

Regulations Amending the Food and Drug Regulations

Statutory Authority

Controlled Drugs and Substances Act

Sponsoring Department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

For the Regulatory Impact Analysis Statement, see the Regulations Amending the Narcotic Control Regulations and other Related Regulations.

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act* ([see footnote e](#)), proposes to make the annexed *Regulations Amending the Food and Drug Regulations*.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Shereen Khan, Office of Controlled Substances, Department of Health, Address Locator 3503 D, Ottawa, Ontario K1A 1B9 (Fax: (613) 946-4224; e-mail: OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, September 18, 2003

EILEEN BOYD
Assistant Clerk of the Privy Council

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS

AMENDMENTS

1. (1) The definition "licence" in subsection G.01.001(1) of the *Food and Drug Regulations* ([see footnote 6](#)) is repealed.

(2) The definition "licensed dealer" in subsection G.01.001(1) of the Regulations is replaced by the following:

"licensed dealer" means the holder of a licence issued under section G.02.003.2; (*distributeur autorisé*)

(3) Subsection G.01.001(1) of the Regulations is amended by adding the following in alphabetical order:

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

"international obligation" means an obligation in respect of a controlled drug set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres; (*obligation internationale*)

"qualified person in charge" means the individual with the qualifications specified in subsection G.02.001.2(2) who is responsible for supervising the activities carried out by a licensed dealer under their licence at the premises specified in the licence; (*personne qualifiée responsable*)

(4) Subsection G.01.001(2) of the Regulations is amended by adding the following in alphabetical order:

"designated criminal offence" means

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

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

(c) the offence of laundering proceeds of crime against section 462.31 of the *Criminal Code*;

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

(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 paragraphs (a) to (d). (*infraction désignée en matière criminelle*)

"Security Directive" means the *Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances)* published by the Department, as amended from time to time. (*Directive en matière de sécurité*)

2. The portion of section G.01.003 of the French version of the Regulations before paragraph (a) is replaced by the following:

G.01.003. L'article C.01.004 ne s'applique pas à une drogue contrôlée fournie par un pharmacien d'après une ordonnance, mais l'étiquette de l'emballage de la drogue contrôlée doit porter :

3. Section G.02.001 of the Regulations is replaced by the following:

G.02.001. Subject to this Part, no person except a licensed dealer shall produce, make, assemble, import, export, sell, provide, transport, send or deliver a controlled drug.

G.02.001.1. To be eligible for a dealer's licence, a person must be

(a) an individual who ordinarily resides in Canada;

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

(c) an individual who occupies a position that includes responsibility for controlled drugs on behalf of a department of the government of Canada or of a province, a police force, a hospital or a university in Canada.

G.02.001.2. (1) A licensed dealer

(a) shall designate no more than one qualified person in charge, who may be the licensed dealer if the licensed dealer is an individual, who must work at the premises specified in the licence, have responsibility for supervising activities with respect to controlled drugs specified in the licence and for ensuring on behalf of the licensed dealer that those activities comply with these Regulations; and

(b) may designate an alternate qualified person in charge who must work at the premises specified the licence and have authority to replace the qualified person in charge when that person is absent.

(2) The qualified person in charge and, if applicable, the alternate qualified person in charge

(a) shall be familiar with the provisions of the Act and the regulations under it that apply to the licence of the licensed dealer who designated them and have knowledge of chemistry and pharmacology and experience in those fields to properly carry out their duties;

(b) shall be a pharmacist or a practitioner registered with a licensing body of a province or possess a degree in an applicable science — such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, organic chemistry or chemical engineering — that is awarded by a Canadian university or, if awarded by a foreign university, that is recognized by a Canadian university or a Canadian professional association; and

(c) shall not have been convicted, as an adult, within the preceding 10 years, of

- (i) a designated drug offence,
- (ii) a designated criminal offence, or
- (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii).

4. Sections G.02.003 to G.02.007 of the Regulations are replaced by the following:

G.02.003. (1) To apply for a dealer's licence, a person shall submit an application to the Minister containing:

(a) their name or, if the applicant is a corporation, their corporate name and any other name registered with a province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself,

(b) the address, telephone number and, if applicable, the facsimile number and e-mail address for the premises to which the dealer's licence would apply and, if different, the mailing address for the premises;

(c) the name, date of birth and gender of the individual in charge of the premises;

(d) with respect to the qualified person in charge and, if applicable, the alternate qualified person in charge at the premises,

- (i) their name, date of birth and gender,
- (ii) their academic qualifications, training and work experience relevant to their duties,
- (iii) their hours of work at the premises,
- (iv) their title at the premises,

(v) the name and title of their immediate supervisor at the premises, and
(vi) in the case of a pharmacist or a practitioner, the name of the province in which the person's current professional licence, certification or authorization was issued and the professional licence, certification or authorization number;

(e) the name and gender of the individuals authorized to place an order for a controlled drug on behalf of the applicant;

(f) in the case of a product or compound that contains a controlled drug but is not a test kit and that would be made or assembled for or by the applicant, a list that sets out

- (i) the brand name, if any, of each product or compound,
- (ii) the controlled drug in each product or compound,
- (iii) the strength per unit of the controlled drug in each product or compound,
- (iv) the quantity or package sizes of each product or compound, and
- (v) if the product or compound would be made or assembled by or for another licensed dealer under a custom order, the name, address and the dealer's licence number of the other dealer;

(g) the activities referred to in section G.02.001 for which the licence is sought that would be carried out at the premises to which the dealer's licence would apply;

(h) if the licence is sought to produce a controlled drug other than a product or compound that contains a controlled drug,

- (i) the name of the controlled drug to be produced,
- (ii) the quantity that the applicant expects to produce under the dealer's licence and the period during which that quantity would be produced, and
- (iii) if the controlled drug would be produced for another licensed dealer under a custom order, the name, address and dealer's licence number of the other dealer;

(i) a detailed description of the security measures at the premises, determined in accordance with the Security Directive,

(j) a detailed description of the method that the applicant proposes to use for recording their controlled drug transactions; and

(k) for any activity referred to in section G.02.001, other than the activities described in paragraphs (f) and (h), the controlled drug and the purpose for carrying out the activity.

(2) An application for a dealer's licence must

(a) be signed by the individual in charge of the premises to which the licence would apply; and

(b) be accompanied by a statement signed by the individual in charge indicating that

- (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
- (ii) the individual has the authority to bind the applicant.

