phenyl-2H-1,4-benzodiazepin-2-one) (31) Quazepam (7-chloro-5-(o-fluorophenyl)-1,3-dihydro-1-(2,2,2-trifluoroethyl)-2H-1,4-benzodiazepine-2-thione) (32) Temazepam (7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one) (33) Tetrazepam (7-chloro-5-(cyclohexen-1-yl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepin-2-one) (34) Triazolam (8-chloro-6-(o-chlorophenyl)-1-methyl-4H-s-triazolo-[4,3-a][1,4]benzodiazepine) but not including (35) Clozapine (8-chloro-11-(4-methyl-1-piperazinyl)-5H-dibenzo[b,e][1,4]diazepine) and any of its salts (36) Flunitrazepam (5-(o-fluorophenyl)-1,3-dihydro-1-methyl-7-nitro-2H-1,4-benzodiazepin-2-one) and any of its salts or derivatives (37) Olanzapine (2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-b][1,5]benzodiazepine) and its salts (38) Clozapine N-oxide (8-chloro-11-(4-methyl-4-oxido-1-piperazinyl)-5H-dibenzo[b,e][1,4]diazepine) and its salts
2	Clotiazepam (5-(o-chlorophenyl)-7-ethyl-1,3-dihydro-1-methyl-2H-thieno[2,3-e]-1,4-diazepin-2-one) and its salts
3	Ethchlorvynol (ethyl-2-chlorovinyl ethynyl carbinol)
4	Ethinamate (1-ethynylcyclohexanol carbamate)
5	Fencamfamin (d,l-N-ethyl-3-phenylbicyclo[2,2,1]heptan-2-amine) and its salts
6	Fenproporex (d,l-3-[(alpha-methylphenethyl)amino]propionitrile) and its salts
7	Mazindol (5-(p-chlorophenyl)-2,5-dihydro-3H-imidazo[2,1-a]isoindol-5-ol)
8	Mefenorex (d,l-N-(3-chloropropyl)-alpha-methylbenzeneethanamine) and its salts
9	Meprobamate (2-methyl-2-propyl-1,3-propanedioldicarbamate)
10	Methyprylon (3,3-diethyl-5-methyl-2,4-piperidinedione)
11	Pipradrol (alpha,alpha-diphenyl-2-piperidinemethanol) and its salts
12	Zolpidem (N,N,6-trimethyl-2-(4-methylphenyl)imidazo[1,2-a]pyridine-3-acetamide) and its salts
13	Carisoprodol (2-((carbamoyloxy)methyl)-2-methylpentyl isopropylcarbamate)

SCHEDULE 4

(Subsections 1(1) and 6(1) and (2), paragraphs 11(1)(f), 12(1)(c) and (i), 34(1)(h), 39(d), 42(1)(h), 47(d), 56(d), 61(d), 62(d) and 69(1)(d), subparagraph 72(e)(iv), paragraphs 73(1)(g), 75(d), 76(d), 77(a), 78(b), 80(g), 81(d), 82(d), 83(b), 84(e), 85(1)(a), 128(2)(d), 129(d), 141(c), 142(d), 143(2)(e), 146(f) and 147(f),

section 198, paragraphs 205(1)(g), 210(d), 213(1)(g), 218(d) and 229(1)(c) and item 1 of Part 1 of Schedule 2)

Restricted Drugs

PART 1

Item	Name
1	The following amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues: (1) N-ethylamphetamine (N-ethyl-alpha-methylbenzeneethanamine) (2) 4-methyl-2,5-dimethoxyamphetamine (STP) (2,5-dimethoxy-4,alpha-dimethylbenzeneethanamine) (3) 3,4-methylenedioxyamphetamine (MDA) (alpha-methyl-1,3-benzodioxole-5-ethanamine) (4) 2,5-dimethoxyamphetamine (2,5-dimethoxy-alpha-methylbenzeneethanamine) (5) 4-methoxyamphetamine (4-methoxy-alpha-methylbenzeneethanamine) (6) 2,4,5-trimethoxyamphetamine (2,4,5-trimethoxy-alpha-methylbenzeneethanamine) (7) N-methyl-3,4-methylenedioxyamphetamine (MDMA) (N,alpha-dimethyl-1,3-benzodioxole-5-ethanamine) (8) 4-ethoxy-2,5-dimethoxyamphetamine (4-ethoxy-2,5-dimethoxy-alpha-methylbenzeneethanamine) (9) 5-methoxy-3,4-methylenedioxyamphetamine (7-methoxy-alpha-methyl-1,3-benzodioxole-5-ethanamine) (10) N,N-dimethyl-3,4-methylenedioxyamphetamine (N,N,alpha-trimethyl-1,3-benzodioxole-5-ethanamine) (11) N-ethyl-3,4-methylenedioxyamphetamine (N-ethyl-alpha-methyl-1,3-benzodioxole-5-ethanamine) (12) 4-ethyl-2,5-dimethoxyamphetamine (DOET) (4-ethyl-2,5-dimethoxy-alpha-methylbenzeneethanamine) (13) 4-bromo-2,5-dimethoxyamphetamine (4-bromo-2,5-dimethoxy-alpha-methylbenzeneethanamine) (14) 4-chloro-2,5-dimethoxyamphetamine (4-chloro-2,5-dimethoxy-alpha-methylbenzeneethanamine) (15) 4-ethoxyamphetamine (4-ethoxy-alpha-methyl-benzeneethanamine) (16) N-Propyl-3,4-methylenedioxyamphetamine (alpha-methyl-N-propyl-1,3-benzodioxole-5-ethanamine) (17) N-hydroxy-3,4-methylenedioxyamphetamine (N-[alpha-methyl-3,4-(methylenedioxy)phenethyl]hydroxylamine) (18) 3,4,5-trimethoxyamphetamine (3,4,5-trimethoxy-alpha-methylbenzeneethanamine)
2	Lysergic acid diethylamide (LSD) (N,N-diethyllysergamide) and its salts
3	N,N-Diethyltryptamine (DET) (3-[(2-diethylamino)ethyl]indole) and its salts
4	N,N-Dimethyltryptamine (DMT) (3-[(2-dimethylamino)ethyl]indole) and its salts
5	N-Methyl-3-piperidyl benzilate (LBJ) (3-[(hydroxydiphenylacetyl)oxy]-1-methylpiperidine) and its salts

6	Harmaline (4,9-dihydro-7-methoxy-1-methyl-3H-pyrido(3,4-b)indole) and its salts
7	Harmalol (4,9-dihydro-1-methyl-3H-pyrido(3,4-b)indol-7-ol) and its salts
8	Psilocin (3-[2-(dimethylamino)ethyl]-4-hydroxyindole) and its salts
9	Psilocybin (3-[2-(dimethylamino)ethyl]-4-phosphoryloxyindole) and its salts
10	N-(1-phenylcyclohexyl)ethylamine (PCE) and its salts
11	1-[1-(2-Thienyl)cyclohexyl]piperidine (TCP) and its salts
12	1-Phenyl-N-propylcyclohexanamine and its salts
13	Mescaline (3,4,5-trimethoxybenzeneethanamine) and its salts, but not peyote (lophophora)
14	2-Methylamino-1-phenyl-1-propanone and its salts
15	1-[1-(Phenylmethyl)cyclohexyl]piperidine and its salts
16	1-[1-(4-Methylphenyl)cyclohexyl]piperidine and its salts
17	Etryptamine (3-(2-aminobutyl)indole) and its salts
18	Rolicyclidine (1-(1-phenylcyclohexyl)pyrrolidine) and its salts
19	Benzylpiperazine (BZP), namely 1-benzylpiperazine and its salts, isomers and salts of isomers
20	Trifluoromethylphenylpiperazine (TFMPP), namely 1-(3-trifluoromethylphenyl)piperazine and its salts, isomers and salts of isomers
21	Methylenedioxypyrovalerone (MDPV), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues
22	Cathinone ((-)-alpha-aminopropiophenone) and its salts
23	2C-phenethylamines and their salts, derivatives, isomers and salts of derivatives and isomers that correspond to the following chemical description: any substance that has a 1-amino-2-phenylethane structure substituted at the 2' and 5' or 2' and 6' positions of the benzene ring by an alkoxy or haloalkoxy group, or substituted at two adjacent carbon atoms of the benzene ring which results in the formation of a furan, dihydrofuran, pyran, dihydropyran or methylenedioxy group — whether or not further substituted on the benzene ring to any extent, whether or not substituted at the amino group by one or two, or a combination of, methyl, ethyl, propyl, isopropyl, hydroxyl, benzyl (or benzyl substituted to any extent) or benzylene (or benzylene substituted to any extent) groups and whether or not substituted at the 2-ethyl (beta carbon) position by a hydroxyl, oxo or alkoxy group — and its salts and derivatives and salts of derivatives, including (1) 4-bromo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25B-NBOMe) (2) 4-chloro-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25C-NBOMe) (3) 4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25I-NBOMe) (4) 4-bromo-2,5-dimethoxybenzeneethanamine (2C-B)
24	AH-7921 (1-(3,4-dichlorobenzamidomethyl)cyclohexyldimethylamine), its salts, isomers and salts of isomers

25	MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, including (1) Diphenidine (DEP) (1-(1,2-diphenylethyl)piperidine) (2) Methoxphenidine (2-MeO-Diphenidine, MXP) (1-[1-(2-methoxyphenyl)-2-phenylethyl]piperidine) (3) Ephenidine (NEDPA, EPE) (N-ethyl-1,2-diphenylethylamine) (4) Isophenidine (NPDPA) (N-isopropyl-1,2-diphenylethylamine) but not including (5) Lefetamine ((-)-N,N-dimethyl-alpha-phenylbenzeneethanamine), its salts, derivatives and isomers and salts of derivatives and isomers
26	W-18 (4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-piperidinylidene]benzenesulfonamide), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues
27	U-47700 (3,4-dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, including (1) Bromadoline (4-bromo-N-(2-(dimethylamino)cyclohexyl)benzamide) (2) U-47109 (3,4-dichloro-N-(2-(dimethylamino)cyclohexyl)benzamide) (3) U-48520 (4-chloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide) (4) U-50211 (N-(2-(dimethylamino)cyclohexyl)-4-hydroxy-N-methylbenzamide) (5) U-77891 (3,4-dibromo-N-methyl-N-(1-methyl-1-azaspiro[4.5]decan-6-yl)benzamide)

PART 2

Item	Name
1	*Salvia divinorum* (*S. divinorum*), its preparations and derivatives, including (1) Salvinorin A ((2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(3-furanyl)dodecahydro-6a,10b-dimethyl-4,10-dioxo-2H-naphtho[2,1-c]pyran-7-carboxylic acid methyl ester)
2	*Catha edulis* Forsk, its preparations, derivatives, alkaloids and salts, including (1) Cathine (d-threo-2-amino-1-hydroxy-1-phenylpropane) but not including (2) Cathinone ((-)-alpha-aminopropiophenone) and its salts

PART 3

Item	Column 1 Substance	Column 2 Period

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Order or the regulations*.)

Executive summary

Issues: The current regulatory framework governing legitimate activities with controlled substances requires consolidation and modernization. The framework features inconsistencies across similar provisions that apply to different categories of controlled substances. It also lacks a regular authorization pathway for certain legitimate activities and contains provisions that have not kept pace with the evolution of current practices and operations of regulated parties. This has caused unnecessary burden and challenges for Health Canada and regulated parties with respect to the administration of and compliance with the regulations.

Description: The *Controlled Substances Regulations* (CSR), which will come into force on October 1, 2026, consolidate the *Narcotic Control Regulations*, the *Benzodiazepines and Other Targeted Substances Regulations*, Parts G and J of the *Food and Drug Regulations,* and the *New Classes of Practitioners Regulations* and incorporate six class exemptions into one new set of regulations. The CSR will provide a comprehensive regulatory framework governing legitimate activities with all categories of controlled substances (i.e. narcotics, controlled drugs, targeted substances, and restricted drugs) conducted by licensed dealers, pharmacists, practitioners, hospitals and individuals. The CSR contain harmonized regulatory authorizations with respect to regulated activities and requirements regarding record-keeping, security, and reporting. In addition, consequential and coordinating amendments to related regulations (i.e. the *Cannabis Regulations*, the *Precursor Control Regulations*, the *Food and Drug Regulations* and certain fees regulations) are included.

Rationale: Given the gaps and inconsistencies that exist in the current regulations, regulatory changes are the only option to address the identified issues. As set out in Health Canada and the Public Health Agency of Canada's September 2025 Report on Red Tape Reduction, consolidation of the regulations will streamline and simplify the overall regulatory framework, while also removing unnecessary regulatory barriers and improving the clarity and readability of the regulations.

The CSR will bring benefits and costs to regulated parties as well as to provincial, territorial and federal governments. Benefits to regulated parties include expanded authorizations for certain activities (e.g. central filling of prescriptions), removal of regulatory barriers (enabling therapeutic substitution of medications containing controlled substances), reduction in administrative costs (reduced reporting requirements) and improvement in the clarity and consistency of regulatory provisions. Benefits to provincial / territorial governments include the removal of a federal regulatory barrier with respect to therapeutic substitution. The benefits to

Health Canada are associated with reductions in activities associated with the administration of the regulations due to their consolidation. Regulatory costs to industry are associated with new record-keeping and notification requirements and with transition to the new regulations. For Health Canada, the primary costs relate to compliance promotion, regulatory administration and enforcement activities. Costs at the provincial/territorial level are associated with changes to regulations, guidance and bylaws, as necessary, to reflect the CSR. Over 10 periods of 12 months, the regulations will result in estimated benefits of $4.85 million in present value (PV) and costs of $4.22 million (PV). Overall, the CSR and the amendments to the *Cannabis Regulations* will result in a net benefit of $0.62 million (PV) or an annualized net benefit of $88,674.

Issues

The Canadian legislative and regulatory framework for controlled substances has evolved over decades to address emerging issues and meet international commitments under the United Nations *International Drug Control Conventions*. This evolution has resulted in a series of regulations that, while containing broadly aligned provisions, also feature gaps and inconsistencies with respect to the authorizations and requirements that apply to the four different categories of controlled substances. While these regulations have been amended from time to time, the regulatory framework for controlled substances presents the following issues:

- Inconsistencies in the regulations for various categories of controlled substances can cause confusion and create unnecessary burden for Health Canada and regulated parties to administer the regulations or comply with them. For example, a pharmacist conducting activities with narcotics and targeted substances must comply with similar but sometimes different requirements under the *Narcotic Control Regulations* and the *Benzodiazepines and Other Targeted Substances Regulations*, respectively. As well, Health Canada inspectors must follow different compliance guidance when conducting an inspection, as requirements may vary for different categories of controlled substances under different regulations.
- In the absence of applicable authorizations in the current regulations (the *Narcotic Control Regulations*, the *Benzodiazepines and Other Targeted Substances Regulations*, Parts G and J of the *Food and Drug Regulations* and the *New Classes of Practitioners Regulations*), certain activities have been authorized through class exemptions granted under subsection 56(1) of the *Controlled Drugs and Substances Act*. This causes challenges for regulated parties who must be aware of the regulatory requirements as well as the various class exemptions that have been issued, resulting in further confusion regarding the manner in which to comply.
- Health Canada, through various consultations, heard that the regulatory provisions pertaining to pharmacists should be amended. Respondents requested that amendments be made to the regulations to make permanent certain authorizations provided through a time-limited class exemption (e.g. the extending/renewing of existing prescriptions by pharmacists) and to allow

pharmacists to substitute one controlled substance for another in the context of therapeutic substitutions. They also requested that pharmacy technicians be allowed to independently conduct activities with controlled substances in a pharmacy setting, in line with their scope of practice, and that barriers to central fill services with controlled substances be removed.

