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CONTROLLED DRUGS AND SUBSTANCES ACT

### Regulations Amending the Narcotic Control Regulations and Other Related Regulations

P.C. 2004-1237 26 October, 2004



Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act* ([see footnote a](#)), hereby makes the annexed *Regulations Amending the Narcotic Control Regulations and Other Related Regulations*.

## REGULATIONS AMENDING THE NARCOTIC CONTROL REGULATIONS AND OTHER RELATED REGULATIONS

### AMENDMENTS

1. (1) The definition "licence" in section 2 of the *Narcotic Control Regulations* ([see footnote 1](#)) is repealed.

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

"licensed dealer" means the holder of a licence issued under

section 9.2; (*distributeur autorisé*)

**(3) Section 2 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 narcotics into or from the country; (*autorité compétente*)

"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 any of paragraphs (a) to (d); (*infraction désignée en matière criminelle*)

"international obligation" means an obligation in respect of a narcotic 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 8.3(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*)

"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 heading before section 8 of the Regulations is replaced by the following:**

*Dealers' Licences and Licensed Dealers*

**3. Subsection 8(1) of the Regulations is replaced by the following:**

**8.** (1) Subject to these Regulations, no person except a licensed dealer shall produce, make, assemble, import, export, sell, provide, transport, send or deliver a narcotic.

**4. Section 9 of the Regulations is replaced by the following:**

**8.2** 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) the holder of a position that includes responsibility for narcotics on behalf of a department of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada.

**8.3** (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 narcotics 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 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 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).

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

(a) if the licence is sought for

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

(ii) a corporation, the corporation's name and any other name registered with a province, under which it intends to carry out the activities specified in its dealer's licence or intends to identify itself; and

(iii) the holder of a position mentioned in paragraph 8.2(c), the applicant's name and the title of the position;

(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 narcotic on behalf of the applicant;

(f) the activities referred to in section 8 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 narcotic but is not a test kit and that would be made or assembled for or by the applicant,

(i) the brand name, if any, of each product or compound,

(ii) the narcotic in each product or compound,

(iii) the strength per unit of the narcotic 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 licence number of the other dealer;

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

(i) the name of the narcotic 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 narcotic 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 narcotic transactions; and

(k) for any activity referred to in section 8, other than the activities described in paragraphs (g) and (h), the name of the narcotic 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 previous 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 8.3(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 8.3(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 narcotic, a copy of the inner label, as defined in section A.01.010 of the *Food and Drug Regulations*, 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 narcotic transactions in accordance with section 15; and

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

(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*.

**9.1** The Minister may, on receiving an application made under these Regulations, 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.

**9.2** Subject to section 9.4, the Minister shall, after examining the information and documents required under sections 9 and 9.1, issue a dealer's licence that contains

(a) the licence number;

(b) the name of the applicant or the title of the position they hold, as the case may be, 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 narcotic 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 narcotic being diverted to an illicit market or use;

(j) in the case of a producer of a narcotic, the quantity of the narcotic 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 narcotic 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 narcotic in each product or compound,

(iv) the strength per unit of the narcotic in each product or

compound, and

(v) the quantity or package sizes of each product or compound.

**9.3** A licensed dealer may, subject to the terms and conditions of their licence, produce, make, assemble, sell, provide, transport, send or deliver only narcotics specified in their licence.

**9.4 (1)** The Minister shall refuse to issue, renew or amend a dealer's licence if

(a) the applicant is not eligible under section 8.2;

(b) an inspector who has requested an inspection has not been given the opportunity by the applicant to conduct an inspection under section 16;

(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 narcotic 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 narcotic 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 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);

(j) the proposed method referred to in paragraph 9(1)(j) is not capable of recording narcotic transactions as required under section 15 or of permitting the Minister to audit the applicant's activities with respect to narcotics in a timely manner; or

(k) the additional information required under section 9.1 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.

**9.5** (1) To apply to renew a dealer's licence, a licensed dealer shall submit to the Minister

(a) the information referred to in paragraphs 9(1)(a) to (k); and

(b) the following documents, namely,

(i) the documents referred to in paragraphs 9(3)(a) and (d) and, subject to subsection 9(5), the document referred to in paragraph 9(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 9(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 9.4, the Minister shall, after examining the information and documents required under subsections (1) and (2) and section 9.1, issue a renewed dealer's licence that contains the information specified in paragraphs 9.2(a) to (k).

**9.6 (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 9 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 9.4, 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 the security level referred to in paragraph 9.2(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 narcotic being diverted to an illicit market or use.