(3) An application for a dealer's licence must be accompanied by

(a) declarations signed by the individual in charge of the premises, the qualified person in charge and, if applicable, the alternate qualified person in charge, stating that they have not been convicted, as an adult, during the preceding 10 years of

- (i) a designated drug offence,
- (ii) a designated criminal offence, or
- (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(b) a document issued by a Canadian police force with respect to each of the persons referred to in paragraph (a), stating whether the person has or has not been convicted, as an adult, during the preceding 10 years, of a designated drug offence or a designated criminal offence;

(c) if any of the persons referred to in paragraph (a) has ordinarily resided in a country other than Canada during the preceding 10 years, a document issued by a police force of that country stating whether the person has or has not been convicted in that country, as an adult, during the preceding 10 years, of an offence that would have constituted a designated drug offence or a designated criminal offence if committed in Canada;

(d) a statement, signed and dated by the individual in charge of the premises to which the application applies, stating that the qualified person in charge and, if applicable, the alternate qualified person in charge have the knowledge and experience required under paragraph G.02.001.2(2)(a);

(e) if the qualified person in charge or, if applicable, the alternate qualified person in charge is not a pharmacist or a practitioner registered with a licensing body of a province, a copy of the person's degree required under paragraph G.02.001.2(2)(b) and a copy of the course transcript for that degree;

(f) if the applicant's name appears on the label of a product or compound that contains a controlled drug, a copy of the inner label, as defined in section A.01.010, for each product or compound to which the licence would apply; and

(g) if the applicant is a corporation, a copy of

- (i) the certificate of incorporation or other constituting instrument, and
- (ii) any document filed with the province in which the premises to which the licence would apply are located that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.

(4) The method proposed by the applicant under paragraph (1)(j) must

(a) allow for the recording of controlled drug transactions in accordance with section G.02.014; and

(b) permit the Minister to audit the activities of the licensed dealer with respect to controlled drugs.

(5) The documents referred to in paragraphs (3)(b) and (c) are not required if the persons referred to in those paragraphs consent in writing

(a) to having a criminal record check carried out for them, as an adult, in respect of the offences referred to in those paragraphs during the preceding 10 years;

(b) to provide all necessary information and to submit to any means of identification required to obtain the criminal record check; and

(c) to pay the fee established by the *Royal Canadian Mounted Police, Criminal Record Verification for Civil Purposes Fee Regulations*.

G.02.003.1. The Minister may, on receiving an application made under this Part, require the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to process the application.

G.02.003.2. Subject to section G.02.003.3, the Minister shall, after examining the information and documents required under sections G.02.003 and G.02.003.1, issue a dealer's licence that contains:

(a) the licence number;

(b) the name of the licensee or, if the applicant is a corporation, its corporate name;

- (c) a list of the activities that are permitted;
- (d) the address of the premises at which the licensed dealer may carry on the permitted activities;
- (e) the name of the controlled drug for which the activities are permitted;
- (f) the security level at the premises;
- (g) the effective date of the licence;
- (h) the expiry date of the licence, which may not be later than three years after its effective date;
- (i) any conditions to be met by the holder of the licence to
 - (i) ensure that an international obligation is respected,
 - (ii) provide the security level referred to in paragraph (f), or
 - (iii) reduce the potential security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use;
- (j) in the case of a producer of a controlled drug, the quantity of the controlled drug that may be produced under the licence and the period during which that quantity may be produced; and
- (k) in the case of the maker or assembler of a product or compound that contains a controlled drug but is not a test kit, an annexed list that sets out the following information for each type of product or compound that may be made or assembled under the licence:
 - (i) the licence number,
 - (ii) the brand name, if any, of each product or compound,
 - (iii) the controlled drug in each product or compound,
 - (iv) the strength per unit of the controlled drug in each product or compound, and
 - (v) the quantity or package sizes of each product or compound.

G.02.003.3. (1) The Minister shall refuse to issue, renew or amend a dealer's licence if:

- (a) the applicant is not an eligible person under section G.02.001.1;
- (b) an inspector who has requested an inspection has not been given the opportunity by the applicant to conduct an inspection under section G.02.015;

(c) false or misleading information or false or falsified documents were submitted in or with the application;

(d) an activity for which the licence is requested would not be in compliance with an international obligation;

(e) information received from a competent authority or the United Nations raises a reasonable belief that the applicant has been involved in the diversion of a controlled drug to an illicit market or use or has been involved in an activity that was not in compliance with an international obligation;

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

(g) the applicant is in contravention of or has contravened during the preceding 10 years

- (i) a provision of the Act or the regulations made or continued under it, or
- (ii) a term or condition of another dealer's licence or of an import or export permit issued to the applicant under any regulations made or continued under the Act;

(h) the issuance, amendment or renewal of the licence would likely create a risk to public health, safety or security, including the risk of a controlled drug being diverted to an illicit market or use;

(i) the individual in charge of the premises, the qualified person in charge or, if applicable, the alternate qualified person in charge has been convicted, as an adult, within the previous 10 years, of

- (i) a designated drug offence,
- (ii) a designated criminal offence, or
- (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(j) the proposed method referred to in paragraph G.02.003(1)(j) is not capable of recording controlled drug transactions as required under section G.02.014 or permitting the Minister to audit the applicant's activities with respect to controlled drugs in a timely manner; or

(k) the additional information required under section G.02.003.1 has not been provided or is insufficient to process the application.

(2) The Minister is not required to refuse to issue, renew or amend a licence under paragraph (1)(c) or (g) if the applicant

(a) does not have a history of non-compliance with the Act or any regulation made or continued under it; and

(b) has carried out, or signed an undertaking to carry out, specified corrective measures to ensure compliance with the Act and these Regulations.

G.02.003.4. (1) To apply to renew a dealer's licence, a licensed dealer shall submit to the Minister

(a) the information referred to in paragraphs G.02.003(1)(a) to (k); and

(b) the following documents, namely,

(i) the documents referred to in paragraphs G.02.003(3)(a) and (d) and, subject to subsection G.02.003(5), the document referred to in paragraph G.02.003(3)(b),

(ii) if applicable and if not previously submitted in respect of the dealer's licence that is being renewed, the document referred to in paragraph G.02.003(3)(e), and

(iii) the original dealer's licence that is to be renewed.

(2) An application for renewal must

(a) be signed by the individual in charge of the premises to which the renewed dealer's licence would apply; and

(b) be accompanied by a statement signed by the individual in charge indicating that

(i) all information and documents submitted in support of the application

are correct and complete to the best of their knowledge, and

(ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section G.02.003.3, the Minister shall, after examining the information and documents required under subsections (1) and (2) and section G.02.003.1, issue a renewed dealer's licence that contains the information specified in paragraphs G.02.003.2(a) to (k).