Background

Legislative framework for controlled substances

The *Controlled Drugs and Substances Act* (CDSA) provides a legislative framework for the control of substances that can alter mental processes and that pose risks to public health and public safety when used inappropriately or diverted to the illegal market. Defined as controlled substances, these substances are listed in Schedules I, II, III, IV and V to the CDSA. Some controlled substances have legitimate uses, for example, as marketed drugs that have been authorized pursuant to the *Food and Drugs Act* and its Regulations for the treatment of various medical conditions further to a scientific review of their safety, efficacy and quality. Among other things, the CDSA enables the Governor in Council to make regulations with respect to authorizing legitimate activities with controlled substances for medical, scientific or industrial purposes and to minimize the risk of them being diverted to the illegal market or activities.

The CDSA is one of the means by which Canada, as a signatory, fulfills its obligations under the United Nations *Single Convention on Narcotic Drugs, 1961* (1961 Convention), the *Convention on Psychotropic Substances, 1971* (1971 Convention) and the United Nations *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988* (1988 Convention). These conventions form the basis for the current international drug control system and require parties to the conventions to, among other things, place national controls on legitimate activities conducted by authorized persons or businesses with substances listed in the schedules of the conventions.

In general, and depending on which schedule a substance is listed in, the CDSA prohibits any person from conducting activities such as production, sale/provision, importation and exportation of controlled substances unless authorized by regulation or an exemption, and specifies the range of offences and penalties associated with conducting unauthorized activities with specific controlled substances.

The CDSA was enacted in 1996 by consolidating the *Narcotic Control Act* and Parts III and IV of the *Food and Drugs Act,* along with regulations made under them at the time. Since then, additional regulations have been made under the CDSA. Following the coming into force of the CDSA and its regulations in 1997, changes have been made to various provisions to address emerging issues and allow Canada to meet its international obligations under the above-mentioned United Nations conventions.

There are nine sets of regulations made or deemed to have been made under the CDSA. Among them, the following regulations, which will be repealed when the CSR take effect on October 1, 2026, provide a regulatory framework governing legitimate activities with four categories of controlled substances (i.e. narcotics, controlled drugs, targeted substances and restricted drugs) conducted by regulated parties such as licensed dealers, pharmacists, practitioners and hospitals:

- *Narcotic Control Regulations* (NCR): Originally made under the *Narcotic Control Act*, the NCR set out the circumstances and requirements under which producers, distributors, importers, exporters, pharmacists, practitioners and hospitals may conduct regulated activities with narcotics (mainly opioids such as morphine, codeine and fentanyl, and other substances such as cocaine).
- *Food and Drug Regulations — Part G* (FDR-G): Originally made under the *Food and Drugs Act* but deemed to be made under the CDSA, the FDR-G set out circumstances and requirements under which producers, distributors, importers, exporters, pharmacists, practitioners and hospitals may conduct activities with controlled drugs (mainly stimulants such as certain amphetamines with approved medical use, sedatives such as phenobarbital, and anabolic steroids such as testosterone).
- *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR): Made under the CDSA, the BOTSR, similar to the NCR, set out the circumstances and requirements under which producers, distributors, importers, exporters, pharmacists, practitioners and hospitals may conduct regulated activities with targeted substances (mainly central nervous system depressants such as benzodiazepines).
- *Food and Drug Regulations — Part J* (FDR-J): Originally made under the *Food and Drugs Act,* but deemed to be made under the CDSA, the FDR-J set out circumstances and requirements for producers, distributors, importers, exporters and researchers to conduct regulated activities with restricted drugs (stimulants such as certain amphetamines with no approved medical use and psychedelics such as psilocybin and LSD) for scientific research purposes. As restricted drugs have no approved therapeutic uses, the FDR-J contain no provisions in relation to pharmacists, practitioners and hospitals. Rather, these Regulations set out a unique mechanism whereby researchers can be authorized to obtain a restricted drug for scientific purposes, including for the purpose of clinical trials evaluating the safety and efficacy of restricted drugs.
- *New Classes of Practitioners Regulations* (NCPR): Made under the CDSA, the NCPR expand the definition of practitioner under the CDSA to include midwives, nurse practitioners and podiatrists so that they are authorized to conduct activities, including the prescribing of marketed drugs containing a controlled substance, in accordance with the NCR, the BOTSR and the FDR-G (with the exclusion of certain controlled substances).
- *Regulations Exempting Certain Precursors and Controlled Substances from the Application of the Controlled Drugs and Substances Act* (Exemption Regulations): These Regulations came into force

at the same time as the CDSA. The objective of the Exemption Regulations is to exempt certain precursors and controlled substances from the application of the CDSA until such a time as they can be scheduled under regulations. While most of the precursors and controlled substances have since been removed from the Exemption Regulations, three substances remain. Of these, two (bezitramide and piritramide) are opioids, and both are scheduled internationally. While currently there are no approved drugs containing these substances in Canada, it is possible that such drugs may be available in the future, since they are marketed in other countries. Both of these substances have been proposed to be added to the new schedule in the CSR for narcotics, ensuring that they will be subject to the CDSA and its regulations moving forward. The third substance (propylhexedrine) was previously scheduled internationally, but was removed from Schedule IV of the 1971 Convention in 1991. This substance has been proposed to remain uncontrolled in Canada.

Legitimate activities with controlled substances can be authorized either through regulations or through exemptions granted under subsection 56(1) of the CDSA. In order to address situations not captured by the regulations, Health Canada has issued class exemptions, including the following, which will also be repealed when the CSR take effect:

- *Section 56 Class Exemption For Travellers Who Are Importing or Exporting Prescription Drug Products Containing a Narcotic or a Controlled Drug*: Modelled after relevant provisions in the BOTSR, this exemption allows travellers to come into and depart from Canada with prescription drugs containing cannabis, a narcotic, or a controlled drug for their medical use.
- *Subsection 56(1) Class Exemption for Pharmacists, Practitioners, Persons in Charge of a Hospital and Licensed Dealers for the Provision and Destruction of Unserviceable Stock and Post-consumer Returns*: This exemption authorizes pharmacists, practitioners and hospitals to destroy controlled substances and cannabis on-site or to send them to a licensed dealer for the purpose of destruction. This exemption also permits individuals to take a prescription drug containing a controlled substance or cannabis (defined as a post-consumer return in the exemption) to a retail pharmacy for the purpose of destruction. Furthermore, a licensed dealer is exempted from the record-keeping requirement set out in regulations with respect to the name and quantity of a controlled substance in the context of post-consumer return.
- *Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada*: Originally issued in response to the COVID-19 pandemic, this exemption expands certain authorities set out in the regulations under the CDSA with respect to the practice of pharmacists, such as prescribing and selling a controlled substance to a patient in order to extend or renew an existing prescription, and allowing practitioners to verbally prescribe any controlled substance.
- *Subsection 56(1) class exemption for practitioners, agents, pharmacists, persons in charge of a hospital, hospital employees, and licensed dealers to conduct activities with psilocybin and MDMA in*

relation to a special access program authorization: Health Canada's Special Access Program (SAP) allows practitioners to request access to drugs that have shown promise in clinical trials or have been approved in other countries, but that have not been authorized for sale in Canada. This program provides access to non-marketed drugs for the emergency treatment of patients with serious or life-threatening conditions in instances where conventional therapies have failed, are unsuitable or are unavailable. The ability for health care practitioners to request access to restricted drugs such as N-methyl-3,4-methylenedioxyamphetamine (MDMA) and psilocybin through the SAP was restored in January 2022 through regulatory amendments to Part C of the Food and Drug Regulations (FDR). This exemption authorizes the relevant regulated parties mentioned above to conduct activities with psilocybin and MDMA if the sale of the drug has been authorized through the SAP for the emergency treatment of a patient.

- *Subsection 56(1) Class Exemption for Certain Practitioners to Administer Designated Drugs for Therapeutic Use*: This exemption enables practitioners of medicine, dentistry or veterinary medicine and nurse practitioners to administer a prescription medication containing a designated drug (a term defined in the FDR-G referring to amphetamine, benzphetamine, methamphetamine, phenmetrazine and phendimetrazine) to a patient under their professional treatment if they decide the designated drug is required for the condition for which the patient is receiving treatment.
- *Subsection 56(1) Class Exemption for Nurse Practitioners to Prescribe Anabolic Steroids for Therapeutic Use*: This exemption enables nurse practitioners to prescribe and possess a prescription medication containing an anabolic steroid other than testosterone, provided this is allowed under their provincial scope of practice.

Recognizing the need to amend the regulations for controlled substances to improve the administration of and compliance with the regulations, Health Canada undertook a strategic regulatory modernization initiative with a view to updating, harmonizing and eventually consolidating the above-mentioned regulations. As a first step, Health Canada modernized the licensing and permitting scheme in the NCR, the BOTSR, the FDR-G and the FDR-J in 2019. Following targeted consultations on certain aspects of the regulations, on June 1, 2024, Health Canada published the proposed *Controlled Substances Regulations* in the *Canada Gazette*, Part I, for a 60-day public comment period.

Legislative framework for cannabis

The *Cannabis Act* and the *Cannabis Regulations* create a framework for the legal production, distribution, sale and possession of cannabis in Canada. When this legislation came into force in 2018, cannabis was removed from the purview of the CDSA and the NCR, and placed under the *Cannabis Act* and the *Cannabis Regulations*. [6]

Since legitimate activities with cannabis were previously regulated under the NCR, provisions in the *Cannabis Regulations* on drugs containing cannabis and test kits were modelled after certain provisions of the NCR.

In accordance with transitional provisions under the *Cannabis Act*, the *Section 56 Class Exemption For Travellers Who are Importing or Exporting Prescription Drug Products Containing a Narcotic or a Controlled Drug* applies to prescribed drugs containing cannabis (e.g. Sativex and Epidiolex) and controlled substances and will continue to do so until this exemption is revoked when the CSR come into force. It is important to note that it remains illegal to take other cannabis, such as cannabis products and cannabis for medical purposes, across the Canadian border. The *Subsection 56(1) Class Exemption for Pharmacists, Practitioners, Persons in Charge of a Hospital and Licensed Dealers for the Provision and Destruction of Unserviceable Stock and Post-consumer Returns* also applies to controlled substances and cannabis until this exemption is revoked when the CSR come into force.

Objective

The objectives of these Regulations are

- to further improve the administration of and compliance with the regulations by harmonizing, consolidating and modernizing provisions in the regulations for controlled substances and by improving alignment between the *Cannabis Regulations* and the CSR;
- to support pharmacy innovation in Canada and enable pharmacists and pharmacy technicians to more fully use their expertise as medication experts; and
- to further enhance the clarity and readability of the regulations by consolidating and improving alignment for controlled substances, drugs containing cannabis, and test kits containing a controlled substance or cannabis with the application of up-to-date legislative drafting conventions.

Description

Controlled Substances Regulations

With a view to maintaining and modernizing the regulations for controlled substances, upon coming into force on October 1, 2026, the CSR will

- consolidate the different regulations into one new set of regulations for controlled substances, while harmonizing provisions as needed, and streamlining and removing out-of-date provisions where appropriate;
- incorporate authorizations granted through the subsection 56(1) class exemptions listed in the “Background” section above; and
- create new provisions to address gaps and issues identified by Health Canada and through public consultations.

The CSR contain the following parts:

Interpretation

This part contains definitions for terms used in the regulations. Most of the definitions are consolidated from the current regulations; however, new definitions are also provided with respect to certain terms now used in the CSR and to enhance clarity and improve readability of the regulatory text. For example, in addition to definitions for categories of controlled substances, definitions are added for finished products and mixtures to improve clarity with respect to requirements that apply to forms of products that contain controlled substances.

General

Consolidating and streamlining provisions in the current regulations, this part contains a provision regarding non-application for members of a police force and a provision regarding non-application for agricultural implants containing anabolic steroids (which are regulated as veterinary drugs under the FDR). For greater clarity, this part also includes a provision setting out authorizations and requirements for agents and mandataries of a person regulated under the CSR. For instance, while being authorized to independently conduct certain activities, a pharmacy technician can also conduct an activity as an agent or mandatary of a pharmacist if the pharmacist delegates such activity to the pharmacy technician. The pharmacy technician must comply with the requirements that apply to the pharmacist with respect to that activity.

Possession

Because the possession of controlled substances listed in Schedules I, II and III of the CDSA is prohibited unless authorized, this part consolidates provisions in the current regulations that provide authorizations for regulated persons such as licensed dealers, pharmacists, pharmacy technicians, practitioners, and hospitals, as well as members of a police force, certain government employees, persons exempted under subsection 56(1) of the CDSA, and other authorized persons and individuals to legally possess such substances.

Licensed dealers

This part sets out a licensing scheme governing the activities conducted by producers, distributors, importers and exporters of controlled substances. As the regime related to licensed dealers was streamlined and modernized in 2019, provisions regarding licensed dealers in the CSR remain largely the same in comparison with those in the current regulations. The following key elements of this part remain unchanged:

- With specified eligibility, a business or individual must obtain a licence to produce, package, sell or provide to other regulated or exempted parties, import, export, send, deliver and transport controlled substances.

- Licensed dealers can import or export controlled substances; to do so, they must first obtain an import or export permit.
- A licensed dealer must comply with requirements with respect to responsible personnel, record-keeping, security for storage and during transportation, and reporting on regulated activities and loss or theft. Non-compliance may result in the suspension or revocation of their licence or permit.
- This part also sets out circumstances in which a licensed dealer may destroy a controlled substance.

Additional regulatory changes will be made through the CSR, including the following:

- Consistent with regulations such as the *Cannabis Regulations* and the *Precursor Control Regulations*, the CSR include new provisions that will authorize the Minister to partially suspend a licence with respect to any activities with controlled substances.
- The current regulations require annual reports on regulated activities, even though, in practice, such reports are provided monthly. To align the regulations with current practice, the CSR will require that such reports be submitted monthly.
- Instead of requiring that a licensed dealer report unexplainable losses of controlled substances to both a member of a police force and Health Canada, as in the current regulations, the CSR will require a licensed dealer to report such losses only to Health Canada. As is currently the case, the CSR will require licensed dealers to report thefts to both police and Health Canada. Further, as losses and thefts must be reported to Health Canada as per prescribed timelines, the CSR will reduce reporting duplication by no longer requiring that such information also be included in monthly reports.
- Further to the authorization in the current regulations that allows a licensed dealer, whose licence permits them to do so to sell or provide a restricted drug to an authorized researcher, the CSR will allow them to sell or provide a restricted drug to a practitioner if a letter of authorization has been granted by Health Canada's SAP in accordance with section C.08.010 of the FDR. In response to stakeholder feedback indicating the need for licensed dealers to be able to sell or provide restricted drugs to other licensed dealers for operational reasons, such as testing and packaging, the CSR will also authorize a licensed dealer to sell or provide a restricted drug to another licensed dealer.
- Adding to the requirements with respect to record-keeping set out in the current regulations, the CSR will establish a simplified record-keeping requirement for controlled substances returned by an individual to a pharmacy, as set out in the class exemption regarding destruction by health care professionals. Further, the CSR will require that licensed dealers receive approval from the Minister to make changes to their record-keeping methods before implementing such changes.