**9.7 (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, 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 narcotic 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 9,

(ii) the application to renew the dealer's licence under section

9.5, 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 9,

(ii) the application to renew the dealer's licence under section 9.5, 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 9(1)(c), and

(ii) the declarations specified in paragraph 9(3)(a) and, subject to subsection 9(5), the documents specified in paragraphs 9(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 9(1)(d), and

(ii) the documents specified in paragraphs 9(3)(a), (d) and (e) and, subject to section 9(5), the documents specified in paragraphs 9(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 narcotic on behalf of the licensed dealer, the individual's name and gender.

**9.8** 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.

**9.9** (1) Subject to subsection (2), the Minister shall revoke a dealer's licence in accordance with section 9.92 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 these Regulations;

(c) the licensed dealer is no longer eligible under section 8.2; or

(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 narcotic 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.

**9.91** 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 narcotic from being diverted to an illicit market or use.

**9.92** (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a dealer's licence under these Regulations, 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 these Regulations 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.

**5. Section 11 of the Regulations is repealed.**

**6. Section 13 of the Regulations is replaced by the following:**

**13.** The Minister shall revoke or suspend a permit issued under these Regulations 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.

**7. Subsection 14(1) of the Regulations is replaced by the following:**

**14.** (1) 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 9.8, 9.9 or 9.91.

**8. Paragraphs 15(a) to (c) of the Regulations are replaced**

**by the following:**

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

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

(c) the name and quantity of any narcotic 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

**9. Section 16 of the Regulations is replaced by the following:**

**16.** (1) The Minister may, in respect of an applicant for a dealer's licence or a licensed dealer, require an inspection, at any reasonable time, of

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

(b) the process and conditions of 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 narcotic.

**10. Paragraphs 19(b) and (c) of the Regulations are replaced by the following:**

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

(c) the process and conditions of the producing, making,

assembling or storing.

**11. (1) Subsection 24(1) of the Regulations is replaced by the following:**

24. (1) No licensed dealer shall sell or provide a narcotic to any person except in accordance with this section and sections 27 and 28.

**(2) The portion of subsection 24(2) of the Regulations before paragraph (a) is replaced by the following:**

(2) Subject to section 25, a licensed dealer may sell or provide any narcotic other than diacetylmorphine (heroin) or methadone to

**(3) The portion of subsection 24(3) of the Regulations before paragraph (a) is replaced by the following:**

(3) Subject to section 25, a licensed dealer may sell or provide methadone to

**(4) The portion of subsection 24(4) of the Regulations before paragraph (a) is replaced by the following:**

(4) Subject to section 25, a licensed dealer may sell or provide diacetylmorphine (heroin) to

**12. (1) The portion of subsection 27(1) of the Regulations before paragraph (a) is replaced by the following:**

27. (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 narcotic other than diacetylmorphine (heroin) or methadone to a person referred to in subsection 24(2), sell or provide methadone to a person referred to in subsection 24(3) and sell or provide diacetylmorphine (heroin) to a person referred to in subsection 24(4) if the licensed dealer has, on the premises specified in the licence, received

**(2) The portion of subsection 27(2) of the Regulations before paragraph (b) is replaced by the following:**

(2) A licensed dealer who has received an order referred to in paragraph (1)(a) may sell or provide a narcotic other than diacetylmorphine (heroin) or methadone to a person referred to

in subsection 24(2), sell or provide methadone to a person referred to in subsection 24(3) and sell or provide diacetylmorphine (heroin) to a person referred to in subsection 24(4) if

(a) the order is signed and dated

(i) if the narcotic is to be sold or provided to a person referred to in paragraph 24(2)(a), (b), (c), (e) or (f), 24(3)(a), (b) or (d) or 24(4)(a) or (c), by that person, or

(ii) if the narcotic 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; and

**(3) Subsections 27(3) and (3.1) of the English version of the Regulations are replaced by the following:**

(3) A licensed dealer who has received an order referred to in paragraph (1)(b) or (c) may provide a narcotic 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.

(3.1) A licensed dealer who has received an order sent through a computer from a remote input device referred to in paragraph (1)(b) may provide methadone to a hospital employee or to a practitioner in a hospital if the order has been placed by a practitioner exempted under section 56 of the Act with respect to methadone.

**(4) Subsection 27(4) of the Regulations is replaced by the following:**

(4) A licensed dealer may sell or provide a narcotic 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 (6) and (7).