G.02.003.5. (1) To have its dealer's licence amended, a licensed dealer shall submit to the Minister

(a) an application in writing describing the proposed amendment, accompanied by the supporting documents referred to in section G.02.003 that are relevant to the proposed amendment; and

(b) the original dealer's licence.

(2) An application for amendment must

(a) be signed by the individual in charge of the premises to which the amended dealer's licence would apply; and

(b) be accompanied by a statement signed by the individual in charge indicating that

- (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
- (ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section G.02.003.3, the Minister shall, after examining the application for amendment and the supporting documentation, amend the dealer's licence in accordance with the application and may add any conditions to be met by the holder of the licence to

(a) ensure that an international obligation is respected;

(b) provide for the security level referred to in paragraph G.02.003.2(f) or the new level required as a result of the amendment being implemented; or

(c) reduce the potential security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use.

G.02.003.6. (1) A licensed dealer shall

(a) obtain the Minister's approval before making any of the following changes, namely,

- (i) a change relating to the security at the premises referred to in the dealer's licence, or
- (ii) the replacement or addition of
 - (A) the individual in charge of the premises to which the dealer's licence applies,
 - (B) the qualified person in charge and, if applicable, the alternate qualified person in charge at the premises to which the dealer's licence applies, and
 - (C) an individual authorized to place an order for a controlled drug on behalf of the licensed dealer;

(b) notify the Minister, not later than 10 days after the change, when a person referred to in clause (a)(ii)(A) or (C) ceases to carry out their duties as specified in

- (i) the application for the dealer's licence under section G.02.003,
- (ii) the application to renew the dealer's licence under section G.02.003.4,
- or
- (iii) the request for approval under paragraph (a); and

(c) notify the Minister, not later than the next business day after the change, when a person referred to in clause (a)(ii)(B) ceases to carry out their duties as specified in

- (i) the application for the dealer's licence under section G.02.003,
- (ii) the application to renew the dealer's licence under section G.02.003.4,
- or
- (iii) the request for approval under paragraph (a).

(2) The licensed dealer shall, with the request for approval referred to in subparagraph (1)(a)(ii), provide the Minister with the following information and documents with respect to the new person:

(a) in the case of the replacement of the individual in charge of the premises to which the dealer's licence applies,

- (i) the information specified in paragraph G.02.003(1)(c), and
- (ii) the declarations specified in paragraph G.02.003(3)(a) and, subject to subsection G.02.003(5), the documents specified in paragraphs G.02.003(3)(b) and (c);

(b) in the case of the replacement of the qualified person in charge or the replacement or addition of the alternate qualified person in charge at the premises to which the dealer's licence applies,

- (i) the information specified in paragraph G.02.003(1)(d), and
- (ii) the documents specified in paragraphs G.02.003(3)(a), (d) and (e) and, subject to section G.02.003(5), the documents specified in paragraphs G.02.003(3)(b) and (c); and

(c) in the case of the replacement or addition of an individual who is authorized to place an order for a controlled drug on behalf of the licensed dealer, the individual's name and gender.

G.02.003.7. The Minister shall revoke a dealer's licence at the request of the licensed dealer or on being notified by the licensed dealer that the licence has been lost or stolen.

G.02.003.8. (1) Subject to subsection (2), the Minister shall revoke a dealer's licence in accordance with section G.02.003.91 if:

(a) the licence was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application;

(b) the licensed dealer has failed to comply with a provision of the Act, a regulation under it or a term or condition of the licence or of an import or export permit issued under this Part;

(c) the licensed dealer is no longer an eligible person under section G.02.001.1;

(d) it is discovered that the individual in charge of the premises to which the licence applies, the qualified person in charge or, if applicable, the alternate qualified person in charge at those premises, has been convicted, as an adult, within the preceding 10 years, of

- (i) a designated drug offence,
- (ii) a designated criminal offence, or
- (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii); or

(e) information received from a competent authority or the United Nations raises a reasonable belief that the licensed dealer has been involved in the diversion of a controlled drug to an illicit market or use.

(2) The Minister is not required to revoke a dealer's licence under paragraph (1)(a) or (b) if the licensed dealer

(a) has no history of non-compliance with the Act and the regulations made or continued under it; and

(b) has carried out, or signed an undertaking to carry out, corrective measures to ensure compliance with the Act and these Regulations.

G.02.003.9. The Minister shall suspend a dealer's licence without prior notice if it is necessary to do so to protect security, public health or safety, including preventing a controlled drug from being diverted to an illicit market or use.

G.02.003.91. (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a dealer's licence under this Part, the Minister shall

(a) send a notice to the applicant or to the holder of the licence, together with a written report that sets out the reasons for the proposed refusal or revocation; and

(b) give the applicant or holder an opportunity to be heard in respect of the proposed refusal or revocation.

(2) The suspension of a dealer's licence under this Part takes effect as soon as the Minister notifies the holder of the licence of the decision to suspend and provides a written report that sets out the reasons for the suspension.

(3) A person who receives a notice of suspension referred to in subsection (2) may, within 10 days after receiving the notice, provide the Minister with reasons why the suspension of the licence is unfounded.

G.02.004. A licensed dealer may, subject to the terms and conditions of their licence, produce, make, assemble, sell, provide, transport, send or deliver only the controlled drugs specified in their dealer's licence.

5. Sections G.02.011 and G.02.012 of the Regulations are replaced by the following:

G.02.011. The Minister shall revoke or suspend a permit issued under this Part if the Minister determines that the person to whom the permit was issued has failed to comply with any term or condition of the permit or any provision of these Regulations.

G.02.012. A dealer's licence is valid until the earlier of

(a) the expiry date set out in the licence; and

(b) the revocation or suspension of the licence under section G.02.003.7, G.02.003.8 or G.02.003.9.

6. Paragraphs G.02.014(1)(a) to (c) of the Regulations are replaced by the following:

(a) the name and quantity of any controlled drug received by the licensed dealer, the name and address of the person who sold or provided it and the date it was received;

(b) the name, quantity and form of any controlled drug sold or provided by the licensed dealer, the name and address of the person to whom it was sold or provided and the date it was sold or provided;

(c) the name and quantity of any controlled drug used in the making or assembling of a product or compound containing that narcotic, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;

(c.1) the name and quantity of any narcotic produced and the date on which it was placed in stock; and

7. Section G.02.015 of the Regulations is replaced by the following:

G.02.015. (1) The Minister may, in respect of a licensed dealer, require an inspection to be made, at any reasonable time, of

(a) the premises used or intended to be used in producing, making, assembling or storing a controlled drug;

(b) the process and conditions of the producing, making, assembling or storing; and

(c) the record of information referred to in section G.02.014.