- The current regulations require designated responsible personnel to provide proof of a criminal record check conducted by a police force. The CSR will allow the submission of proof of a criminal record check conducted by a fingerprinting service that is accredited to reflect the fact that such companies are now accredited by the Royal Canadian Mounted Police for conducting criminal record checks and issuing reports.
- The CSR will require additional information on an import or export permit application with respect to the shipment, such as proposed port of entry/exit and mode of transportation, so that Health Canada can conduct a better informed review of the application.
- Further to the authorization that allows a pharmacist or hospital to return a controlled substance to the licensed dealer who sold or provided it or to a licensed dealer who is specialized in destruction, the CSR will authorize a pharmacist, practitioner or hospital to sell or provide a controlled substance to any licensed dealers (for purposes such as return or destruction).
- Finally, in response to feedback received during the comment period of the prepublication, the CSR will further authorize a licensed dealer to possess a controlled substance received from a practitioner, a hospital or a particular person (defined in the regulations as a person that, in the course of their operations, unexpectedly receives a controlled substance from an individual for the purposes of destruction) that was returned to them by an individual for the purpose of destruction.

Pharmacists and pharmacy technicians

As with the current regulations, this part sets out circumstances in which pharmacists may conduct activities with controlled substances (other than restricted drugs). This part is not applicable to pharmacists working in a hospital. Pharmacists working in a hospital are considered hospital employees who must conduct activities with controlled substances in accordance with the provisions in the part for hospitals.

By consolidating relevant provisions in the current regulations, the CSR will continue to authorize a pharmacist to, among other activities,

- sell or provide a controlled substance to a patient pursuant to a prescription issued by a practitioner;
- sell or provide a controlled substance to a person exempted under subsection 56(1) of the CDSA, provided the exemption permits the sale or provision;
- sell or provide a controlled substance to another pharmacist for emergency purposes;
- sell or provide a controlled substance to another pharmacist, a practitioner or a hospital; and
- sell or provide a controlled substance to a licensed dealer for the purposes of return or destruction.

Further to the above, the authorization for sale or provision also permits pharmacists to conduct the following activities, as long as the quantity dispensed does not exceed the total quantity originally specified in a prescription issued by a practitioner:

- Adjusting the formulation, dose or regimen;
- De-prescribing; and
- Part-filling.

For consistency and where appropriate, the CSR contain more detailed requirements regarding record-keeping, protective measures and reporting of losses or thefts, as well as provisions regarding restrictions on sale under specified circumstances. Modelled after relevant provisions in the BOTSR, the CSR further authorize a pharmacist to compound, send, deliver and transport a controlled substance to a patient pursuant to a prescription, sell or provide a controlled substance to a practitioner or the Minister, and transfer a prescription to another pharmacist.

The CSR also incorporate authorizations for pharmacists conducting certain activities currently permitted pursuant to certain subsection 56(1) class exemptions, such as destroying a controlled substance on site or sending such product to a licensed dealer who is specialized in destruction, and extending a prescription issued by a practitioner. To address feedback received on the draft regulations, the final CSR specify that a pharmacist can only extend a prescription for up to two years since they received the prescription, to align with timelines associated with record-keeping.

In addition to current authorizations regarding sale/provision by pharmacists, the CSR will allow a pharmacist to sell or provide a controlled substance to another pharmacist for the purpose of filling a prescription. This authorization will provide additional flexibility with respect to how prescriptions are filled and will enable models such as central fill services for controlled substances.

In response to the publication of the draft regulations, Health Canada heard from pharmacy stakeholders that allowing pharmacists to substitute a controlled substance for another medication with an equivalent effect (therapeutic substitution) would benefit patients by allowing pharmacists to substitute medications in situations such as a drug shortage, or if the patient does not tolerate the prescribed medication. To address the feedback received, the final CSR will allow pharmacists to substitute a controlled substance for another controlled substance specified in a prescription, provided they have been authorized to do so in the province where they practise. Therapeutic substitution for certain medications by pharmacists has been authorized under provincial laws in the majority of jurisdictions in Canada, aiming to further ensure the continuity of patient care.

The CSR will authorize a pharmacy technician to independently conduct many of the activities that a pharmacist is authorized to conduct. The intent is to enable pharmacy technicians to independently conduct certain activities with controlled substances in accordance with their scope of practice. These authorized activities include compounding, sending, delivering or transporting a controlled substance, transferring a prescription to a pharmacist or another pharmacy technician, or destroying

a controlled substance on site. Further, in response to stakeholder feedback on the draft regulations, the final CSR subject a pharmacy technician to the responsibilities of record-keeping and security for activities they are allowed to conduct independently.

It should be noted that only pharmacists are authorized, with patient consultation, to sell or provide prescription drugs to a patient, including those that contain controlled substances (patient consultation is not part of the scope of practice for pharmacy technicians regulated under provincial legislation).

Practitioners

This part sets out circumstances in which "practitioners," as defined in the CDSA (physicians, dentists and veterinarians) and as prescribed in the CSR (currently: nurse practitioners, midwives and podiatrists), can conduct activities with controlled substances, similar to the current regulations.

Once in force, the CSR will continue to authorize a practitioner to prescribe, administer, sell or provide a narcotic, controlled drug or targeted substance to a patient who is under their professional care.

In addition, the CSR contain more detailed requirements regarding record-keeping (including newly added requirements with respect to post-consumer returns), protective measures and reporting of losses or thefts. Modelled after provisions in the BOTSR that apply to targeted substances, the CSR will also authorize a practitioner to send, deliver and transport a controlled substance, and to sell or provide a controlled substance to a licensed dealer or the Minister.

In response to stakeholder feedback that health care practitioners' offices should be legally authorized to accept post-consumer returns, the CSR will also authorize a practitioner to destroy a post-consumer return or to sell or provide controlled substances to a licensed dealer specialized in destruction so that the products can be destroyed.

The CSR also incorporate authorizations for practitioners conducting certain activities currently allowed through subsection 56(1) class exemptions, such as verbally prescribing any controlled substance, destroying a controlled substance on site or sending it to a licensed dealer who is specialized in destruction, or administering, selling or providing a restricted drug to a patient if the sale of the restricted drug has been authorized under the SAP in accordance with section C.08.010 of the FDR.

Paragraph G.04.001(3)(a) of the FDR-G limits the prescribing, sale or provision of "designated drugs" by certain practitioners to certain indications only (e.g. hyperkinetic disorders in children), despite additional authorized uses and off-label uses. A subsection 56(1) class exemption was put in place in 2023, which allows doctors of medicine, dentistry, or veterinary medicine and nurse practitioners to prescribe designated drugs for therapeutic use without any limitations. Consistent with this class exemption, the CSR do not include any limits on how these drugs can be prescribed.

Hospitals

As with the current regulations, this part sets out circumstances in which hospitals, including pharmacists or practitioners working in a hospital, can conduct activities with controlled substances (other than restricted drugs).

Consistent with the current regulations, the CSR will continue to authorize a person in charge of a hospital to permit the following activities with controlled substances in that hospital:

- Administration of a controlled substance to a patient pursuant to a prescription issued by a practitioner;
- Selling or providing a controlled substance to a patient pursuant to a prescription; and
- Selling or providing a controlled substance to a pharmacist, or another hospital for emergency purposes.

In addition, the CSR contain provisions that set out more detailed requirements regarding record-keeping, protective measures and reporting of losses or thefts. Modelled after provisions in the BOTSR, the CSR will authorize a hospital to sell or provide a controlled substance to a practitioner for emergency purposes, a licensed dealer or the Minister, and to send, deliver and transport a controlled substance.

The CSR also allow hospitals to conduct certain activities by incorporating authorizations set out in class exemptions granted under subsection 56(1) for a person in charge of a hospital, such as destroying a controlled substance on site or sending it to a licensed dealer who is specialized in destruction.

In response to stakeholder feedback that hospitals should be legally authorized to accept post-consumer returns, the CSR will authorize a hospital to destroy a post-consumer return or to sell or provide it to a licensed dealer specialized in destruction for the purpose of destruction and will require the keeping of relevant records.

To align with the authorized activities for pharmacists and pharmacy technicians, this part will authorize the person in charge of a hospital to allow compounding of controlled substances in the hospital.

For improved clarity and readability, the CSR include a new definition for person in charge of a hospital and a new provision setting out the following persons who can conduct activities with controlled substances if allowed by the person in charge of a hospital:

- Health care professionals, in accordance with their scope of practice; and
- Other hospital employees in accordance with their duties and functions.

Minister

Modelled after provisions in the current regulations with necessary adjustments, this part will authorize the Minister to, in certain circumstances, communicate factual information that has been obtained under the CDSA or the CSR about a pharmacist, pharmacy technician, practitioner or any other health professional to the relevant provincial professional regulatory authority. In response to feedback from stakeholders on the draft regulations, this provision has been further expanded to include a new circumstance in which the Minister will be able to communicate such information to a provincial government or a provincial professional regulatory authority if the Minister has reasonable grounds to believe that the provision of such information is necessary to assist the provincial government or the regulatory authority in monitoring the professional conduct of a relevant professional in accordance with the laws of a province, for the purpose of protecting public health and safety.

Under the CDSA, the Minister has the authority to temporarily schedule a substance of concern for a period of one year, through a pathway known as temporary accelerated scheduling. This involves listing the substance in Schedule V to the CDSA and the schedule of the FDR-J. The CSR will continue to include a provision authorizing the Minister to add, by order, a temporarily scheduled substance to the appropriate CSR schedule as a restricted drug in accordance with Schedule V to the CDSA.

Consistent with regulations such as the *Cannabis Regulations* and the *Precursor Control Regulations*, the CSR include new provisions that will authorize the Minister to communicate certain information collected under the CSR and, in some cases, the CDSA with a customs officer, the International Narcotics Control Board and foreign competent authorities to mitigate the risk of diversion and fulfill Canada's international obligations under the United Nations drug control conventions.

Within Health Canada, the Office of Controlled Substances has played a long-standing role in assisting authorized researchers and health care practitioners who are not licensed to import controlled substances into Canada. Under the current regulations, Health Canada's Office of Controlled Substances must be licensed in order to conduct such activities, creating unnecessary administrative burden. The final CSR include newly added provisions excluding the Minister from the application of the provisions in the licensed dealer part. Once the CSR are in force, the Minister will be authorized to import a controlled substance that is intended to be sold or provided to a person exempted under subsection 56(1) of the CDSA or a practitioner who is named in a letter of authorization under section C.08.010 of the FDR (under the SAP). The Minister will also be authorized to export a controlled substance.

Government laboratories

Government-operated laboratories providing forensic and toxicology services play an important role in supporting administration and enforcement of the CDSA. Further to comments received after the prepublication, the final CSR now introduce a new framework, similar to the one that exists for cannabis under subsection 4(1) of the *Cannabis Regulations*, to authorize forensic and toxicology laboratories operated by the federal or a provincial government to conduct activities with controlled

substances. While these laboratories will still need to obtain a permit to import or export a controlled substance, they will not need to obtain a licence to produce, sell, provide, send, deliver, transport, import or export a controlled substance.

Particular persons

In response to stakeholder feedback after prepublication that municipalities should be legally authorized to accept post-consumer returns, this new part in the final CSR will authorize a person (e.g. a municipal waste management facility) who unexpectedly receives a controlled substance for the purpose of destruction to sell, provide, send, deliver and transport that substance to a pharmacist, licensed dealer or police force for the purpose of destruction.

Individuals

This part authorizes an individual to sell, provide, import, export, deliver or transport a controlled substance under certain circumstances.

Modelled after provisions in the BOTSR and incorporating the subsection 56(1) class exemption that allows individuals to import or export prescription drugs containing cannabis, a narcotic or a controlled drug required to meet their medical needs when entering or leaving Canada, the CSR will authorize an individual to import or export a controlled substance, other than a restricted drug, that has been authorized by a health care provider to them for their personal use, or that of an accompanying individual or animal. The new authorization will allow for up to a 90-day supply of the controlled substance to be imported or exported, which is longer than the 30 days that apply to narcotics and controlled drugs under the subsection 56(1) class exemption, but consistent with the provisions in the BOTSR that apply to targeted substances.

The CSR also incorporate authorizations to conduct activities that are currently permitted through subsection 56(1) class exemptions, namely allowing an individual to bring a controlled substance to a retail pharmacy for its destruction, and delivering a prescription drug containing a controlled substance to a patient. Based on feedback from stakeholders after prepublication, the final CSR will also allow an individual to bring a controlled substance to a practitioner, hospital or particular person (e.g. a municipal waste management facility) for the purpose of destruction as per requirements set out in the CSR.

Test kits

As with the current regulations, this part exempts certain activities from the application of the CSR with respect to test kits.

Consistent with the current regulations, the CSR set out the framework under which, with a test kit registration number issued by Health Canada, any person can possess, sell, provide, import, export, send, deliver or transport a test kit. Further, the CSR streamline the registration number issuance process by removing the provision in the current regulations regarding issuing a new registration number to replace a cancelled number.

In addition, similar to paragraph 9(2)(b) of the BOTSR, the CSR provide further clarity regarding the permitted activities with a test kit in the situation where Health Canada has cancelled the registration number upon request by the registration number holder. These provisions make it clear that any test kits remaining after the cancellation of the registration number may continue to be sold, imported and exported.

Miscellaneous provisions

As in the current regulations, this part contains a provision which prohibits advertising of a controlled substance to the general public and imposes restrictions on such advertising to regulated parties (i.e. a licensed dealer, pharmacist, pharmacy technician, practitioner or hospital). This part also contains a provision that outlines the prior notification requirements in the case where an application to a justice is being made by a person whose controlled substance was seized or acquired in accordance with the CDSA for the return of that substance pursuant to subsection 24(1) of the CDSA.

Repeals

The CSR will repeal the NCR, the BOTSR, the FDR-G, the FDR-J, the NCPR and the Exemption Regulations when the CSR come into force.

Coming into force

The CSR will come into force on October 1, 2026, to provide an appropriate transition period.

On the day the CSR come into force, Health Canada will revoke the above-mentioned subsection 56(1) class exemptions and issue public communications, including on its website, to make sure that regulated parties are aware that the CSR are now in force.

Schedules

Each of the NCR, BOTSR, FDR-G, and FDR-J include a schedule with one or more parts. Substances listed in the schedule to the NCR, for instance, are considered “narcotics.” Under the CSR, there will continue to be separate schedules for the different categories of controlled substances, as follows:

- Schedule 1 — Narcotics
- Schedule 2 — Controlled Drugs (Part 1, Part 2 and Part 3)
- Schedule 3 — Targeted Substances (Part 1 and Part 2)
- Schedule 4 — Restricted Drugs (Part 1, Part 2 and Part 3)

Additional changes

It should be noted that the following provisions in the current regulations are not included in the CSR, either because they do not align with the best available scientific evidence or because they are redundant.

Restrictions on activities with diacetylmorphine in the NCR

The NCR and the NCPR authorize a doctor of medicine or nurse practitioner to prescribe, administer, sell or provide diacetylmorphine and restrict a dentist or veterinarian from conducting activities with diacetylmorphine only in a hospital setting. This restriction was established based on the approved indications for this narcotic and an assessment of the risks posed by diacetylmorphine to public health and public safety at the time. No such restrictions exist in the NCR for other narcotics, such as fentanyl, which is more potent than diacetylmorphine. This is an example of where the current regulations have not kept pace with the best available science or the approved indications for this narcotic. The intent of removing these restrictions is not to expand access to diacetylmorphine. The restriction on midwives and podiatrists conducting activities with diacetylmorphine set out in the NCPR will be maintained in the CSR.

Prescribing of certain controlled substances by nurse practitioners

The NCPR do not permit nurse practitioners to prescribe or conduct activities with opium, coca leaves or anabolic steroids (except testosterone). The CSR do not contain any such restrictions for nurse practitioners in much the same way that no such restrictions apply to physicians, veterinarians and dentists. Restrictions on prescribing opium and coca leaves are not needed, since practitioners can only prescribe marketed drugs. Furthermore, consistent with the subsection 56(1) class exemption authorizing nurse practitioners to conduct activities with any anabolic steroid within their scope of practice, the CSR do not restrict the prescribing of anabolic steroids by nurse practitioners. Of note, since the NCPR were put in place in 2012, two additional marketed drugs containing anabolic steroids have been authorized by Health Canada. This is another example of where the current regulations have not kept pace with the best available science or approved indications for this category of drugs.