**(5) The portion of subsection 27(5) of the Regulations before paragraph (c) is replaced by the following:**

(5) A licensed dealer who has received a verbal order referred to in paragraph (1)(c), and has sold or provided a verbal

prescription narcotic to a person referred to in paragraph 24(2)(b), (c) or (d), shall immediately record

(a) the name of the person to whom the verbal prescription narcotic was sold or provided;

(b) if the verbal prescription narcotic was provided to a hospital employee or a practitioner in a hospital, the name of the person who placed the order; and

**(6) The portion of subsection 27(9) of the Regulations before paragraph (a) is replaced by the following:**

(9) If a licensed dealer has not obtained a receipt from a pharmacist or practitioner under subsection (8) within the time prescribed by that subsection, the dealer shall not, until after obtaining the receipt, sell or provide a narcotic to the pharmacist or practitioner pursuant to any further

**13. Section 28 of the Regulations is replaced by the following:**

**28.** (1) No licensed dealer shall sell or provide a narcotic unless it is labelled in accordance with the *Food and Drug Regulations*.

(2) No licensed dealer shall sell or provide a narcotic, other than a preparation described in section 36, unless the narcotic is securely packed in its immediate container and sealed in such a manner that the container cannot be opened without breaking the seal.

**14. (1) Subsection 31(1) of the Regulations is replaced by the following:**

**31.** (1) No pharmacist shall sell or provide narcotics except in accordance with subsections (2) and (3) and sections 34 to 36.

**(2) The portion of subsection 31(2) of the Regulations before paragraph (a) is replaced by the following:**

(2) A pharmacist may sell or provide a narcotic other than methadone to a person

**(3) The portion of subsection 31(3) of the Regulations**

**before paragraph (a) is replaced by the following:**

(3) A pharmacist may sell or provide methadone to

**15. Section 35 of the Regulations is replaced by the following:**

**35. (1)** Subject to subsection (2), a pharmacist may provide a narcotic to an employee of a hospital or a practitioner in a hospital if the pharmacist receives a written order for the narcotic signed and dated by

(a) the pharmacist in charge of the dispensary of the hospital;  
or

(b) a practitioner who is authorized by the person in charge of the hospital to order the narcotic and who, in the case of methadone, is exempted under section 56 of the Act with respect to methadone.

(2) Before providing a narcotic under subsection (1), the pharmacist receiving the order must know the signature on the order or verify it.

**16. (1) The portion of subsection 36(1) of the Regulations before paragraph (a) is replaced by the following:**

**36. (1)** Subject to subsection (2), a pharmacist may, without a prescription, sell or provide a preparation containing not more than 8 mg or its equivalent of codeine phosphate per tablet or per unit in other solid form or not more than 20 mg or its equivalent of codeine phosphate per 30 mL in a liquid preparation if

**(2) Subsection 36(2) of the Regulations is replaced by the following:**

(2) No pharmacist shall sell or provide a preparation referred to in subsection (1) if the pharmacist has reasonable grounds to believe that the preparation is to be used for purposes other than recognized medical or dental purposes.

**17. Paragraphs 38(d) and (e) of the Regulations are replaced by the following:**

(d) the name or initials of the pharmacist who sold or provided

the narcotic;

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

**18. Paragraph 39(f) of the Regulations is replaced by the following:**

(f) the date on which such oral prescription narcotic was sold or provided; and

**19. Subsections 45(1) and (2) of the Regulations are replaced by the following:**

**45. (1)** A pharmacist may, on receiving a written order for a narcotic signed and dated by

(a) the licensed dealer who sold or provided the narcotic to the pharmacist, return that narcotic to that dealer; or

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

(2) A pharmacist shall, immediately after returning, selling or providing a narcotic under subsection (1) or after receiving a narcotic under paragraph (1)(b) or subsection 65(4), enter the details of the transaction in a book, register or other record maintained for the purpose of recording such transactions.

**20. (1) Subsection 53(1) of the Regulations is replaced by the following:**

**53. (1)** No practitioner shall administer a narcotic to a person or animal, or prescribe, sell or provide a narcotic for a person or animal, except as authorized under this section or the *Marihuana Medical Access Regulations*.

**(2) The portion of subsection 53(2) of the Regulations before paragraph (a) is replaced by the following:**

(2) Subject to subsections (3) and (4), a practitioner may administer a narcotic to a person or animal, or prescribe, sell or provide a narcotic for a person or animal, if

**(3) Subsections 53(3) and (4) of the Regulations are**

**replaced by the following:**

(3) No practitioner shall administer methadone to a person or animal, or prescribe, sell or provide methadone for a person or animal, unless the practitioner is exempted under section 56 of the Act with respect to methadone.

(4) A practitioner shall not administer diacetylmorphine (heroin) to an animal or to a person who is not an in-patient or out-patient of a hospital providing care or treatment to persons, and shall not prescribe, sell or provide diacetylmorphine (heroin) for an animal or such a person.