(2) The Minister may, in respect of a licensed dealer, require a verification to be made, at any reasonable time, of the qualifications of its technical staff concerned with producing, making, assembling or storing a controlled drug.

8. Paragraphs G.02.018(b) and (c) of the Regulations are replaced by the following:

(b) the premises in which a controlled drug is produced, made, assembled or stored; and

(c) the process and conditions of the producing, making, assembling or storing.

9. (1) The portion of section G.02.024 of the Regulations before paragraph (a) is replaced by the following:

G.02.024. A licensed dealer shall not sell or provide a controlled drug to any person other than a

(2) Paragraph G.02.024(e) of the Regulations is replaced by the following:

(e) Regional Director of the Department; or

10. Paragraphs G.02.024.1(a) to (d) of the Regulations are replaced by the following:

(a) sell or provide a controlled drug, other than a preparation, to a pharmacist named in a notice given by the Minister under section G.03.017.2;

(b) sell or provide a preparation to a pharmacist named in a notice given by the Minister under section G.03.017.2;

(c) sell or provide a controlled drug, other than a preparation, to a practitioner named in a notice given by the Minister under section G.04.004.2; or

(d) sell or provide a preparation to a practitioner named in a notice given by the Minister under section G.04.004.2.

11. (1) The portion of subsection G.02.025(1) of the Regulations before paragraph (b) is replaced by the following:

G.02.025. (1) Subject to this section, a licensed dealer may, in accordance with the terms and conditions of their dealer's licence, sell or provide a controlled drug to a person referred to in section G.02.024 if

(a) the drug is contained in a package that is authorized and described in the dealer's licence of the producer, maker or assembler of the drug; and

(2) Subsections G.02.025(2) and (3) of the Regulations are replaced by the following:

(2) A licensed dealer who has received an order referred to in subparagraph (1)(b)(i) and verified the signature on the order may sell or provide a controlled drug to a person referred to in section G.02.024, if the order is signed and dated by one of the following persons:

(a) if the controlled drug is to be sold or provided to a person referred to in paragraph G.02.024(2)(a), (b), (c), (e) or (f), by that person; or

(b) if the controlled drug is to be provided to a hospital employee or a practitioner in a hospital, by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to sign the order.

(3) A licensed dealer may sell or provide a controlled drug pursuant to an order received from a remote input device through a computer if the computer program and the remote input device meet the requirements of subsections (5) and (6).

(3) Subsections G.02.025(3.1) and (3.2) of the English version of the Regulations are replaced by the following:

(3.1) A licensed dealer who has received an order sent through a computer from a remote input device referred to in subparagraph (1)(b)(ii) may provide a controlled drug to a hospital employee or to a practitioner in a hospital if the order has been placed by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to place the order.

(3.2) A licensed dealer who has received a verbal order referred to in subparagraph (1)(b)(iii) may provide a controlled drug listed in Part II or III of the schedule to this Part to a hospital employee or to a practitioner in a hospital if the order has been placed by the pharmacist in charge of the dispensary of the

hospital or by a practitioner authorized by the person in charge of the hospital to place the order.

(4) Subsection G.02.025(4) of the Regulations before paragraph (c) is replaced by the following:

(4) A licensed dealer who has received a verbal order referred to in subparagraph (1)(b)(iii), and has provided a controlled drug listed in Part II or III of the schedule to this Part to a person referred to in paragraphs G.02.024(b) to (d), shall immediately record

(a) the name of the person to whom the controlled drug was sold or provided;

(b) if the drug was provided to a hospital employee or a practitioner in a hospital, the name of the pharmacist in charge of the dispensary of the hospital or the name of the practitioner authorized by the person in charge of the hospital to sign the order; and

(5) The portion of subsection G.02.025(8) of the Regulations before paragraph (a) is replaced by the following:

(8) If a licensed dealer has not received a receipt from a pharmacist or practitioner under subsection (7) within the time prescribed by that subsection, the dealer shall not, until after receiving the receipt, sell or provide a controlled drug to the pharmacist or practitioner pursuant to a further

(6) Paragraphs G.02.025(8)(a) and (b) of the English version of the Regulations are replaced by the following:

(a) order sent through a computer from a remote input device referred to in subparagraph (1)(b)(ii); or

(b) verbal order referred to in subparagraph (1)(b)(iii).

12. (1) The portion of section G.02.026 of the Regulations before subparagraph (a)(i) is replaced by the following:

G.02.026. A licensed dealer shall not sell or provide a controlled drug more than once in respect of one order unless

(a) the order for the drug states that the quantity of the drug is to be sold or provided

(2) Paragraph G.02.026(b) of the Regulations is replaced by the following:

(b) at the time of receipt of the order the licensed dealer temporarily does not have in stock the quantity of the drug ordered, in which case the dealer may sell or provide against the order the quantity of the drug that the dealer has available and deliver the balance later in accordance with the order.

13. Subsection G.03.001(1) of the Regulations is replaced by the following:

G.03.001. (1) A pharmacist, on receipt of a controlled drug from a licensed dealer, shall keep a record of the name and quantity of the controlled drug received by them, the name and address of the person who sold or provided it and the date it was received.

14. (1) The portion of section G.03.002 of the Regulations before paragraph (a) is replaced by the following:

G.03.002. No pharmacist shall, except as otherwise provided in this Part, sell or provide a controlled drug to any person unless the pharmacist has first been provided with a prescription for it, and

(2) Paragraphs G.03.002 (a) and (b) of the French version of the Regulations are replaced by the following:

a) si l'ordonnance est écrite, s'assurer qu'elle est signée et datée par le praticien dont elle émane et vérifier lui-même toute signature qu'il ne connaît pas;

b) si l'ordonnance est verbale, prendre les précautions raisonnables pour s'assurer que la personne la prescrivante est bien un praticien.

15. Paragraphs G.03.002.1(a) to (d) of the Regulations are replaced by the following:

(a) sell or provide a controlled drug, other than a preparation, to a pharmacist named in a notice given by the Minister under section G.03.017.2;

(b) sell or provide a preparation to a pharmacist named in a notice given by the Minister under section G.03.017.2;

(c) dispense, sell or provide a controlled drug, other than a preparation, to, or pursuant to a prescription or order given by, a practitioner named in a notice given by the Minister under section G.04.004.2; or

(d) dispense, sell or provide a preparation to a practitioner or pursuant to a prescription or order given by a practitioner named in a notice given by the Minister under section G.04.004.2.