Provisions in the NCR and the FDR-G regarding analysis and identification of controlled substances by practitioners

Available information shows that these provisions have not been used for decades and are no longer relevant.

Requirement in the BOTSR with respect to permits for transit and transhipment of targeted substances

Since the BOTSR came into force in 2001, no permit has been requested or issued under this provision; therefore, this provision is no longer relevant.

FDR-J research authorization for restricted drugs

Most research with controlled substances is authorized through subsection 56(1) exemptions. Restricted drugs are an exception to this, in that the FDR-J require an institution to request an authorization from the Minister in order to obtain a restricted drug for scientific purposes from a licensed dealer. These two separate authorization schemes for research with controlled substances create confusion for both applicants and the regulator. In the case of a researcher requiring different categories of controlled substances for one research project, they may have to obtain authorizations

through separate procedures. Under the CSR, there will no longer be a separate research authorization pathway for restricted drugs. Instead, subsection 56(1) exemptions will be the mechanism by which Health Canada authorizes researchers to obtain any controlled substances for scientific purposes. In the future, Health Canada may consider developing an alternate authorization scheme that would apply to research with controlled substances.

Notice of prohibition of sale

The NCR, the BOTSR and the FDR-G provide the Minister with the authority to restrict the sale of a controlled substance to a pharmacist or practitioner who requests such a restriction or who is not in compliance with the CDSA regulations or provincial professional regulatory practice requirements. Over the years, all notices were issued at the request of provincial professional regulatory authorities that have a similar and more effective mechanism as part of their health professional practice monitoring system. Usually, the notices issued by Health Canada in accordance with these provisions are not as comprehensive and timely in comparison with the restrictions imposed by provincial regulatory authorities. Health Canada has determined that the notice of restriction in the current regulations is redundant and, therefore, this has not been included in the CSR.

Test kits that are subject to the CDSA regulations as well as the *Medical Devices Regulations* (MDR) as in vitro diagnostic devices

Under the current regulations, the registration number for certain test kits must be cancelled if its authorization as a medical device is revoked under the MDR. Given that these regulations and the MDR regulate test kits from different perspectives (prevention of diversion and inappropriate use vs. quality control), revoking an authorization for a test kit under the MDR may not necessarily provide the proper grounds for the cancellation of the test kit registration number issued under the CDSA regulations. Therefore, revocation of an authorization under the MDR is not reflected in the CSR as grounds for a test kit registration number to be cancelled under the CDSA.

Possession authorization provisions for persons exempted in accordance with subsection 56(1) of the CDSA in the current regulations

These provisions are redundant, as possession is already authorized when a subsection 56(1) exemption is issued.

Schedule II of the BOTSR

Schedules I and II of the BOTSR contain the same information with respect to targeted substances, but Schedule II refers to the name of a substance as “specified name.” With no differences between the two schedules and with Schedule II adding no value, Schedule II will not be maintained in the CSR.

Regulations Amending Certain Regulations Made Under the Food and Drugs Act and the Controlled Drugs and Substances Act (Controlled Substances)

Consequential and coordinating amendments to the following regulations will be made to replace references to the current regulations with a reference to the CSR and to ensure consistency between regulations:

- *Food and Drug Regulations*
- *Medical Devices Regulations*
- *Precursor Control Regulations*

Coordinating amendments between the *Precursor Control Regulations* and the CSR include changes that align certain requirements for controlled substances under the CSR with those under the *Precursor Control Regulations*, such as alignment of requirements as they apply to criminal record checks, a requirement for registered dealers to provide information on their criminal history both in Canada and abroad, and Health Canada reporting to the International Narcotics Control Board.

The draft CSR had proposed that licensed dealers of controlled substances would no longer be required to report unexplainable losses to law enforcement. In response to stakeholder feedback following prepublication, this same change will be made for other regulated parties (e.g. licensed and registered dealers of precursors, pharmacists, and practitioners).

These amendments will come into force the same day the CSR come into force or on the day they are registered, if it is after that date.

Regulations Amending Certain Regulations Made under the Financial Administration Act (Controlled Substances)

Consequential amendments to the following regulations will be made to replace references to the NCR and FDR-G with references to the CSR and to ensure consistency between regulations:

- *Licensed Dealers for Controlled Drugs and Narcotics (Veterinary Use) Fees Regulations*
- *Fees in Respect of Dealer's Licences Regulations*

These amendments will come into force on the same day the CSR come into force or on the day they are registered if it is after that date.

Order Amending Schedules I, III, IV, VI to the Controlled Drugs and Substances Act

During the development of the CSR, Health Canada identified the need to modify the chemical names of certain substances in the schedules to the CDSA in order to reflect up-to-date nomenclature used for naming these substances and correct errors. For instance, Greek characters need to be replaced by spelled-out English and French terms and two repetitive names for the same substances need to be removed. This Order aligns the CDSA schedules with the schedules to the CSR by using the same nomenclature to reflect the names of substances.

These amendments will come into force on October 1, 2026, the same day the CSR come into force.

Regulations Amending the Cannabis Regulations (Harmonization with Certain Provisions of the Controlled Substances Regulations)

Consequential and coordinating amendments will be made to the *Cannabis Regulations*, in particular in Part 8 (Drugs Containing Cannabis) and Part 13 (Test Kits).

Test kits containing cannabis

Relevant provisions will be amended to make a series of changes to support continued alignment with certain requirements pertaining to test kits under the CSR.

Drugs containing cannabis

Amendments will be made to certain provisions to

- ensure consistent use of the terms “prescription drug,” “drug containing cannabis,” “name,” “brand name,” “common name,” “proper name,” “attestation” and “declaration”;
- expand authorities to allow pharmacists, practitioners and hospitals to sell and distribute drugs containing cannabis for the purpose of destruction to all licensed dealers [7] (currently these parties are only authorized to distribute drugs containing cannabis to licensed dealers specialized in destruction) and introduce corresponding record-keeping requirements to enable document review and compliance activities conducted under these expanded authorizations;
- expand authorities to allow licensed dealers who are not specialized in destruction to possess, distribute and sell drugs containing cannabis in certain circumstances, and introduce corresponding record-keeping requirements to enable document review and compliance activities;
- allow pharmacists to sell and distribute prescription drugs containing cannabis to another pharmacist for the purpose of filling a prescription to enable services such as central fill services, and for the purpose of depleting stock in certain circumstances (e.g. closure of pharmacy). Corresponding record-keeping requirements have been introduced to enable document review and compliance activities;
- improve alignment between the *Cannabis Regulations* and the CSR with respect to requirements for witness qualifications for on-site destruction by licensed dealers specialized in destruction; and
- introduce a requirement for cannabis licence holders and licensed dealers to record the drug identification number (DIN) for prescription drugs containing cannabis when they conduct certain activities with these drugs (e.g. import, export, sale, and distribution) to support document review and compliance activities.

For improved alignment with the CSR, the *Cannabis Regulations* will be further amended following prepublication to

- allow hospital pharmacists (not only the pharmacist in charge of the hospital's pharmacy) to place a written order for prescription drugs containing cannabis;
- no longer require pharmacists, practitioners, and individuals in charge of a hospital to keep records under Part 8 of the *Cannabis Regulations* in certain circumstances (e.g. pharmacy, clinic, or hospital closure; retirement, etc.). The person that is responsible for that place of operations will assume responsibility for these records; and
- expand the record-keeping requirements related to destruction activities with prescription drugs containing cannabis to require a DIN (e.g. to further support document review and compliance activities).

Note, unlike the CSR, the *Cannabis Regulations* will not be amended to authorize activities specifically for pharmacy technicians. This is because a pharmacy technician can already be authorized under the *Cannabis Act* to conduct activities with drugs containing cannabis as an agent, mandatary or employee of a pharmacist.

Destruction of cannabis that an individual brings to a regulated party

In alignment with the CSR, the *Cannabis Regulations* will be expanded following prepublication to authorize an individual to distribute cannabis to a pharmacist, pharmacy technician, practitioner, or hospital for the purpose of destruction under certain circumstances. The amendments to the *Cannabis Regulations* will consider the cannabis received by these regulated parties to be a controlled substance for the purpose of its destruction only. This way, a pharmacist, practitioner, or hospital will be authorized to either destroy this cannabis on site or sell or provide it to a licensed dealer specialized in destruction. This change reflects and expands authorizations with respect to cannabis that were granted through the subsection 56(1) class exemption for post-consumer returns that will be revoked.

To help facilitate compliance with the post-consumer returns provisions, further amendments to the *Cannabis Regulations* made following prepublication will clarify that once regulated parties receive cannabis from individuals for its destruction, they must meet all of the applicable requirements under the CSR that apply to controlled substances (specifically, a "finished product" under the CSR) that are provided by an individual for destruction purposes. If regulated parties do not meet the relevant requirements under the CSR, compliance and enforcement activities for cannabis under the *Cannabis Act* and *Cannabis Regulations* may apply.

Individuals importing or exporting drugs containing cannabis for personal medical use

The *Cannabis Regulations* will be amended to authorize individuals to travel with up to a 90-day supply of prescribed drugs containing cannabis (e.g. Sativex or Epidiolex) for personal medical use subject to specific requirements. Note that under the *Cannabis Act*, it remains illegal for an individual to enter Canada or leave Canada with other cannabis, such as cannabis products and cannabis for

medical purposes. This change maintains authorizations that were granted through the subsection 56(1) class exemption for travellers that will be revoked and improves alignment with the CSR.

Following prepublication, Health Canada identified the need to provide additional clarity to individuals with respect to personal possession limits for drugs containing cannabis under the *Cannabis Regulations*. The *Cannabis Regulations* will be amended to clarify that individuals will be able to possess prescribed drugs containing cannabis, including imported drugs containing cannabis, obtained from a health care provider such as a practitioner or under a prescription without impacting any other quantities of cannabis that these individuals are legally authorized to possess in public (e.g. 30 grams of dried cannabis or its equivalent) under the *Cannabis Act*.

Other changes

The *Cannabis Regulations* will be amended to replace references to the *Narcotic Control Regulations* with references to the "former *Narcotic Control Regulations*" or the *Controlled Substances Regulations*, as appropriate. The *Cannabis Regulations* will also be amended to clarify certain wording, to better align English and French terms, and improve readability without substantively changing requirements (e.g. clarify wording on qualification requirements for the position of qualified person in charge and define the term "drug identification number").

For improved alignment with the CSR, the *Cannabis Regulations* will be further amended following prepublication to clarify additional wording (e.g. use of the terms "prescription" and "order"), and to replace specific terminology (i.e. "provincial professional licensing authority" with "provincial professional regulatory authority", and "medical professional" with "health care provider").

These amendments will come into force on October 1, 2026, the same day the CSR come into force.

Regulatory development

Consultation

Health Canada has consulted stakeholders on a series of notices of intent related to certain portions of this regulatory proposal since 2017.

These notices related to the destruction of controlled substances by health care professionals and hospitals, test kits and provisions pertaining to pharmacists. Feedback received in response to those consultations was generally supportive. In particular, stakeholders indicated that regulations made under the CDSA should enable pharmacists to more fully practise their profession, that pharmacy technicians should be authorized to independently conduct certain activities with controlled substances, and that central fill services should be enabled.

In addition, certain gaps in the current regulations identified by stakeholders had previously been addressed through subsection 56(1) class exemptions. Stakeholders generally noted that the exemptions had had positive impacts; this helped Health Canada to identify areas that needed to be

further addressed in regulations. For instance, pharmacists, pharmacist associations, provincial regulatory authorities for pharmacists and some provincial governments had expressed strong support for the subsection 56(1) class exemption authorizing, among other things, pharmacists to conduct additional activities with controlled substances.

Consultation following prepublication of the Regulations in the *Canada Gazette*, Part I, on June 1, 2024

Health Canada published the draft regulatory proposal on June 1, 2024, for a 60-day public comment period in the *Canada Gazette*, Part I. At the end of the consultation period, Health Canada collected 190 comments pertaining to the CSR from 44 stakeholders representing licensed dealers and their association, health care professional associations and regulatory authorities, provincial governments and individuals. Half of the comments received were from pharmacy associations, regulatory colleges for pharmacists, and individual pharmacists, and participation from other stakeholder groups was limited. In addition, Health Canada received 12 submissions pertaining to cannabis from a variety of stakeholders, including a cannabis industry association, health care groups, including associations, and individuals.

Overall, stakeholders were very supportive of the efforts to consolidate and streamline the regulations, incorporate several subsection 56(1) class exemptions, and make regulatory changes in support of pharmacy innovation, particularly in enabling more flexible central filling and in authorizing pharmacy technicians to conduct certain activities with controlled substances. A number of comments of a technical nature to improve or clarify the regulatory text were also submitted, and were considered when finalizing the CSR and the amendments to the *Cannabis Regulations*. Finally, a few additional comments were out of scope of this regulatory proposal (e.g. legalization and decriminalization of controlled substances, expungement of all criminal records for drug-related offences). The following summarizes the key comments made and outlines Health Canada's response.

1. Comments pertaining to the *Controlled Substances Regulations*

Prescribing, therapeutic substitution and administration of controlled substances by pharmacists

Provincial colleges of pharmacists, individual pharmacists and their association expressed the view that the proposed CSR did not go far enough to fully support pharmacy innovation in Canada and strongly urged Health Canada to expand the authorizations in the CSR for pharmacists to allow them to more fully utilize their expertise as medication experts as authorized under provincial legislation. These stakeholders requested that the CSR authorize pharmacists to prescribe controlled substances or to authorize pharmacists to substitute one controlled substance for another with a similar function (also known as "therapeutic substitution"), for example, to address a patient's needs in the event of a drug shortage or an adverse reaction, and to administer a controlled substance.

Health Canada response

Health Canada recognizes that the practice of pharmacy continues to evolve and that, in some provinces, pharmacists are authorized to initiate prescriptions for certain medications. Health Canada is committed to undertaking further consultations on this issue, including with pharmacy stakeholders, other relevant categories of health care professionals, and provincial and territorial governments.

Health Canada also recognizes that, in most provinces, pharmacists have been authorized to make a therapeutic substitution for a drug specified in a prescription issued by a practitioner. This authority allows pharmacists to better support patients, such as in the event of a drug shortage or an adverse reaction to a prescribed medication. To address feedback received, Health Canada has included a new provision in the CSR to authorize a pharmacist to substitute a controlled substance specified in a prescription with another controlled substance, provided this is permitted at the provincial and territorial level. This change is expected to address the most pressing need for pharmacists, while consultations on whether to more broadly authorize prescribing of controlled substances by pharmacists are continuing.

Adjusting, de-prescribing, part-filling a prescription for a controlled substance

Pharmacy stakeholders suggested that the final CSR should be amended to reflect the Health Canada published guidance entitled *Prescription management by pharmacists with controlled substances under the Controlled Drugs and Substances Act and its regulations*. This document clarifies that other related activities by pharmacists that are included in the meaning of "sell" or "provide" are permitted under the current regulations, as long as the quantity dispensed does not exceed the amount originally authorized. These activities include, but are not limited to adjusting the formulation, adjusting the dose and regimen, de-prescribing and part-filling of a prescription.

Health Canada response

In the above-mentioned guidance, Health Canada clarifies that these activities are already authorized for pharmacists in the regulations through the meaning of "sell" or "provide" as long as the quantity dispensed does not exceed the total quantity originally prescribed. Thus, the CSR will not pose any restrictions for these activities.