**21. Subsection 54(1) of the Regulations is replaced by the following:**

**54.** (1) A practitioner who sells or provides a narcotic to a person for self-administration or for administration to an animal shall, whether or not the practitioner charges for the narcotic, keep a record showing the name and quantity of the narcotic 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 narcotic exceeds

(a) three times the maximum daily dosage recommended by the producer, maker or assembler of the narcotic for that narcotic; or

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

**22. Subparagraph 55(a)(i) of the Regulations is replaced by the following:**

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

**23. Section 56 of the Regulations is replaced by the following:**

**56.** If a practitioner alleges or, in any prosecution for an offence under the Act or these Regulations, pleads that their possession of a narcotic 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 animal who or that was a patient

under their professional treatment and that the narcotic 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.

**24. Subparagraphs 63(a)(iii) and (iv) of the Regulations are replaced by the following:**

(iii) the name and quantity of any narcotic used in the making or assembling of a product or compound containing that narcotic,

(iv) the name and quantity of any product or compound that was made or assembled and that contains that narcotic and the date on which the product or compound was made or assembled,

**25. (1) Subsections 65(1) to (5) of the Regulations are replaced by the following:**

**65. (1)** No person in charge of a hospital shall permit a narcotic to be sold, provided or administered except in accordance with this section.

(2) Subject to subsection (5), 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 narcotic other than diacetylmorphine (heroin) 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 the person in charge of the animal.

(3) Subject to subsections (5) and (5.1), the person in charge of a hospital may permit a narcotic to be provided, for emergency purposes, to a hospital employee or 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 (5.1), the person in charge of a hospital may permit a narcotic other than diacetylmorphine (heroin) to be sold or provided, for emergency purposes, to a pharmacist on receipt of a written order signed and dated by the pharmacist.

(5) No person in charge of a hospital shall permit methadone to be sold, provided or administered under subsection (2) or (3)

unless the prescribing or ordering practitioner is exempted under section 56 of the Act with respect to methadone.

(5.1) No person in charge of a hospital shall permit a narcotic 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 narcotic or has been verified.

**(2) Subsection 65(6) of the English version of the Regulations is replaced by the following:**

(6) A person in charge of a hospital may permit a narcotic to be provided to a person who is exempted under section 56 of the Act with respect to the narcotic and who is employed in a research laboratory in the hospital for the purpose of research.

**(3) Subsection 65(7) of the Regulations is replaced by the following:**

(7) The person in charge of a hospital providing care or treatment to persons may permit diacetylmorphine (heroin) to be sold, provided or administered to a person under treatment as an in-patient or out-patient of the hospital on receipt of a prescription or a written order signed and dated by a practitioner.

**26. (1) The portion of subsection 68(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 narcotic in their possession, provide or deliver the narcotic to

**(2) Paragraph 68(4)(a) of the Regulations is replaced by the following:**

(a) for the purpose of its identification or analysis, provide or deliver the narcotic to a person exempted under section 56 of the Act with respect to the possession of that narcotic for that purpose; or

**(3) The portion of subsection 68(5) of the Regulations before paragraph (a) is replaced by the following:**

(5) An agent of a practitioner of medicine who has received a narcotic under subsection (3) shall immediately provide or deliver the narcotic

**(4) Paragraph 68(6)(a) of the Regulations is replaced by the following:**

(a) for the purpose of its identification or analysis, provide or deliver the narcotic to a person exempted under section 56 of the Act with respect to the possession of that narcotic for that purpose; or

**27. The portion of section 69 of the Regulations before paragraph (a) is replaced by the following:**

**69.** Every person who is exempted under section 56 of the Act with respect to the possession of a narcotic, other than a person to whom a narcotic has been administered, sold, provided, distributed or delivered by a practitioner of medicine exempted under section 56 of the Act from the application of any subsection of section 53 with respect to that narcotic, every practitioner of medicine who has received a narcotic under subsection 68(3) or (5) and every agent of a practitioner of medicine who has received a narcotic under subsection 68(3) shall

## CONSEQUENTIAL AMENDMENTS

### *Industrial Hemp Regulations*

**28. The definition "competent laboratory" in section 1 of the *Industrial Hemp Regulations* ([see footnote 2](#)) is replaced by the following:**

"competent laboratory" means a laboratory that is owned or operated by a person who is a licensed dealer as defined in section 2 of the *Narcotic Control Regulations*, or a laboratory outside Canada that is recognized as a qualified laboratory, for the application of the United Nations' *Single Convention on Narcotic Drugs, 1961*, as amended from time to time, by the competent authorities of the country in which it is located.  
(*laboratoire compétent*)