16. (1) The portion of section G.03.003 of the Regulations before paragraph (a) is replaced by the following:

G.03.003. A pharmacist may sell or provide a controlled drug to a practitioner for use in their practice

(2) Paragraph G.03.003(a) of the French version of the Regulations is replaced by the following:

a) sur réception d'une commande écrite, signée et datée par le praticien, pourvu qu'il vérifie la signature du praticien si elle lui est inconnue;

(3) Paragraph G.03.003(b) of the English version of the Regulations is replaced by the following:

(b) upon a verbal order specifying the name and quantity of the drug if the pharmacist has taken reasonable precautions to satisfy themselves that the person making the order is a practitioner.

17. Section G.03.004 of the Regulations is replaced by the following:

G.03.004. A pharmacist shall, in respect of controlled drugs sold or provided to a practitioner under section G.03.003, keep in a special prescription file a record showing the date, the name and address of the practitioner, and the quantity and kind of controlled drug sold or provided.

18. Section G.03.005 of the English version of the Regulations is replaced by the following:

G.03.005. A pharmacist may provide a controlled drug to a hospital employee or to a practitioner in a hospital on receipt of a written order signed and dated by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to sign the order, if the signature of that pharmacist or practitioner is known to the pharmacist or, if unknown, has been verified.

19. Paragraph G.03.007(e) of the Regulations is replaced by the following:

(e) the date on which the controlled drug was sold or provided; and

20. Paragraph G.03.008(f) of the Regulations is replaced by the following:

(f) the date on which the controlled drug was sold or provided; and

21. Paragraphs G.03.014(a) to (d) of the Regulations are replaced by the following:

(a) the licensed dealer who sold or provided that drug to them, return that drug to that dealer;

(b) another pharmacist, sell or provide any quantity of that drug to that other pharmacist that is specified in the order as being required for emergency purposes;

(c) a Regional Director of the Department, sell or provide to or in accordance with the order of that Director any quantity of that drug, specified in the order, that is required by the Director in connection with their duties; and

(d) a person exempted under section 56 of the *Controlled Drugs and Substances Act* with respect to that controlled drug, sell or provide to that person any quantity of that drug that is specified in the order.

22. Section G.03.015 of the Regulations is replaced by the following:

G.03.015. A pharmacist shall immediately after receiving, selling or providing a controlled drug under paragraph G.03.014(b) or (c) or subsection G.05.003(4) enter the details of the transaction in a book, register or other record maintained for the purpose of recording such transactions.

23. The definition "administer" in subsection G.04.001(1) of the Regulations is replaced by the following:

"administer" includes to prescribe, sell or provide; (*administret*)

24. Subsection G.04.002(1) of the Regulations is replaced by the following:

G.04.002. (1) A practitioner who sells or provides a controlled drug to a person for self-administration or for administration to an animal shall, whether or not the practitioner charges for the drug, keep a record showing the name and quantity of the controlled drug sold or provided, the name and address of the person to whom it was sold or provided and the date on which it was sold or provided if the quantity of the controlled drug exceeds

(a) three times the maximum daily dosage recommended by the producer, maker or assembler of the controlled drug; or

(b) three times the generally recognized maximum daily therapeutic dosage for that controlled drug if the producer, maker or assembler has not recommended a maximum daily dosage.

25. Subparagraph G.04.002A(a)(i) of the Regulations is replaced by the following:

(i) the use by the practitioner of controlled drugs received — including the administering, selling or providing of the drugs to a person — , and

26. Section G.04.003 of the Regulations is replaced by the following:

G.04.003. If a practitioner alleges or, in any prosecution for an offence under the Act, the *Food and Drugs Act* or this Part, pleads that their possession of a controlled drug was for use in their practice or that they administered it to a person or animal, or prescribed, sold, or provided it for a person or an animal who or that was a patient under their professional treatment and that the controlled drug was required for the condition for which the patient received treatment, the burden of proof in respect of the allegation or plea shall be on the practitioner.

27. Paragraph G.05.001(1)(c) of the Regulations is replaced by the following:

(c) the name and quantity of any controlled drug used in the making or assembling of a product or compound containing that controlled drug, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;

(c.1) the name and quantity of any controlled drug produced and the date on which it was placed in stock;

28. (1) Subsections G.05.003(1) to (4) of the Regulations are replaced by the following:

G.05.003. (1) No person in charge of a hospital shall permit a controlled drug to be sold, provided or administered except in accordance with this section.

(2) On receipt of a prescription or a written order signed and dated by a practitioner, the person in charge of a hospital may permit a controlled drug to be administered to a person or an animal under treatment as an in-patient or out-patient of the hospital, or to be sold or provided to the person or to the person in charge of the animal.

(3) Subject to subsection (6), the person in charge of a hospital may permit a controlled drug to be provided, for emergency purposes, to a hospital employee or a practitioner in another hospital on receipt of a written order signed and dated by a pharmacist in the other hospital or a practitioner authorized by the person in charge of the other hospital to sign the order.

(4) Subject to subsection (6), the person in charge of a hospital may permit a controlled drug to be sold or provided, for emergency purposes, to a pharmacist on receipt of a written order signed and dated by the pharmacist.

(2) Subsection G.05.003(5) of the English version of the Regulations is replaced by the following:

(5) The person in charge of a hospital may permit a controlled drug to be provided to a person employed in a research laboratory in that hospital for the purpose of research.

(3) Section G.05.003 of the Regulations is amended by adding the following after subsection (5):

(6) No person in charge of a hospital shall permit a controlled drug to be sold or provided under subsection (3) or (4) unless the signature of the pharmacist in the other hospital or of the practitioner authorized by the person in charge of the other hospital to sign an order is known to the person who sells or provides the controlled drug or has been verified.

29. (1) The portion of subsection G.06.001(3) of the Regulations before paragraph (a) is replaced by the following:

(3) Despite anything in these Regulations, a person may, for the purpose of identification or analysis of a controlled drug in their possession, provide or deliver the drug to

(2) The portion of subsection G.06.001(4) of the Regulations before paragraph (a) is replaced by the following:

(4) If an agent of a practitioner of medicine receives a controlled drug under subsection (3), they shall immediately provide or deliver it

(3) The portion of subsection G.06.001(5) of the Regulations before paragraph (a) is replaced by the following:

(5) A practitioner of medicine who receives a controlled drug under subsection (3) or (4) shall immediately provide or deliver it

30. Subparagraph G.06.002.1(b)(i) of the Regulations is replaced by the following:

(i) the name of the producer, maker or assembler,

31. (1) The definition "licence" in section J.01.001 of the Regulations is repealed.