Expanding authorized activities by pharmacy technicians

Associations representing pharmacy regulatory authorities and pharmacists pointed out that, in the majority of provinces where pharmacy technicians are allowed to practise their profession, as part of their scope of practice, pharmacy technicians play a key role in the operations of a pharmacy with respect to inventory management. They commented that the CSR should further allow pharmacy technicians to conduct additional activities such as ordering controlled substances. They also indicated that administration of drugs is within the scope of practice for pharmacy technicians who receive additional training and recommended that Health Canada authorize such activity in the CSR.

Health Canada response

Health Canada acknowledges this feedback and will further consider it as part of future regulatory changes.

Pharmacists and pharmacy technicians practising in any jurisdiction

An association of regulatory authorities commented that the definitions for pharmacist and pharmacy technician should not restrict such professionals from practising their profession only in one jurisdiction, as they may work in a jurisdiction that is not where they are originally licensed to practise their profession. They also recommended replacing the wording "provincial professional licensing authority" with "provincial professional regulatory authority" in the final CSR to reflect the fact that these authorities do more than just licensing health care professionals.

Health Canada response

Health Canada has made various editorial changes to terms used to address stakeholder concerns, including those expressed by professional regulatory authorities. The definitions in the CSR, through the meaning of "entitled", do not create any federal barrier that would prevent a pharmacist or pharmacy technician from working in any jurisdiction so long as they are entitled to do so under the applicable provincial laws.

Communication of factual information about a health care professional collected under the CSR to a provincial professional regulatory authority

An association of regulatory authorities requested that the provision allowing the Minister to communicate certain information to a provincial professional regulatory authority be expanded to include a broader scope of information that would assist the authority in ensuring the professional conduct of their members, especially given that the CSR no longer include provisions regarding notice of restriction of sale of controlled substances for certain health care professionals. One province also expressed the desire to receive such information so that they may further develop proper compliance strategies in support of public health and public safety.

Health Canada response

Health Canada recognizes the importance of sharing relevant information to support provincial partners and has expanded the relevant provision to allow such communication if the Minister has reasonable grounds to believe that the provision of factual information is necessary to assist the provincial government or the provincial professional regulatory authority in monitoring the professional conduct of a health professional in accordance with the laws of a province for the purpose of protecting public health and public safety.

Prescription medications possibly containing controlled substances provided by individuals for destruction

An industry association indicated that their members collect for disposal unwanted medications that may contain controlled substances from local pharmacies and veterinarian clinics in accordance with provincial or territorial legislation in certain jurisdictions or programs such as "producer care responsibilities." They also pointed out that patients in hospitals sometimes leave unwanted medications that may contain controlled substances at the hospitals for disposal. In light of this, they recommended that other regulated parties, such as hospitals and practitioners, be legally authorized to collect these unwanted medications for destruction. Further, some stakeholders commented that members of the public sometimes return unwanted medications, which may contain controlled substances, or cannabis to organizations such as municipal waste management facilities. They indicated that, while the facilities have set out proper procedures to dispose of such medications, there is currently no legal coverage under the CDSA regulations to allow them to handle unwanted medications containing controlled substances. They suggested that Health Canada make necessary changes to the CSR to provide the necessary legal coverage.

Health Canada response

In order to facilitate proper disposal of unwanted medications that may contain controlled substances and to further protect the environment, Health Canada has further expanded the authorization for pharmacists in the final CSR to accept returns of unwanted medications for their destruction and has also made it applicable to practitioners and hospitals. Health Canada has also added a new provision to the CSR authorizing a particular person (e.g. a waste management facility) that receives a medication that may contain a controlled substance for the purpose of destruction, to sell, provide, deliver, send and transport such medication to a licensed dealer, pharmacist or police force for the purpose of destruction as per requirements set out in the CSR. The provision allowing an individual to provide such medication has also been revised to authorize them to return such medications to practitioners, hospitals or particular persons, in addition to pharmacists and pharmacy technicians.

Prescribing physician assistants as practitioners

An association representing physician assistants requested that physician assistants be prescribed as practitioners in the CSR so that they would be authorized to conduct activities with controlled substances, including prescribing.

Health Canada response

Physician assistants are currently regulated in some provinces, with various scope of practice. In most cases, they practise their profession under the supervision of a physician. Health Canada is committed to undertaking further consultations on this issue, including with health care stakeholders and provincial and territorial governments. In parallel with publication of the proposed CSR in the *Canada Gazette*, Part I, on June 1, 2024, Health Canada published in the *Canada Gazette*, Part I, the *Notice of intent to consult on modernization of provisions pertaining to hospitals and*

practitioners in regulations made under the Controlled Drugs and Substances Act. The outcome of these ongoing consultations will inform Health Canada's approach to modernizing the parts for practitioners and hospitals in the CSR.

Harmonization with the *Precursor Control Regulations* with respect to loss and theft reporting

An association representing licensed dealers pointed out that the revision, made in the CSR to the provision regarding loss or theft, to remove the requirement of reporting of unexplainable losses by licensed dealers to law enforcement should also be made to the relevant provision in the *Precursor Control Regulations*.

Health Canada response

Health Canada acknowledges there are benefits to aligning the *Precursor Control Regulations* with the CSR to the extent possible, despite slightly different requirements between the two regulations, recognizing that a number of licensed dealers are regulated under both the CSR and the *Precursor Control Regulations*. Amendments have been made to the *Precursor Control Regulations* to align the loss and theft reporting requirements with those of the CSR.

Coming into force

The draft CSR proposed that the CSR would come into force one year following publication of the final regulations in the *Canada Gazette*, Part II. Stakeholders expressed different views on the time frame for coming into force of the CSR. Some suggested that a shorter coming-into-force period (180 days) would be preferable so that stakeholders could more rapidly benefit from expected efficiency gains, while others noted that sufficient time would be needed to transition to the new regulations. Many stakeholders noted the importance of ensuring the continuity of authorities provided by the current *Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada*; that exemption is currently set to expire on September 30, 2026.

Health Canada Response

To ensure no gap in the authorities provided by the current subsection 56(1) class exemption for pharmacists, the CSR will come into force on October 1, 2026.

2. Comments pertaining to the amendments to the *Cannabis Regulations*

Of the 12 submissions pertaining to the amendments to the *Cannabis Regulations*, 5 provided recommendations which were deemed out of scope for this package (e.g. requesting that cannabis for medical purposes be authorized and dispensed by pharmacists without the need for a medical sales licence).

Of the remaining seven submissions, stakeholders were generally supportive or neutral towards the amendments to the *Cannabis Regulations*. Stakeholders indicated their support specifically for several amendments, including allowing central fill activities for drugs containing cannabis, the test kit provisions, and formalizing the CDSA subsection 56(1) exemption on import/export of drugs containing cannabis by individuals under the *Cannabis Regulations*.

Overall, there were a few requests for wording or structural changes to the amendments (e.g. combining certain sections with a particular provision) that stakeholders advised would help clarify the intent of the amendments. In addition, stakeholders requested clarity as to why certain amendments made under the CSR (e.g. removing provisions on ministerial notices of restriction of sale of controlled substances for certain health care professions) were not being made under the *Cannabis Regulations*.

Health Canada response

Health Canada considered these comments to improve clarity and alignment between the *Cannabis Regulations* and the CSR when finalizing the Regulations. However, overall, the *Canada Gazette*, Part I, proposal has been maintained. Notably, regarding ministerial notices of restriction, Health Canada has decided to maintain this requirement for drugs containing cannabis due to the lack of consultation regarding its removal for cannabis specifically and the need to fully consider potential implications for the cannabis regulatory framework.

3. Comments on the cost-benefit analysis

Health Canada received feedback on its cost-benefit analysis from three stakeholders during the *Canada Gazette*, Part I, public consultation period. None opposed the findings of the cost-benefit analysis nor provided substantive information to refine its underlying assumptions. An individual commenter largely supported the conclusions, with minor suggestions focused on administrative and operational cost implications.

One non-profit organization recommended broadening the scope of the cost-benefit analysis to include both direct and indirect costs related to the overdose crisis and costs associated with criminalization.

Health Canada response

Health Canada considered the comments while finalizing the cost-benefit analysis. However, as criminal penalties are set out in the CDSA and not its regulations, specifically broadening the scope of the cost-benefit analysis to account for these costs is beyond the scope of the analysis for the regulatory proposal.

Indigenous engagement, consultation and modern treaty obligations

The CSR consolidate and modernize the regulatory framework for controlled substances and improve alignment between the *Cannabis Regulations* and the CSR. While the CSR include amended or modernized provisions to respond to stakeholder comments and to reflect current practice by businesses and pharmacies, they are aimed at all people in Canada and do not have any targeted impacts on any groups, including Indigenous groups. Similarly, the amendments to the *Cannabis Regulations* improve alignment with the CSR and ensure clarity and consistency of provisions, but they do not specifically target Indigenous peoples. As part of its consultations during the *Canada Gazette*, Part I, consultation period, Health Canada welcomed feedback from all impacted and interested stakeholders, including Indigenous peoples and organizations. No comments were received from individuals who identified themselves as Indigenous peoples.

As per the *Cabinet Directive on the Federal Approach to Modern Treaty Implementation*, a preliminary assessment of modern treaty implications was conducted, which examined the geographical scope and subject matter of the regulatory proposal in relation to modern treaties in effect. The preliminary assessment did not identify any potential impact on the rights of Indigenous peoples recognized and affirmed under section 25 of the *Constitution Act, 1982,* and no impacts related to modern treaties with the Indigenous peoples of Canada are expected. The preliminary assessment concluded that the CSR did not trigger any modern treaty obligations.

Instrument choice

To address the issues and to meet the objectives outlined above, it was determined that the only viable option would be to consolidate the implicated regulations and exemptions with necessary alignments and additional authorizations.

Maintaining the status quo or taking voluntary approaches were not considered to be feasible options, since the issues and gaps that resulted during the course of the long history of the development of regulations made under the CDSA would continue to pose challenges to Health Canada and regulated parties in terms of administration and compliance with the regulations.

By also incorporating authorizations specified in various class exemptions, the streamlined and updated regulations provide a unified regulatory framework for all controlled substances. Covering authorizations and requirements in consolidated regulations will enable Health Canada to better administer the regulatory regime and facilitate compliance with the regulations by regulated parties, with reduced administrative burden and improved clarity and readability of the regulatory provisions.

Further, regulatory amendments are the only viable option to ensure that the *Cannabis Regulations* and other federal regulations that make reference to the regulations for controlled substances remain aligned where necessary and that consistency across regulations is maintained.

Regulatory analysis

Analytical framework

A cost-benefit analysis was conducted to estimate the impacts of the CSR and amendments to the *Cannabis Regulations* on regulated parties, researchers, individuals, provincial and territorial governments and professional regulatory authorities, and the Government of Canada. These impacts were derived by comparing a baseline scenario to a regulatory scenario. It should be noted that many authorizations and requirements included in the "Description" section above were already in place through the current regulations and subsection 56(1) class exemptions (e.g. returning controlled substances to a pharmacy for destruction). Therefore, as these already exist in the baseline scenario, they are not treated as incremental impacts for the cost-benefit analysis.

Health Canada sought feedback through various means (e.g. questionnaires, targeted consultations) from affected stakeholders to validate assumptions and gather additional data. The collected information was used in developing the cost-benefit analysis.

All identified impacts are quantified and monetized to the extent possible. Where this is not possible due to data limitations or inability to make reasonable assumptions for quantification, the impacts are described qualitatively. Together, the monetized and non-quantified impacts provide a more accurate picture of the costs and benefits to stakeholders and allow for an adequate assessment of the net impact of the CSR and the amendments to the *Cannabis Regulations*.

All costs and benefits are estimated over 10 periods of 12 months. These costs and benefits are expressed in constant 2022 Canadian dollars and are discounted to period 1 using a 7% discount rate.

The cost-benefit analysis has been updated following the publication of the regulatory proposal in the *Canada Gazette*, Part I.

Major revisions have been made to the cost estimates to reflect newly introduced amendments to the CSR and updates to amendments to the *Cannabis Regulations* (e.g. enabling pharmacists to perform therapeutic substitution of controlled substances in provinces and territories, where permitted, and requiring them to record specified information; authorizing practitioners to receive post-consumer returns containing controlled substances for destruction and requiring them to record specified information; and requiring licensed dealers to record the DIN when destroying unserviceable stock of drugs containing cannabis).

With new data on the volume of prescriptions for drugs containing cannabis becoming available, the estimated costs to licensed dealers for recording the DIN have been revised accordingly.

Additionally, a minor methodological adjustment was made (i.e. whole numbers were used instead of fractional values, which were previously derived from percentage-based calculations) when estimating the number of licensed dealers.

Overall, these updates have led to an increase in total estimated costs, from $4.09 million to $4.22 million (PV). Correspondingly, the net benefits have decreased from $0.76 million to $0.62 million (PV).

All other new modifications to provisions in the CSR and to amendments to other regulations, including the *Precursor Control Regulations* and *Cannabis Regulations*, are discussed qualitatively.

The details of the estimates are included in the cost-benefit analysis report. A copy of the cost-benefit analysis report is available upon request from csd.regulatory.policy-politique.reglementaire.dsc@hc-sc.gc.ca.

Benefits and costs

Benefits

Benefits to all parties

Improved alignment, certainty, clarity and consistency of the regulations

As discussed in the "Background" section, there are currently multiple regulations under the CDSA that govern activities with the four categories of controlled substances. While many of the activities authorized through these regulations are similar, the regulatory requirements are not completely harmonized across those regulations. This has led to confusion for many regulated parties with respect to interpreting the authorizations and the manner in which to comply with some of the regulatory requirements. To add further complexity, certain regulatory gaps that have been identified over the years have been addressed through the use of class exemptions provided in accordance with subsection 56(1) of the CDSA. Through consolidation, the CSR will result in the same authorizations and requirements being applied to activities with all categories of controlled substances, with some exceptions, and clarify authorizations and requirements for agents/mandataries of regulated persons. Following publication of the draft regulations, further changes were made to the CSR to further improve clarity and facilitate compliance. Specifically, the CSR now clarify the time frame for prescription extensions or transfers and will explicitly authorize a "particular person" to receive and transport controlled substances for disposal. In addition, the final CSR will expand the scope of information that the Minister can share with provincial authorities. The regulatory consolidation is expected to result in a more streamlined and efficient regulatory framework for controlled substances, thereby providing additional certainty and clarity for regulated parties, and facilitating compliance with the regulations. Similarly, the regulatory consolidation will help improve the administration of regulations by Health Canada and other federal government departments.

Through the CSR and the amendments to the *Cannabis Regulations*, harmonization between the *Cannabis Regulations* and the regulations for controlled substances will be improved, further facilitating stakeholder compliance with the two regulatory frameworks. For example, the CSR and the amendments to the *Cannabis Regulations* will benefit licensed dealers by improving alignment of

witness requirements for on-site destruction of drugs containing cannabis under the *Cannabis Regulations* with the witness requirements under the CSR for destruction of controlled substances by a licensed dealer at the site specified on their licence. There are additional benefits to certain regulated parties, including increased operational flexibility for pharmacists, practitioners, and hospitals, as they will be authorized to sell or distribute drugs containing cannabis for the purpose of destruction to any licensed dealer. Finally, record keeping requirements for similar activities will also be harmonized across the two regulations, which will facilitate compliance.