(2) The definition "licensed dealer" in section J.01.001 of the Regulations is replaced by the following:

"licensed dealer" means the holder of a licence issued under section J.01.007.2;
(*distributeur autorisé*)

(3) Section J.01.001 of the Regulations is amended by adding the following in alphabetical order:

"competent authority" means a public authority of a foreign country that is authorized under the laws of the country to approve the importation or exportation of restricted drugs into or from the country; (*autorité compétente*)

"international obligation" means an obligation in respect of a restricted drug set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres; (*obligation internationale*)

"qualified person in charge" means the individual with the qualifications specified in subsection J.01.003.2(2) who is responsible for supervising the activities carried out by a licensed dealer under their licence at the premises specified in the licence; (*personne qualifiée responsable*)

32. Section J.01.003 of the Regulations is replaced by the following:

J.01.003. Subject to this Part, no person except a licensed dealer shall produce, make, assemble, import, export, sell, provide, transport, send or deliver a restricted drug.

J.01.003.1. To be eligible to apply for a dealer's licence, a person must be

(a) an individual who ordinarily resides in Canada;

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

(c) an individual who occupies a position that includes responsibility for restricted drugs on behalf of a department of the government of Canada or of a province, a police force, a hospital or a university in Canada.

J.01.003.2. (1) A licensed dealer

(a) shall designate no more than one qualified person in charge, who may be the licensed dealer if the licensed dealer is an individual, who must work at the premises specified in the licence, have responsibility for supervising activities with respect to restricted drugs specified in the licence and for ensuring, on behalf of the licensed dealer, that those activities comply with these Regulations; and

(b) may designate an alternate qualified person in charge who must work at the premises set out in the licence and have authority to replace the qualified person in charge when that person is absent.

(2) The qualified person in charge and, if applicable, the alternate qualified person in charge

(a) shall be familiar with the provisions of the Act and the regulations under it that apply to the licence of the licensed dealer who designated them and have knowledge of chemistry and pharmacology and experience in those fields to properly carry out their duties;

(b) shall be a pharmacist or a practitioner registered with a licensing body of a province or possess a degree in an applicable science — such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, organic chemistry or chemical engineering — that is awarded by a Canadian university or, if awarded by a foreign university, that is recognized by a Canadian university or a Canadian professional association; and

(c) shall not have been convicted, as an adult, within the previous 10 years, of

- (i) a designated drug offence,
- (ii) a designated criminal offence, or
- (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii).

33. Sections J.01.007 and J.01.008 of the Regulations are replaced by the following:

J.01.007. (1) To apply for a dealer's licence, a person shall submit an application to the Minister containing:

(a) their name or, if the applicant is a corporation, their corporate name and any other name registered with a province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself,

(b) the address, telephone number and, if applicable, the facsimile transmission number and e-mail address for the premises to which the dealer's licence would apply and, if different, the mailing address for the premises;

(c) the name, date of birth and gender of the individual in charge of the premises;

(d) with respect to the qualified person in charge and, if applicable, the alternate qualified person in charge at the premises,

- (i) their name, date of birth and gender,
 - (ii) their academic qualifications, training and work experience relevant to their duties,
 - (iii) their hours of work, at the premises,
 - (iv) their title at the premises,
 - (v) the name and title of their immediate supervisor at the premises, and
 - (vi) in the case of a pharmacist or a practitioner, the name of the province in which the person's current professional licence, certification or authorization was issued and the professional licence, certification or authorization number;
- (e) the name and gender of the individuals authorized to place an order for a restricted drug on behalf of the applicant;
- (f) the activities referred to in section J.01.003 for which the licence is sought that would be carried out at the premises to which the dealer's licence would apply;
- (g) in the case of a product or compound that contains a restricted drug but is not a test kit and that would be made or assembled for or by the applicant, a list that sets out
- (i) the name, number or identifying mark, if any, of each product or compound,
 - (ii) the restricted drug in each product or compound,
 - (iii) the strength per unit of the restricted drug in each product or compound,
 - (iv) the quantity or package sizes of each product or compound, and
 - (v) if the product or compound would be made or assembled by or for another licensed dealer under a custom order, the name, address and the dealer's licence number of the other dealer;
- (h) if the licence is sought to produce a restricted drug other than a product or compound that contains a restricted drug
- (i) the restricted drug to be produced,
 - (ii) the quantity that the applicant expects to produce under the dealer's licence and the period during which that quantity would be produced, and
 - (iii) if the restricted drug would be produced for another licensed dealer under a custom order, the name, address and licence number of the other dealer;
- (i) a detailed description of the security measures at the premises, determined in accordance with the Security Directive;
- (j) a detailed description of the method that the applicant proposes to use for recording their restricted drug transactions; and

(k) for any activity referred to in section J.01.003, other than the activities described in paragraphs (g) and (h), the restricted drug and the purpose for carrying out the activity.

(2) An application for a dealer's licence must

(a) be signed by the individual in charge of the premises to which the licence would apply; and

(b) be accompanied by a statement signed by the individual in charge indicating that

- (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
- (ii) the individual in charge has the authority to bind the applicant.

(3) An application for a dealer's licence must be accompanied by

(a) declarations signed by the individual in charge of the premises, the qualified person in charge and, if applicable, the alternate qualified person in charge, stating that they have not been convicted, as an adult, during the previous 10 years of

- (i) a designated drug offence,
- (ii) a designated criminal offence, or
- (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(b) a document issued by a Canadian police force with respect to each of the persons referred to in paragraph (a), stating whether the person has or has not been convicted, as an adult, during the preceding 10 years of a designated drug offence or a designated criminal offence;

(c) if any of the persons referred to in paragraph (a) has ordinarily resided in a country other than Canada during the preceding 10 years, a document issued by a police force of that country stating whether the person has or has not been convicted in that country, as an adult, during the preceding 10 years, of an offence that would have constituted a designated drug offence or a designated criminal offence if committed in Canada;

(d) a statement, signed and dated by the individual in charge of the premises, stating that the qualified person in charge and, if applicable, the alternate qualified person in charge have the knowledge and experience required under paragraph J.01.003.2(2)(a);

(e) if the qualified person in charge or, if applicable, the alternate qualified person in charge is not a pharmacist or a practitioner registered with a licensing body of a province, a copy of the person's degree required under paragraph J.01.003.2(2)(b) and a copy of the course transcript for that degree;

(f) if the applicant's name appears on the label of a product or compound that contains a restricted drug, a copy of the inner label, as defined in section A.01.010, for each product or compound to which the licence would apply; and

(g) if the applicant is a corporation, a copy of

- (i) the certificate of incorporation or other constituting instrument, and
- (ii) any document filed with the province in which the premises to which the licence would apply are located that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.

(4) The method proposed by the applicant under paragraph (1)(j) must

(a) allow for the recording of restricted drug transactions in accordance with section J.01.021; and

(b) permit the Minister to audit the activities of the licensed dealer with respect to restricted drugs.