There are additional qualitative benefits to impacted stakeholders, resulting from changes that are mainly of an administrative nature. These changes improve clarity and interpretation of the regulations, including ensuring consistency and proper use of terminologies (e.g. the term "prescription" is only used when the transaction is directly related to a patient; "health care provider" is used to encompass various health professionals). They also clarify, for example, that with respect to cannabis, an individual can publicly have, in their possession, quantities of prescribed drugs containing cannabis in addition to any other amounts of cannabis authorized under *the Cannabis Act* (e.g. 30 grams of dried cannabis or its equivalent).

Time saved by reviewing one set of regulations instead of multiple regulations

There will be one-time cost savings to regulated parties newly conducting activities with controlled substances (e.g. a new licensed dealer, pharmacist, pharmacy technician or practitioner) because they will only need to review the CSR instead of multiple regulations and applicable class exemptions. Considering that the length of the CSR, in terms of number of pages, is less than that of the current regulations and class exemptions combined, regulated parties will spend less time reviewing the regulations than they do currently. The monetized benefits to regulated parties in time saved [8] reviewing only one regulation are estimated to be $2.85 million (PV) or $406,046 annually.

In addition, from time to time, it is assumed that regulated parties consult the regulations or the class exemptions to confirm their understanding of permitted activities and associated requirements. Going forward, regulated parties will consult one set of modernized regulations instead of multiple regulations, thereby saving review time.

Benefits to licensed dealers

Reduced costs related to reporting losses and thefts

Under the CSR, licensed dealers will no longer be required to report unexplainable losses of controlled substances to a police force, though they will continue to report such losses to Health Canada. According to Health Canada's administrative data, on average per year, there are approximately 500 reports of unexplainable losses to police. It is assumed that 15 minutes are spent on reporting one incidence of unexplainable loss to a police force. This reduction in reporting requirements will result in compliance cost savings to licensed dealers.

In addition, licensed dealers will no longer have to include unexplainable loss and theft information in their monthly reports submitted to Health Canada. Health Canada's administrative data indicates that, on average per year, there are about 60 licensed dealers that experience losses and thefts and spend 20 minutes to record this information in their monthly reports, in addition to providing this information following their occurrence. The regulatory change will remove this reporting duplication, resulting in administrative cost savings to licensed dealers.

The monetized benefits to controlled substance licensed dealers related to these reduced compliance and administrative requirements are estimated to be $30,353 (PV) or $4,322 annually.

Further, under the baseline scenario, the *Precursor Control Regulations* require precursor licensed dealers, registered dealers, pharmacists, practitioners, and hospitals to report losses of precursor chemicals to both a police force and Health Canada. It is estimated that it takes about 15 minutes to report the loss of a precursor substance to a police force. In response to stakeholder feedback on the draft regulations, amendments have also been made to the *Precursor Control Regulations* to remove the requirement to report such losses to a police force, while maintaining the requirement to report them to Health Canada. This regulatory change will ensure alignment with the CSR and further reduce compliance burden on affected parties.

Economic benefit to licensed dealers providing third-party distribution services for drugs containing cannabis destined for destruction

Under the baseline scenario, licensed dealers who specialize in destruction (but no other licensed dealers) are authorized to possess drugs containing cannabis for the purpose of destruction. The amendments to the *Cannabis Regulations* will expand authorization for possession, distribution and sale of drugs containing cannabis that are unserviceable stock for the purpose of destruction to licensed dealers who are not specialized in destruction. This will benefit these licensed dealers, as they will be able to collect revenues from providing this service as intermediaries to both the sender (e.g. health professionals such as pharmacists) and licensed dealers specialized in destruction.

Benefits to holders of test kit registration numbers

Administrative savings associated with only notifying the Minister of modifications to test kits

Holders of registration numbers for test kits containing a controlled substance will no longer need to go through the application process to request cancellation of an existing test kit registration number and issuance of a new one when they modify their test kits. They will only need to send a notification to the Minister regarding the changes. Under the baseline scenario, it is estimated that about five requests for cancellation and issuance of test kit numbers, on average per year, are submitted and that 40 minutes are spent to prepare and submit a request. With the simplified process, under the regulatory scenario, 30 minutes will be saved, as a test kit holder will only spend 10 minutes to prepare and submit a notification to Health Canada. The monetized benefits as a result of time saved are estimated to be $523 (PV) or $75 annually.

Economic benefits associated with continued sales of test kits that are no longer medical devices

There will be additional benefits to holders of test kit registration numbers because the regulator will no longer be required to cancel the registration numbers issued under the CDSA or the *Cannabis Act* for test kits containing a controlled substance or cannabis that are medical devices when these test kits are no longer authorized for sale as a medical device under the MDR. This regulatory change ensures those test kits may still continue to be sold and used as test kits despite no longer being authorized as a medical device. The modernized regulatory provisions also clarify that when a test kit number is cancelled following a request from the holder as a result of ending manufacture or assembly of the test kit, it will be possible to continue selling any remaining stock. While there might be economic benefits to some holders of these registration numbers from continued sales, these benefits cannot be quantified due to a lack of data.

Benefits to pharmacists and pharmacy technicians

Enabling pharmacy technicians to independently conduct certain activities with controlled substances

The CSR will provide qualitative benefits to pharmacy technicians, as these health professionals will be allowed to independently conduct certain activities with controlled substances (e.g. delivering, sending, transporting, destroying, or compounding).

Providing central fill services without being licensed

Pharmacists are currently authorized, by their professional regulatory authority, to fill some but not all patient-specific prescriptions on behalf of another pharmacist, pursuant to an order from the originating pharmacy. This business practice, known as centralized prescription processing (or "central fill") services, benefits pharmacies utilizing this service, as it enables them to improve operational efficiency or reduce operational costs (stock keeping, processing time and related activities, etc.). Under the baseline scenario, this activity is not allowed for prescription drugs containing cannabis or a controlled substance unless the pharmacy possesses a dealer's licence under the applicable CDSA regulations or a cannabis drug licence under the *Cannabis Regulations*. The sale of prescription drugs containing cannabis or a controlled substance between pharmacists is currently only permitted in the case of an emergency.

The CSR and amendments to the *Cannabis Regulations* will authorize patient-specific non-emergency sales of prescription drugs containing cannabis or a controlled substance between pharmacists, effectively enabling central fill services for all categories of prescription drugs. The removal of this regulatory barrier will provide benefits to pharmacists providing central fill services, as they will no longer need to apply for or renew their licence. It is expected that, in 2025, about 50 pharmacies are providing central fill services for controlled substances, and this number is expected to grow by 5 each period. Over the 10 periods of 12 months, about 80 pharmacists will save 20 hours each, from no longer needing to meet the regulatory requirements (e.g. applying for or renewing their licence;

meeting reporting requirements) associated with being a licensed dealer. The monetized benefits to pharmacists providing central fill services for controlled substances are estimated to be $1.46 million (PV) or $207,887 annually. It is further assumed that the requirement to apply for a dealer's licence may have been a barrier that prevented certain pharmacists from offering central fill services for prescription drugs containing controlled substances. With the removal of this regulatory barrier, it is anticipated that more pharmacists may choose to take advantage of this business model. However, given the lack of available data, it is not possible to make reasonable assumptions as to how many pharmacists may choose to offer central fill services for controlled substances and cannabis. Therefore, these potential parties are not accounted for in the estimates provided above.

Reduced administrative burden associated with pharmacy closures

Pharmacists will benefit from reduced administrative burden, as they will no longer need to submit a notification to the Minister when they close their pharmacies and/or transfer drugs containing controlled substances or cannabis to another place or pharmacist. This will result in a saving of 10 minutes per avoided notification per affected pharmacist. The time savings is estimated to be $15,293 (PV) or an annualized value of $2,177.

Enabling therapeutic substitution of controlled substances by pharmacists

In response to feedback received following publication of the draft regulations, therapeutic substitution by pharmacists of one controlled substance for another will be authorized once the CSR are in effect. Under the baseline scenario, pharmacists are not authorized to substitute one controlled substance for another, despite this being an activity that is within the scope of practice for pharmacists in most provinces. This change will be beneficial in certain situations, such as a drug shortage or where the prescribed medication may not meet the patient's needs. This change may indirectly benefit pharmacists practising in provinces or territories where there are no restrictions on therapeutic substitution by pharmacists and in those that may choose to expand this activity once the federal regulatory barrier preventing this activity by pharmacists has been removed.

Benefits to researchers

Reduced administrative burden associated with eliminating the need for an institutional support letter

Under the baseline scenario, researchers wishing to conduct activities with a restricted drug must apply for an authorization under the FDR-J and submit an institutional support letter as part of their application. Researchers conducting research with any other controlled substance only need to apply for an exemption under subsection 56(1) of the CDSA and they do not need to submit an institutional support letter. This regulatory misalignment places additional burden on researchers conducting activities with restricted drugs (and their institutions) as opposed to other controlled substances. Under the CSR, researchers will be able to apply for a subsection 56(1) exemption to conduct research with any controlled substances, including restricted drugs. This will eliminate the extra

burden on researchers associated with securing a support letter when conducting activities with restricted drugs. According to administrative data available to Health Canada, an average of 70 applications for authorizations for researchers with restricted drugs are submitted every year. Since the only difference between the application requirements for an authorization under the FDR-J and a subsection 56(1) exemption is the institutional support letter, it is assumed that each researcher will save 30 minutes once the requirement to obtain and submit an institutional support letter has been removed. The monetized benefits to researchers associated with time saved are estimated to be $12,422 (PV) or $1,769 annually.

Benefits to individuals or patients

Additional flexibility during transportation of prescription drugs containing controlled substances

Patients who need assistance transporting prescribed drugs containing a narcotic or a controlled drug may benefit from the explicit authorization that allows another individual to possess and transport these drugs on their behalf. This will provide convenience for patients who may need other people's assistance while receiving treatment.

Reduced inconvenience and costs to international travellers

Under the baseline scenario, individuals travelling internationally (i.e. entering or exiting Canada) with prescribed drugs containing cannabis, a narcotic or a controlled drug packaged in a pharmacy or hospital dispensed packaging with the appropriate labelling can only carry a 30-day supply with them. In contrast, international travellers can carry up to a 90-day supply of prescribed drugs containing a targeted substance. This creates inconsistencies between what is allowed for different controlled substances as well as what is allowed for other prescription medications, where an individual can carry a 90-day supply. As a result of this limit, individuals travelling internationally may need a new prescription to ensure continuity of care while they are out of the country, and may bear additional expenses to do so. Some of these travellers have, in the past, requested an exemption under subsection 56(1) of the CDSA in order to meet their medical needs while travelling outside of Canada for longer than 30 days. The CSR and amendments to the *Cannabis Regulations* will improve convenience for travellers by enabling them to carry up to a 90-day supply of any prescription drug, including those containing cannabis, a narcotic, a controlled drug or a targeted substance. This will reduce the burden of applying for an exemption in situations where the traveller needs to carry up to a 90-day supply.

In addition, an individual travelling with an animal will be authorized to have, in their possession, up to a 90-day supply of prescription drugs containing cannabis, a narcotic or a controlled drug, similar to what is allowed for a targeted substance, that have been prescribed for the animal. This will reduce the inconvenience of not having enough supply of the necessary medications and having to seek additional prescriptions for their animal when they arrive at their destination.

Enabling therapeutic substitution of controlled substances by pharmacists

As noted above, a change will be made to the CSR further to publication of the draft regulations to remove a federal regulatory barrier for pharmacists if authorized to do so, under their provincial/territorial scope of practice, to substitute one controlled substance for another. This change will indirectly benefit patients in situations where there may be a shortage of a drug that has been prescribed to them or in situations where the prescribed drug does not meet the patient's needs (e.g. the patient has an adverse reaction or there are drug-drug interactions with another drug they are taking). Patients may benefit from timely intervention by pharmacists, which can help reduce treatment delays and enhance patient safety. Additionally, patients may save time, as they will no longer need to visit a practitioner for a new prescription before the substitution can be made.

Benefits to individuals returning unwanted medications to locations other than pharmacies

Although individuals may occasionally return unwanted medications containing controlled substances to locations other than pharmacies, this activity has not been explicitly authorized under the current regulatory framework for controlled substances. Under the baseline scenario, individuals are only allowed to return unwanted controlled substances to a pharmacist. In response to comments received following publication of the draft regulations, under the CSR, individuals will be explicitly authorized to return these medications to a clinic, a hospital or a particular person (e.g. municipal hazardous waste collection program), in addition to a pharmacy. Individuals will benefit from greater legal certainty and reduction in risk of unintentional non-compliance.

Benefits to provincial governments and health professional regulatory authorities

With the removal of the federal barrier regarding therapeutic substitution of drugs containing controlled substances by pharmacists, provinces and territories and health professional regulatory authorities that do not already permit such activities will now have flexibility to enable the substitution of drugs containing controlled substances in their jurisdictions if they choose to do so. This may result in a reduction of costs to the health care system, as pharmacists will no longer need to spend time reaching practitioners to request a new prescription, and practitioners will not need to spend time writing a new prescription, either upon request from a pharmacist or a patient.

Further, by enabling Health Canada to share certain information with provincial governments and health professional regulatory authorities, the CSR will assist these authorities with the more effective monitoring of the professional conduct of pharmacists, pharmacy technicians or practitioners and the taking of corrective actions.

Benefits to the Government of Canada

Health Canada will benefit from the improved clarity and consistency of the CSR. This will improve the administration of the regulations and result in savings to the Department. More specifically, once the CSR are implemented, it is expected that Health Canada will

- spend less time responding to stakeholder enquiries about topics such as central fill services or tracking during transportation of controlled substances;

- no longer be required to process individual subsection 56(1) exemption requests for carrying quantities of prescription drugs containing cannabis, a narcotic or a controlled drug for periods longer than 30 days, but not exceeding 90 days during travel, review institutional support letters as part of processing research authorization requests under the FDR-J, and process notices of pharmacy closures;
- no longer process applications to cancel the registration number and provide a new one for changes to test kits;
- no longer conduct pre-licence inspections of pharmacies planning to provide central fill services with controlled substances to other pharmacies;
- no longer issue or rescind notices of prohibition of sales; and
- spend less time on providing training to new inspectors.

The total monetized savings to Health Canada associated with the benefits outlined above are estimated to be $476,847 (PV) or $67,892 annually.

In addition, under the final CSR, government-operated laboratories will be permitted to conduct certain activities (e.g. in relation to testing) without the need to obtain a licence. They will, however, still need to apply for import and export permits. These laboratories will benefit from a reduced administrative activity, as they will no longer be required to renew or amend licences or bear costs associated with criminal record checks. There will also be benefits to Health Canada associated with fewer renewals and amendments of licences.

Costs

Costs common to all regulated parties

One-time cost to existing regulated parties associated with reviewing the CSR and amendments to the *Cannabis Regulations*

Existing regulated parties will spend time reviewing the CSR and amendments to the *Cannabis Regulations* to determine what they need to do to ensure compliance. It is estimated that under normal circumstances, 1.5 minutes are spent reviewing one page of regulatory provisions. It is assumed that businesses and professional regulatory authorities and associations will update guidance and other materials to facilitate review of the regulations by their members, which will greatly reduce review time. The total one-time cost to all regulated parties associated with reviewing the CSR and amendments to the *Cannabis Regulations* is estimated to be $3.10 million (PV) or an annualized value of $441,112.

Costs to licensed dealers

Costs associated with obtaining approval of changes to the record-keeping method

Sometimes, licensed dealers make changes to the methods they use to record required information. Under the CSR, licensed dealers will need to seek approval from the regulator before amending their record-keeping methods. It is estimated that, on average, about 30 requests will be submitted by licensed dealers each period and the time associated with preparing and submitting the request is 30 minutes. Therefore, the total ongoing cost is estimated to be $3,140 (PV) or an annualized cost of $447.

Cost associated with recording additional information

All licensed dealers are required to record the DIN assigned to finished products containing a controlled substance or prescription drugs containing cannabis. They also have to record the name and title of individuals involved in activities such as selling, distributing, ordering and transporting controlled substances, and the brand name and quantity of prescription drugs containing cannabis. As the required information is readily available to licensed dealers, the cost associated with recording this information is expected to be minimal. It is estimated that there will be 343 licensed dealers in the first period of analysis and this number is expected to increase by 12 every period thereafter. For every period starting from period 2, each affected licensed dealer will spend 2 hours on recording additional information associated with the controlled substance. It is also assumed that half of the licensed dealers will spend 15 minutes recording additional information related to drugs containing cannabis. The total ongoing costs are estimated to be $176,563 (PV) or $25,139 annually.

Potential costs associated with conducting activities with bezitramide and piritramide

There are currently no known medical, commercial or industrial activities involving these synthetic opioids in Canada. The likelihood of these synthetic opioids being imported into Canada for legitimate activities, other than for research or forensic analysis, is extremely low. However, in the unlikely event that a business decides to conduct activities with these synthetic opioids, it will need to apply for a new licence or amend their existing licence, apply for import and/or export permits, meet reporting and recording requirements under the CSR, and bear any associated costs. While the potential for these costs is acknowledged, they cannot be estimated due to a lack of information and the very low likelihood of activities with these synthetic opioids taking place in the foreseeable future.

Costs to cannabis licence holders

Cost associated with recording additional information

Under the amendments to the *Cannabis Regulations*, cannabis licence holders will be required to record the DIN for prescription drugs containing cannabis when they conduct certain activities (e.g. distribute, sell, or conduct research and development activities or destruction). The total administrative cost associated with this activity is estimated at $4,245 (PV) or $604 in annualized costs. [9]

Costs to pharmacists

Record-keeping costs related to sales between pharmacies (central fill services)

When the CSR come into effect, there will be record-keeping requirements associated with the provision of central fill services. Both parties (originating pharmacies and the central fill pharmacies) involved in the transaction will be required to meet the applicable record-keeping requirements. It is assumed that 5% of central fill pharmacies, which would not have otherwise provided central fill services for prescription drugs containing a controlled substance under the baseline scenario, will now provide central fill services for these drugs and will spend 24 hours per period recording the required information. Additionally, 7.5% of all central fill pharmacies are assumed to begin providing central fill services for prescription drugs containing cannabis and will each spend a maximum of 2 hours per period on recording the required information. Originating pharmacies will spend equivalent total recording time to document the same transactions. The total ongoing cost to affected pharmacies is estimated to be $111,506 (PV), or $15,876 annually.

Record-keeping costs related to therapeutic substitution by pharmacists

The final CSR will require pharmacists to document specific information when substituting one controlled substance for another. This requirement will impose an administrative burden on pharmacists. As indicated earlier, pharmacists are authorized to perform therapeutic substitution in 10 of the 13 jurisdictions in Canada. It is assumed that the 10 jurisdictions that currently allow therapeutic substitution for other drugs will also authorize this for controlled substances. It is estimated that 71.4 million prescriptions are processed on average per year in the 10 jurisdictions. Health Canada consulted with provinces and territories to collect information to help estimate the administrative costs to pharmacists. In accordance with the feedback received, Health Canada assumes a substitution rate of approximately 0.03% of the prescriptions processed in the impacted jurisdiction. It is further assumed that it will take 0.5 minutes to record the required information. Assuming an hourly wage of $60.30, the total ongoing administrative cost to pharmacists is estimated to be $65,507 (PV) or $9,327 in annualized value.

Costs to practitioners and hospitals

Record-keeping costs related to post-consumer returns

Under the baseline scenario, patients occasionally return drugs for disposal, including drugs containing a controlled substance, during a visit to a hospital or a practitioner at a clinic. These returns are not expressly authorized through the current regulations. In order to support proper disposal of unwanted medications and in response to stakeholder feedback at prepublication, practitioners and hospitals will be permitted to receive post-consumer returns of controlled substances for disposal. Practitioners and hospitals will be subject to minimal record-keeping requirements (e.g. recording the identifier on the collection container) in relation to this new authorization. Given the occasional nature and simplicity of this task, and considering that these regulated parties can destroy on site (clinic or hospital), Health Canada expects that only a limited number of clinics and amount of time will be spent on documentation.

It is assumed that, on average per year, 14 027 practitioner clinics will conduct this documentation activity. Assuming 1 minute per year will be spent on recording the required information, and using an average wage of $43.20, the total ongoing administrative cost is estimated to be $61,534 (PV) or $8,761 in annualized value. Hospitals, which are assumed to already have established protocols for documenting the destruction of controlled substances, are not expected to bear additional costs from this record-keeping requirement.

Costs to researchers

Costs associated with seeking authorization for conducting research with bezitramide and piritramide

Under the CSR, bezitramide and piritramide will be controlled as narcotics. Researchers will need a subsection 56(1) exemption to conduct activities with these two synthetic opioids. Currently, Health Canada is not aware of any research activities associated with these two substances and does not expect to receive any applications in the foreseeable future. However, if a researcher wishes to conduct research with either substance, they would need to apply for an exemption and spend an estimated 30 minutes to prepare and submit an application.

Costs to provincial governments and health professional regulatory authorities

Updating regulatory and guidance materials

There will be costs to provincial/territorial governments as well as to health professional regulatory authorities, as they will need to update relevant regulations, bylaws, policies or guidance materials to reflect the CSR (e.g. making reference to the CSR instead of the current regulations/class exemptions, reflecting new authorizations such as central fill or therapeutic substitution) and the amendments to the *Cannabis Regulations*.

Costs to the Government of Canada

Health Canada will bear costs for processing notifications and applications from licensed dealers requesting Health Canada's approval to amend their method of record-keeping under the CSR. It is assumed that the number of such applications will be limited to approximately 30 per year, and that it will take three hours to process each application. The costs to Health Canada for processing these requests are estimated to be $26,314 (PV) or $3,747 annually.

To implement and administer the CSR and amendments to the *Cannabis Regulations*, Health Canada will bear costs associated with updating forms and relevant subsection 56(1) class exemptions, developing training materials for inspectors and developing compliance promotion materials and other communication tools (e.g. updating websites). Health Canada will also bear costs for conducting compliance promotion activities to raise awareness about the new/amended regulatory requirements (e.g. providing compliance promotion and other communication materials to impacted and interested stakeholders, conducting outreach activities), updating internal documents (e.g. standard operating procedures, templates and guidance documents), inspection tools and

databases, as well as providing training to Health Canada inspectors and members of implicated federal agencies (e.g. Canada Border Services Agency). The costs to Health Canada associated with these activities are estimated to be $677,649 (PV) or $96,482 annually.

The total cost to Health Canada is estimated to be $703,963 (PV) or $100,228 in annualized value. These incremental costs will be mainly attributable to the CSR and will be absorbed through existing budgets; no additional funding will be required.

Net impact

Overall, the CSR will result in a net benefit of $0.62 million (PV) or an annualized net benefit of $88,674.

Cost-benefit statement

Number of years: 10 periods of 12 months (2025–2026 to 2034–2035)

Price year: 2022

Present value base year: Period 1 (2025)

Discount rate: 7%

Table 1: Monetized costs

Impacted stakeholders	Description of cost	Base year (Period 1)	Period 2	Period 10	Total (undiscounted)	Total (PV)	Annualized value
Licensed dealers	**Reviewing the CSR and amendments to the *Cannabis Regulations***	$52,797	N/A	N/A	$52,797	$49,343	$7,025
	Requesting approval before amending record keeping method	N/A	$516	$516	$4,641	$3,140	$447
	Recording additional information (e.g. DIN)	N/A	$25,883	$32,897	$264,511	$176,563	$25,139

Cannabis licence holders	**Reviewing the amendments to the *Cannabis Regulations***	$44,014	N/A	N/A	$44,014	$41,135	$5,857
	Recording additional information (e.g. DIN)	N/A	$697	$697	$6,275	$4,245	$604
Pharmacists and pharmacy technicians	**Reviewing the CSR and amendments to the *Cannabis Regulations***	$904,839	N/A	N/A	$904,839	$845,644	$120,401
	Recording information related to central fill transactions	N/A	$18,313	$18,313	$164,815	$111,506	$15,876
	Recording information related to therapeutic substitutions	N/A	$10,758	$10,758	$96,824	$65,507	$9,327
Practitioners	**Reviewing the CSR and amendments to the *Cannabis Regulations***	$2,201,658	N/A	N/A	$2,201,658	$2,057,625	$292,959
	Recording information related to post-consumer returns	N/A	$10,106	$10,106	$90,951	$61,534	$8,761
Hospitals	**Reviewing the CSR and amendments to the *Cannabis Regulations***	$110,949	N/A	N/A	$110,949	$103,690	$14,763
Holders of test kits registration number	**Reviewing the CSR and amendments to the *Cannabis Regulations***	$801	N/A	N/A	$801	$748	$107

Health Canada	**Implementation, compliance and enforcement**	$519,529	$68,238	$14,152	$808,627	$703,963	$100,228
All	**Total costs**	**$3,834,587**	**$134,511**	**$87,438**	**$4,751,702**	**$4,224,644**	**$601,494**

Table 2: Monetized benefits

Impacted stakeholders	Description of benefits	Base year (Period 1)	Period 2	Period 10	Total (undiscounted)	Total (PV)	Annualized value
Licensed dealers	**Spending less time on initial review of the regulatory provisions**	$92,373	$94,607	$110,616	$1,016,585	$706,137	$100,538
	No longer reporting unexplainable losses to a police force	N/A	$4,297	$4,297	$38,675	$26,166	$3,725
	No longer reporting unexplainable losses and thefts in monthly reports to Health Canada	N/A	$688	$688	$6,188	$4,187	$596

Pharmacists and pharmacy technicians	**Spending less time on initial review of the regulatory provisions**	$40,480	$41,695	$53,181	$465,212	$321,285	$45,744
	Providing central fill service without a dealer's licence	$92,900	$82,198	$219,174	$2,183,816	$1,460,113	$207,887
	Not spending time informing Health Canada about pharmacy closure	N/A	$2,512	$2,512	$22,605	$15,293	$2,177
Practitioners	**Spending less time on initial review of the regulatory provisions**	$221,928	$229,935	$318,329	$2,656,176	$1,824,478	$259,765
Holders of a test kit registration number	**Notifying Health Canada instead of requiring a new registration number for modified test kit**	N/A	$86	$86	$774	$523	$75
Researchers	**Simplified process for research authorization**	N/A	$2,040	$2,040	$18,361	$12,422	$1,769
Health Canada	**Reduction in administrative activities**	$15,761	$75,894	$75,894	$698,805	$476,847	$67,892
All	**Total benefits**	**$463,443**	**$533,951**	**$786,816**	**$7,107,196**	**$4,847,451**	**$690,168**

Table 3: Summary of monetized costs and benefits

Impacts	Base year (Period 1)	Period 2	Period 10	Total (undiscounted)	Total (PV)	Annualized value

Total costs	$3,834,587	$134,511	$87,438	$4,751,702	$4,224,644	$601,494
Total benefits	$463,443	$533,951	$786,816	$7,107,196	$4,847,451	$690,168
Net impact	**–$3,371,144**	**$399,440**	**$699,378**	**$2,355,494**	**$622,807**	**$88,674**

Qualitative impacts

Positive impacts

1. *Controlled Substances Regulations*

- All stakeholders will benefit from improved clarity, consistency, and certainty of regulatory requirements, which will result in enhanced compliance and administration of the regulatory scheme.
- All stakeholders will benefit from time savings from consulting one set of regulations instead of multiple regulations and class exemptions.
- Pharmacy technicians will benefit from the ability to independently conduct additional activities involving controlled substances, in alignment with their scope of practice as authorized under provincial legislation.
- Pharmacists may indirectly benefit from the removal of the federal regulatory barrier to therapeutic substitution of drugs containing controlled substances, provided they are authorized to do so under provincial legislation. This change removes a federal barrier to activities within the scope of the practice of pharmacists and supports more responsive patient care.
- Patients may indirectly benefit from timely and effective interventions by pharmacists, reduced wait times, and better management of adverse reactions should pharmacists be authorized under provincial legislation to conduct therapeutic substitution of prescription drugs containing controlled substances.
- Individuals travelling internationally with prescribed drugs containing cannabis or controlled substances (other than restricted drugs) will now be permitted to carry up to a 90-day supply, improving convenience and patient health, and aligning with allowances for other prescription drugs.
- Holders of test kit registration numbers will gain flexibility. For example, test kits containing controlled substances or cannabis will continue to be sold and used even if they are no longer authorized as medical devices under the MDR.
- Provincial governments and professional regulatory authorities will have flexibility in enabling therapeutic substitution for prescription drugs containing controlled substances in their respective jurisdictions. They may also benefit from access to additional information that may assist with the monitoring of professional conduct of regulated health professionals.

- Government-operated laboratories will benefit, as they will now be permitted to conduct certain activities without requiring a licence. This change will reduce administrative burden by eliminating the need for licence renewals, licence amendments, and spending related to criminal record checks.

2. Amendments to the *Cannabis Regulations*

- All stakeholders will benefit from enhanced clarity and consistency in regulatory requirements, reducing confusion and supporting better compliance and administration. For example, new changes since prepublication clarify that individuals may possess prescribed drugs containing cannabis in addition to any cannabis amounts authorized under the *Cannabis Act* (e.g. 30 grams of dried cannabis or equivalent).
- Greater harmonization of requirements and terminologies between the *Cannabis Regulations* and CSR will improve stakeholders' ability to comply with both regulatory regimes.
- Pharmacists, practitioners and hospitals will be newly authorized to sell or distribute drugs containing cannabis for destruction to any licensed dealer, increasing operational flexibility and supporting proper disposal practices.

3. Amendments to the *Precursor Control Regulations*

- Removing the requirement to report losses to a police force, while maintaining the requirement to report them to Health Canada will reduce compliance burden for affected parties, as it will save reporting time.

Negative impacts

1. *Controlled Substances Regulations*

- Once bezitramide and piritramide are controlled as narcotics under the CSR, researchers will be required to obtain a subsection 56(1) exemption under the CDSA before conducting research involving these two synthetic opioids. Although Health Canada is not currently aware of any research involving these opioids, and does not expect applications in the near future, any future applicants will need to spend approximately 30 minutes preparing and submitting an exemption request.
- While bezitramide and piritramide are unlikely to be imported into Canada for legitimate activities beyond research or forensic analysis, businesses that choose to engage in activities with these substances will need to comply with the CSR. Such businesses will need to amend their licences, apply for import/export permits, and fulfill reporting and record-keeping obligations.
- Provincial governments, as well as health professional regulatory authorities, will incur costs to update relevant regulations, bylaws, policies or guidance materials to reflect the CSR (e.g. making reference to the CSR, updating references and guidance with respect to new or

harmonized authorizations or requirements in the CSR and the amendments to the *Cannabis Regulations*).

Small business lens

The analysis conducted under the small business lens concluded that the CSR and the amendments to the *Cannabis Regulations* are expected to affect a significant number of small businesses (e.g. licensed dealers, cannabis licence holders, pharmacists and holders of test kit registration numbers). It is assumed that about 98% of affected businesses fall within the small business category.

All businesses, including small ones, will face incremental compliance and administrative costs associated with reviewing the regulatory requirements, keeping records and submitting requests to the Minister (for approving changes to record-keeping methods), as applicable. Due to the large number of affected small businesses, the total cost to small businesses for meeting these requirements is estimated to be $2.48 million (PV) or $352,388 annually. The cost per small business is relatively minor and is estimated at $91.02 (PV) or $12.96 annually.