(5) The documents referred to in paragraphs (3)(b) and (c) are not required if the persons referred to in those paragraphs consent in writing

(a) to having a criminal record check carried out for them, as an adult, in respect of the offences referred to in those paragraphs during the preceding 10 years;

(b) to provide all information and to submit to any means of identification required to obtain criminal record check; and

(c) to pay the fee established by the *Royal Canadian Mounted Police, Criminal Record Verification for Civil Purposes Fee Regulations*.

J.01.007.1. The Minister may, on receiving an application made under this Part, require the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to process the application.

J.01.007.2. Subject to section J.01.007.3, the Minister shall, after examining the information and documents required under sections J.01.007 and J.01.007.1, issue a dealer's licence that contains:

- (a) the licence number;
- (b) the name of the licensee or, if the applicant is a corporation, its corporate name;
- (c) a list of the activities that are permitted;
- (d) the address of the premises at which the licensed dealer may carry on the permitted activities;
- (e) the name of the restricted drug for which the activities are permitted;
- (f) the security level at the premises;
- (g) the effective date of the licence;
- (h) the expiry date of the licence, which may not be later than three years after its effective date;
- (i) any conditions to be met by the holder of the licence to
 - (i) ensure that an international obligation is respected,
 - (ii) provide the security level referred to in paragraph (f), or
 - (iii) reduce the potential security, public health or safety hazard, including the risk of the restricted drug being diverted to an illicit market or use;
- (j) in the case of a producer of a restricted drug, the quantity of the restricted drug that may be produced under the licence and the period during which that quantity may be produced; and
- (k) in the case of the maker or assembler of a product or compound that contains a restricted drug but is not a test kit, an annexed list that sets out the following information for each type of product or compound that may be made or assembled under the licence:
 - (i) the licence number,
 - (ii) the name, number or identifying mark, if any, of each product or compound,
 - (iii) the restricted drug in each product or compound,
 - (iv) the strength per unit of the restricted drug in each product or compound, and
 - (v) the quantity or package sizes of each product or compound.

J.01.007.3. (1) The Minister shall refuse to issue, renew or amend a dealer's licence if:

- (a) the applicant is not eligible under section J.01.003.1;
- (b) an inspector who has requested an inspection has not been given the opportunity by the applicant to conduct an inspection under section J.01.025;
- (c) false or misleading information or false or falsified documents were submitted in or with the application;
- (d) an activity for which the licence is requested would not be in compliance with an international obligation;
- (e) information received from a competent authority or the United Nations raises a reasonable belief that the applicant has been involved in the diversion of a restricted drug to an illicit market or use or has been involved in an activity that was not in compliance with an international obligation;
- (f) the applicant does not have in place the security measures set out in the Security Directive in respect of an activity for which the licence is requested;
- (g) the applicant is in contravention of or has contravened during the preceding 10 years
- (i) a provision of the Act or any regulations made or continued under the Act, or
 - (ii) a term or condition of another dealer's licence or of an import or export permit issued to the applicant under any regulations made or continued under the Act;
- (h) the issuance, amendment or renewal of the licence would likely create a risk to public health, safety or security, including the risk of a restricted drug being diverted to an illicit market or use;
- (i) the individual in charge of the premises, the qualified person in charge or, if applicable, the alternate qualified person in charge has been convicted, as an adult, within the previous 10 years, of
- (i) a designated drug offence,
 - (ii) a designated criminal offence, or
 - (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);
- (j) the proposed method referred to in paragraph J.01.007(1)(j) is not capable of recording the applicant's restricted drug transactions as required under section J.01.023 or permitting the Minister to audit the applicant's activities with respect to restricted drugs in a timely manner; or

(k) the additional information required under section J.01.007.1 has not been provided or is insufficient to process the application.

(2) The Minister is not required to refuse to issue, renew or amend a licence under paragraph (1)(c) or (g) if the applicant

(a) does not have a history of non-compliance with the Act or any regulation made or continued under it; and

(b) has carried out, or signed an undertaking to carry out, specified corrective measures to ensure compliance with the Act and these Regulations.

J.01.007.4. (1) To apply to renew a dealer's licence, a licensed dealer must submit to the Minister

(a) the information required under paragraphs J.01.007(1)(a) to (k); and

(b) the following documents, namely,

(i) the documents referred to in paragraphs J.01.007(3)(a) and (d) and, subject to subsection J.01.007(5), the document specified in paragraph J.01.007(3)(b);

(ii) if applicable and if not previously submitted in respect of the dealer's licence that is being renewed, the document referred to in paragraph J.01.007(3)(e), and

(iii) the original dealer's licence that is to be renewed.

(2) An application for renewal must

(a) be signed by the individual in charge of the premises to which the renewed dealer's licence would apply; and

(b) be accompanied by a statement signed by the individual in charge indicating that

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

(ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section J.01.007.3, the Minister shall, after examining the information and documents required under subsections (1) and (2) and section J.01.007.1, issue a renewed dealer's licence that contains the information specified in paragraphs J.01.007.2(a) to (k).

J.01.007.5. (1) To have its dealer's licence amended, a licensed dealer shall submit to the Minister

(a) an application in writing describing the proposed amendment, accompanied by the supporting documents referred to in section J.01.007 that are relevant to the proposed amendment; and

(b) the original dealer's licence.

(2) An application for amendment must

(a) be signed by the individual in charge of the premises to which the amended dealer's licence would apply; and

(b) be accompanied by a statement signed by the individual in charge indicating that

- (i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and
- (ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section J.01.007.3, the Minister shall, after examining the request for amendment and the supporting documentation, amend the dealer's licence in accordance with the request and may add any conditions to be met by the holder of the licence to

(a) ensure that an international obligation is respected;

(b) provide for the security level referred to in paragraph J.01.007.2(f) or the new level required as a result of the amendment being implemented; or

(c) reduce the potential security, public health or safety hazard, including the risk of the restricted drug being diverted to an illicit market or use.

J.01.007.6. (1) A licensed dealer shall

(a) obtain the Minister's approval before making any of the following changes, namely,

- (i) a change relating to the security at the premises referred to in the dealer's licence, or
- (ii) the replacement or the addition of
 - (A) an individual in charge of the premises to which the dealer's licence applies,
 - (B) a qualified person in charge and, if applicable, an alternate qualified person in charge at the premises to which the dealer's licence applies, and
 - (C) an individual authorized to place an order for a restricted drug on behalf of the licensed dealer;

(b) notify the Minister, not later than 10 days after the change, when a person referred to in clause (a)(ii)(A) or (C) ceases to carry out their duties as specified in

- (i) the application for a dealer's licence under section J.01.007,
- (ii) the application to renew a dealer's licence under section J.01.007.4, or
- (iii) the request for approval under paragraph (a); and

(c) notify the Minister, not later than the next business day after the change, when a person referred to in clause (a)(ii)(B) ceases to carry out their duties as specified in

- (i) the application for a dealer's licence under section J.01.007,
- (ii) the application to renew a dealer's licence under section J.01.007.4, or
- (iii) the request for approval under paragraph (a).