No flexibility can be provided to these businesses, as other than spending time to review the regulatory requirements, the main costs stem from meeting record-keeping requirements that are essential for the effective administration of the regulatory framework and represent a minimal cost to individual small businesses.

In addition to the benefits associated with improved clarity and consistency of regulatory requirements and the ability to conduct newly authorized activities, the CSR will reduce burden to small businesses by eliminating certain regulatory obligations and reducing time spent reviewing and consulting regulations. These benefits are estimated to be $3.26 million (PV) or $463,739 annually. On average, each small business will save $119.78 (PV) or $17.05 annually.

Overall, the net impact to small businesses will be a saving of $0.78 million (PV), or $111,351 annually. Per small business, the savings are estimated to be $28.76 (PV) or $4.09 annually.

Small business lens summary

Number of small businesses impacted: 27 192

Number of years: 10 periods of 12 months (2025–2026 to 2034–2035)

Base year for the estimates: 2022

Present value base year: 2025

Discount rate: 7%

Costs to small businesses

Table 4: Compliance costs

Activity	Present value	Annualized value
Spending time to review the CSR and amendments to the *Cannabis Regulations* (not including provisions that impose administrative burden)	$833,838	$118,720

Table 5: Administrative costs

Activity	Present value	Annualized value
Reviewing the CSR and amendments to the *Cannabis Regulations* (provisions that impose administrative burden only)	$1,250,757	$178,080
Requesting approval from Health Canada before amending record-keeping methods (controlled substances only)	$2,669	$380
Recording additional information (e.g. DIN)	$153,900	$21,912
Recording information related to central fill transactions	$109,928	$15,651
Recording information on therapeutic substitutions	$61,534	$8,884
Recording information related to post-consumer returns	$61,534	$8761
Total administrative costs	**$1,641,187**	**$233,668**

Table 6: Total compliance and administrative costs

Total	Present value	Annualized value
Total costs (all impacted small businesses)	$2,475,025	$352,388
Costs per impacted small business	$91	$13

Table 7: Benefits to small businesses [a]

Activity	Present value	Annualized value
Spending less time on initial review of the regulatory provisions	$1,770,605	$252,094
No longer reporting unexplainable losses to a police force	$22,241	$3,167
No longer reporting unexplainable losses and thefts in monthly reports to Health Canada	$3,559	$507

a Only for activities with controlled substances.

Providing central fill service without a dealer's licence	$1,445,512	$205,808
Notifying Health Canada instead of requiring new registration number for modified test kits	$52	$7
Not spending time informing Health Canada about pharmacy closure	$15,141	$2,156
Total benefit (all impacted small businesses)	**$3,257,109**	**$463,739**
Benefit per impacted small business	**$120**	**$17**

a Only for activities with controlled substances.

Table 8: Net impacts

Activity	Present value	Annualized value
Total net benefits	$782,084	$111,351
Net benefits per affected small company	$29	$4

One-for-one rule

The one-for-one rule applies to the CSR and the amendments to the *Cannabis Regulations*. The details of the estimates, including assumptions, are available upon request from csd.regulatory.policy-politique.reglementaire.dsc@hc-sc.gc.ca.

1. *Controlled Substances Regulations*

With the CSR, there is a net reduction in regulatory titles and a net increase in the administrative burden on affected businesses. The one-for-one rule applies and the CSR is considered an "IN" under the rule.

Reduction in regulatory titles

Upon coming into force, the CSR will repeal four existing regulatory titles (i.e. NCR, BOTSR, NCPR and the Exemption Regulations) and will replace them with one new regulatory title. As a result, a net of three titles out is counted under the rule.

Administrative costs to impacted businesses

As explained in the cost-benefit analysis above, affected businesses will incur the following administrative costs:

- Reviewing the regulatory provisions related to administrative requirements by existing businesses;

- Recording of information by licensed dealers, pharmacists, pharmacy technicians and practitioners; and
- Obtaining approval of changes to the record-keeping methods by licensed dealers.

Administrative cost savings to impacted businesses

Affected businesses will also see the following administrative cost savings:

- Time saved reviewing one set of regulations instead of multiple regulations and exemptions by regulated parties after publication of the CSR in the *Canada Gazette*, Part II;
- Reduced reporting requirements for licensed dealers regarding losses and thefts in monthly reports submitted to Health Canada;
- Pharmacists not needing a licence in order to provide central fill services for controlled substances, or to notify Health Canada about a pharmacy closure; and
- Holders of test kit registration numbers only needing to notify the Minister of changes made to a test kit containing a controlled substance instead of requiring new registration numbers.

Net administrative costs

As per the requirements of the *Red Tape Reduction Act* and the *Red Tape Reduction Regulations* (RTRR), the administrative impacts on all affected businesses are estimated in dollars of the year 2012 using the prescribed formula in the RTRR over 10 years (2025–2026 to 2034–2035), and discounted to 2012 using a 7% real discount rate.

The CSR will result in an increase of $516,088 in administrative costs and a decrease of $506,798. Overall, there will be a net increase in administrative burden costs to businesses, estimated to be a net cost of $9,290 (PV) or $1,323 annually.

Number of years: 10 years (2025–2026 to 2034–2035)

Base year for costing: 2012

Present value base year: 2012

Discount rate: 7%

Table 9: Net increase in administrative costs

Net impacts	Present value	Annualized value
Total increase in administrative costs	$516,088	$73,479
Total decrease in administrative costs	$506,798	$72,157
Net increase in administrative costs	**$9,290**	**$1,323**

2. Regulations Amending the Cannabis Regulations (Harmonization with Certain Provisions of the Controlled Substances Regulations)

The one-for-one rule applies, since there is an incremental increase in the administrative burden on business and the amendments to the *Cannabis Regulations* are considered an "IN" under the rule. No regulatory titles are repealed or introduced.

The amendments to the *Cannabis Regulations* will result in an incremental increase in the administrative burden on businesses associated with time that will be spent to review the provisions related to administrative requirements, and recording of information (e.g. recording the DIN, brand name and quantity of the prescription drug containing cannabis). More information can be found in the cost-benefit analysis referenced above.

The amendments to the *Cannabis Regulations* will result in an additional cost of $70,362 (PV) or an annualized $10,018 in administrative costs, as estimated using the *Red Tape Reduction Regulations*' prescribed method.

3. *Regulations Amending Certain Regulations made under the Food and Drugs Act and the Controlled Drugs and Substances Act (Controlled Substances)*

The one-for-one rule does not apply, as the amendments do not affect administrative burden to businesses.

4. *Regulations Amending Certain Regulations Made under the Financial Administration Act (Controlled Substances)*; and *Order Amending Schedules I, III, IV and VI to the Controlled Drugs and Substances Act*

The one-for-one rule does not apply, as there is no impact on business.

Regulatory cooperation and alignment

Since the main focus of the CSR is to consolidate and modernize federal regulatory requirements for controlled substances and improve alignment with the *Cannabis Regulations* without altering the overall policy intent for these regulatory frameworks, it is not necessary to pursue regulatory alignment or regulatory cooperation with any international jurisdictions. Alignment that already exists between the federal regulations and those of any other jurisdiction is maintained. These Regulations will also remove certain federal regulatory barriers, notably those restricting central fill services and therapeutic substitution involving controlled substances. Authority over pharmacists' scope of practice will rest with individual provinces and territories, allowing them to determine whether these activities are permitted.

International obligations

The CDSA, *Cannabis Act*, and regulations made under those acts are the primary means by which Canada, as a signatory, fulfills its international obligations under the United Nations drug control conventions. The regulatory initiative does not change the overall policy intent and the key elements of the regulatory framework for controlled substances and cannabis.

Effects on the environment

The CSR consolidate and modernize the regulatory requirements for controlled substances, and improves the alignment between these requirements and those of the *Cannabis Regulations* to the extent necessary. They will not have any negative or positive effects on the environment. In accordance with the *Cabinet Directive on Strategic Environmental and Economic Assessment*, a preliminary scan concluded that a strategic environmental and economic assessment is not required.

Gender-based analysis plus

A sex- and gender-based analysis plus assessment was conducted as part of developing the CSR and the amendments to the *Cannabis Regulations* to determine

- whether individual people in Canada will be affected; and
- whether the regulatory changes will affect a particular group or subgroup of people in Canada differently than others when compared to the status quo.

The CSR will consolidate several sets of regulations and exemptions. While some changes to regulatory provisions will be made, most of the changes will not affect individual people in Canada. However, there are additional benefits to travelling individuals, compared to the benefit the current exemption provides, as individuals will be able to carry greater quantities (up to a 90-day supply) of prescription medications containing cannabis, a narcotic, a targeted substance or a controlled drug. Therefore, travellers needing to carry a quantity of prescription drugs containing cannabis or a controlled substance for more than 30 days, but up to a 90-day supply, will no longer need to apply for an individual exemption under the CDSA or the *Cannabis Act*. This benefit will be imparted to all categories of travellers — particularly those with chronic medical conditions requiring ongoing treatment beyond 30 days — and will apply equally to all individuals who are travelling into or out of Canada who require prescription medications containing cannabis or a controlled substance to treat their medical conditions. No subgroups of travellers will be disproportionally impacted.

There are several exemptions already in place that pertain to individuals and health care professionals that will be repealed when the CSR take effect. The benefits that these groups currently receive from these exemptions will continue to apply under the CSR. Given that these exemptions would have continued to exist in the absence of regulations, incorporating them into the CSR will not lead to any changes to the benefits the exemptions were providing before their revocation. Therefore, no individual people in Canada or subgroups of people in Canada are expected to be affected by incorporating authorizations in these exemptions into the CSR and no impacts based on sex, gender or other factors are anticipated.

Under the baseline scenario, all Canadian provincial and territorial jurisdictions, except Ontario, the Northwest Territories, and Nunavut, allow pharmacists to substitute one drug for another. However, the current federal regulations for controlled substances do not allow for the substitution of prescription drugs containing controlled substances. Under the regulatory scenario, provinces that currently limit the substitution of drugs containing a controlled substance, in line with the existing

federal regulations, will have the flexibility to decide whether to also authorize therapeutic substitution for drugs containing controlled substances. In jurisdictions where pharmacists will be permitted to substitute prescription drugs containing controlled substances, patients will benefit from more timely substitution of medications and more responsive health care – particularly in cases involving a drug shortage or a drug that does not meet the patient's needs. This will enhance both convenience and safety for patients. Although removing the federal barrier will allow individual jurisdictions to enable therapeutic substitution should they choose to do so, any difference in geographic distribution of this benefit is not directly attributable to the federal regulatory change. The federal regulatory change is not expected to have any direct and disproportionate impact on any groups or subgroups based on sex, gender or any other intersecting factors.

Given that the CSR and amendments to the *Cannabis Regulations* will bring additional benefits to travellers and will maintain the benefits that certain class exemptions currently provide to certain categories of health professionals, no concerns are anticipated from any stakeholders or the public.

Finally, the amendments to the *Cannabis Regulations* will further benefit individuals by clarifying that they may possess quantities of prescription drugs containing cannabis, including imported drugs containing cannabis, without impacting any other authorized amounts of cannabis under the *Cannabis Act*. This benefit will be imparted to all categories of individuals that publicly possess cannabis. No sub-population impacts are expected.

Implementation, compliance and enforcement, and service standards

Implementation

The CSR come into force on October 1, 2026. This delayed coming-into-force date is to provide regulated parties with sufficient time to prepare for the implementation of the CSR and, where necessary, make adjustments to comply with the regulatory requirements around information and record-keeping. For consistency, the consequential and coordinating amendments will come into force on the same day the CSR come into force.

While Health Canada will continue to employ the existing mechanisms to administer the CSR when they come into force, certain administrative adjustments will be made for implementation, including updating application forms (e.g. application form for a dealer's licence), updating web pages as well as certain related existing exemptions, updating internal information management systems and repealing relevant class exemptions.

The CSR and the amendments to the *Cannabis Regulations* will not alter the existing administration and compliance mechanisms for these regulatory frameworks. Health Canada has informed stakeholders about the consolidated and modernized requirements. Health Canada will also reply to stakeholders' enquiries as needed.

Compliance and enforcement

Compliance promotion and outreach activities (including publication of notices and guidance documents aimed at informing and educating stakeholders about the CSR) will be undertaken to increase awareness of the modernized regulatory requirements and will assist regulated parties in further achieving compliance. Limited compliance promotion activities will also be undertaken with respect to the amendments to the *Cannabis Regulations*.

Health Canada is responsible for authorizing (through licences, permits, and exemptions) legitimate activities with controlled substances or cannabis under the CDSA or *Cannabis Act* and their regulations and for monitoring compliance with regulatory requirements. The Canada Border Services Agency supports compliance monitoring for controlled substances and cannabis at the border. Federal, provincial and local law enforcement are responsible for taking enforcement action in response to contraventions of the CDSA or the *Cannabis Act* and their regulations.

In instances of non-compliance, consideration is given to factors such as the nature of the alleged violation, effectiveness in achieving compliance with the CDSA or the *Cannabis Act* and their regulations, and consistency in enforcement when deciding which enforcement measures to take. Under the CDSA and the *Cannabis Act*, a range of compliance and enforcement measures may be taken to address the prohibitions and apply offences associated with activities involving controlled substances or cannabis. These could include warning letters, corrective action plans, seizures and recommendations for prosecutions. The maximum penalty for indictable offences with respect to controlled substances is life imprisonment and with respect to cannabis is imprisonment for a term not exceeding 14 years.

As the CSR represent a consolidation and modernization of current regulations for controlled substances, and amendments to the *Cannabis Regulations* will maintain alignment with the CSR, there will be no change in the manner in which regulations under the CDSA and the *Cannabis Act* are enforced.

Service standards

Although the CSR improve the administration of and compliance with these regulations, no changes in service standards are anticipated. The current service standards that already exist for issuing licences, permits and exemptions remain in place and no additional service standards are required. Similarly, no change in service standards is necessary due to the amendments to the *Cannabis Regulations*.

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Footnotes

a S.C. 2024, c. 17, s. 413(1) to (3)

b S.C. 1996, c. 19

1 C.R.C., c. 870

2 C.R.C., c. 1041; SOR/2019-169, s. 1

3 SOR/97-229

4 SOR/2000-217; SOR/2003-38, s. 1

5 SOR/2012-230

6 It should be noted that industrial hemp falls under the *Cannabis Act*, regulated under the *Industrial Hemp Regulations*, and is not subject to the *Cannabis Regulations*.

7 Licensed dealers are only licensed under the CDSA, but are also authorized under the Cannabis Regulations to conduct particular activities with cannabis.

8 Based on the specific regulatory content that each regulated party will review, the anticipated time savings vary among regulated parties. A newly licensed dealer is expected to save approximately 17.10 hours, while a newly designated responsible person (qualified person in charge, alternate qualified person in charge, or senior person in charge) is expected to save around 4.28 hours per individual. A pharmacist or pharmacy technician will save 0.50 hours, and a practitioner will save approximately 0.35 hours.

9 Record-keeping costs were estimated separately for each type of cannabis licence holder:

- Cannabis drug licence holders: they are expected to record 10 483 entries annually, with each entry taking approximately 5 seconds to complete.
- Research licence holders: It is estimated that 1% of these holders will be impacted. Each affected holder records 10 entries per year, with each entry requiring 5 seconds.
- Analytical testing licence holders: Among the 124 holders, 5% are expected to be affected. Each of these spends approximately 10 minutes annually on recording information.

Additionally, licence holders are required to record the DIN for import/export activities and voluntary recalls. The affected licence holders will record 9 entries annually, with each entry requiring 5 seconds to complete.