(2) The licensed dealer shall, with the request for approval referred to in subparagraph (1)(a)(ii), provide the Minister with the following information and documents with respect to the new person:

(a) in the case of the replacement of the individual in charge of the premises to which the dealer's licence applies,

- (i) the information specified in paragraph J.01.007(1)(c), and
- (ii) the declarations specified in paragraph J.01.007(3)(a) and, subject to subsection J.01.007(5), the documents specified in paragraphs J.01.007(3)(b) and (c);

(b) in the case of the replacement of the qualified person in charge or the replacement or addition of the alternate qualified person in charge at the premises to which the dealer's licence applies,

- (i) the information specified in paragraph J.01.007(1)(d), and
- (ii) the documents specified in paragraphs J.01.007(3)(a), (d) and (e) and, subject to subsection J.01.007(5), the documents specified in paragraphs J.01.007(3)(b) and (c); and

(c) in the case of the replacement or addition of an individual who is authorized to place an order for a restricted drug on behalf of the licensed dealer, the individual's name and gender.

J.01.007.7. The Minister shall revoke a dealer's licence at the request of the licensed dealer or on being notified by the licensed dealer that the licence has been lost or stolen.

J.01.007.8. (1) Subject to subsection (2), the Minister shall revoke a dealer's licence in accordance with section J.01.007.91 if:

(a) the licence was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application;

(b) the licensed dealer has failed to comply with a provision of the Act, a regulation under it or a term or condition of the licence or of an import or export permit issued under this Part;

(c) the licensed dealer is no longer an eligible person under section J.01.003.1;

(d) it is discovered that the individual in charge of the premises to which the licence applies, the qualified person in charge or, if applicable, the alternate qualified person in charge at those premises, has been convicted, as an adult, within the previous 10 years, of

- (i) a designated drug offence,
- (ii) a designated criminal offence, or
- (iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii); or

(e) information received from a competent authority or the United Nations raises a reasonable belief that the licensed dealer has been involved in the diversion of a restricted drug to an illicit market or use.

(2) The Minister is not required to revoke a dealer's licence under paragraphs (1)(a) or (b) if the licensed dealer

(a) has no history of non-compliance with the Act and the regulations made or continued under it; and

(b) has carried out, or signed an undertaking to carry out, corrective measures to ensure compliance with the Act and these Regulations.

J.01.007.9. The Minister shall suspend a dealer's licence without prior notice if it is necessary to do so to protect security, public health or safety, including preventing a restricted drug from being diverted to an illicit market or use.

J.01.007.91. (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a licence under this Part, the Minister shall

(a) send a notice to the applicant or to the holder of the licence, together with a written report that sets out the reasons for the proposed refusal or revocation; and

(b) give the applicant or holder an opportunity to be heard in respect of the proposed refusal or revocation.

(2) The suspension of a licence under this Part takes effect as soon as the Minister informs the holder of the licence of the decision to suspend and provides a written report that sets out the reasons for the suspension.

(3) A person who receives a notice of suspension referred to in subsection (2) may, in the 10 days following the receipt of the notice, provide the Minister with reasons why the suspension of the licence is unfounded.

34. Sections J.01.011 to J.01.013 of the Regulations are replaced by the following:

J.01.011. A licensed dealer may, subject to the terms and conditions of their licence, produce, make, assemble, sell, provide, transport, send or deliver only the restricted drugs specified in their dealer's licence.

J.01.012. The Minister shall revoke or suspend a permit issued under this Part if the Minister determines that the person to whom it was issued has failed to comply with any term or condition of the permit or any provision of this Part.

J.01.013. A dealer's licence is valid until the earlier of

(a) the expiry date set out in the licence; and

(b) the revocation or suspension of the licence under section J.01.007.7, J.01.007.8 or J.01.007.9.

35. Paragraphs J.01.023(a) to (d) of the Regulations are replaced by the following:

(a) the name, quantity and form of any restricted drug received by them, the name and address of the person who sold or provided it and the date it was received;

(b) the name, quantity and form of any restricted drug sold or provided by them, the name and address of the person to whom it was sold or provided and the date it was sold or provided;

(c) the name, quantity and form of any restricted drug they have used in making or assembling a product or compound containing that restricted drug, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;

(d) the name and quantity of any restricted drug produced and the date on which it was placed in stock; and

36. Section J.01.025 of the Regulations is replaced by the following:

J.01.025. (1) The Minister may, in respect of a licensed dealer, require an inspection to be made, at any reasonable time, of

(a) the premises used or intended to be used in producing, making, assembling or storing a restricted drug;

(b) the process and conditions of the producing, making, assembling or storing; and

(c) the records relating to the producing, making, assembling or storing.

(2) The Minister may, in respect of a licensed dealer, require a verification to be made, at any reasonable time, of the qualifications of its technical staff concerned with producing, making, assembling or storing a restricted drug.

37. The portion of section J.01.026 of the Regulations before paragraph (a) is replaced by the following:

J.01.026. Every person who sells or provides a restricted drug shall

38. Paragraphs J.01.027(b) and (c) of the Regulations are replaced by the following:

(b) in the premises in which a restricted drug is produced, made, assembled or stored; and

(c) in the process and conditions of producing, making, assembly or storage of a restricted drug.

39. Paragraph J.01.032(f) of the Regulations is replaced by the following:

(f) the name and address of the producer, maker or assembler of the drug.

40. (1) The portion of subsection J.01.033(3) of the Regulations before paragraph (a) is replaced by the following:

(3) Despite anything in these Regulations, a person may, for the purpose of identification or analysis of a restricted drug, provide or deliver the restricted drug that they have in their possession to

(2) The portion of subsection J.01.033(4) of the Regulations before paragraph (a) is replaced by the following:

(4) if an agent of a practitioner has received a restricted drug under subsection (3), the agent shall immediately provide or deliver it

(3) The portion of subsection J.01.033(5) of the Regulations before paragraph (a) is replaced by the following:

(5) A practitioner who has received a restricted drug under subsection (3) or (4) shall immediately provide or deliver it

41. Subparagraph J.01.033.1(b)(i) of the Regulations is replaced by the following:

(i) the name of the producer, maker or assembler,

COMING INTO FORCE

42. These Regulations come into force on the day on which they are registered.