### *Marihuana Medical Access Regulations*

**29. The definition "medical practitioner" in subsection 1(1)**

of the *Marihuana Medical Access Regulations* ([see footnote 3](#)) is replaced by the following:

"medical practitioner" means a person who is authorized under the laws of a province to practise medicine in that province and who is not named in a notice given under section 59 of the *Narcotic Control Regulations*. (*médecin*)

#### COMING INTO FORCE

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

#### REGULATORY IMPACT ANALYSIS STATEMENT

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

#### ***Description***

The purpose of this regulatory initiative is to amend provisions relating to the application and issuance of dealer's licences within the *Narcotic Control Regulations* (NCR) and Parts G (i.e., controlled drugs) and J (i.e., restricted drugs) of the *Food and Drug Regulations* (FDR).

Under the present NCR and Parts G and J of the FDR, the Minister of Health may issue a dealer's licence to any person who, in the opinion of the Minister, is qualified to be a licensed dealer for narcotics, controlled drugs or restricted drugs. These provisions have not been amended since long before the *Controlled Drugs and Substances Act* (CDSA) came into force in 1997, which consolidated the earlier *Narcotic Control Act* and Parts III and IV of the *Food and Drugs Act*. Most of the information that a person must provide and the requirements that an applicant must meet are not stated in the current regulations. They appear, however, in an information package put together by the Office of Controlled Substances within the Drug Strategy and Controlled Substances Programme, Health Canada. This package is sent to persons wishing to apply for a licence to import, export, produce or distribute controlled drugs and substances in Canada. It includes, among other things, a Circular Letter addressing the requirements to be accepted as a Qualified Person in Charge (QPIC), and a Directive referring to the Physical Security Requirements for Controlled

## Substances.

The Standing Joint Committee for the Scrutiny of Regulations (SJCSR) has recommended that the ministerial discretion provided by the term "in the opinion of the Minister" that appears in subsection 9(1) of the NCR be removed. The SJCSR is the Committee established to monitor the exercise of the power by regulation-making authorities on behalf of Parliament.

To respond to the SJCSR's concerns, Health Canada has amended subsection 9(1) of the NCR, and comparable provisions in Parts G and J of the FDR to replace the discretionary power conferred to the Minister of Health with a more transparent and uniform licensing framework based on objective requirements.

The NCR and Parts G and J of the FDR derive their legislative authority from the CDSA. The CDSA provides a legislative framework for the control of substances that can alter mental processes, and that may produce harm to the health of an individual and to society when diverted or misused. The NCR, and Parts G and J of the FDR govern the activities of importers, exporters, producers, distributors, pharmacists, practitioners and hospitals relating to narcotics (e.g., morphine), controlled drugs (e.g., amphetamines), and restricted drugs (e.g., LSD) respectively.

### Licensing Framework

The licensing framework within this regulatory amendment largely reflects the current administrative process for issuance of licences under the NCR and Parts G and J of the FDR. It has been modelled on the more modern regulatory provisions respecting the issuance of dealer's licence found within two other sets of regulations under the CDSA, the *Benzodiazepines and Other Targeted Substances Regulations* (Targeted Substances Regulations), and the *Precursor Control Regulations* (PCR). The licencing framework is comprised of the following components:

#### Eligibility

States the eligibility criteria to be a licensed dealer: the requirement for the licensed dealer to designate a QPIC of all controlled substance transactions; the possibility for the

licensed dealer to designate an alternate QPIC (A/QPIC) who may perform the duties of the QPIC when that person is absent; and the qualifications of the QPIC and A/QPIC.

During the preparation of the *Canada Gazette*, Part II regulatory package an additional amendment was made to further clarify that persons eligible to be a licensed dealer include a holder of a position that has responsibility for controlled substances on behalf of a department of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada. This amendment reflects current practices.

#### Application for a Dealer's Licence

Describes the information that must be submitted to apply for a dealer's licence. Among the new requirements under the NCR and the FDR, a criminal record check in respect of "designated criminal offences" and "designated drug offences" defined in the regulatory amendments would be required for the individual in charge of the premises, the QPIC and the A/QPIC prior to the issuance of a dealer's licence. This requirement is included in other regulations under the CDSA. The applicant would have the choice to either provide the criminal record check directly to Health Canada, or to have the individual to whom this requirement applies sign a consent form to have the criminal record check carried out for them by Health Canada through the RCMP.

#### Issuance of a Dealer's Licence

Presents the particulars of the content of the dealer's licence, which includes the activities permitted, the substances for which the activities are permitted, the security level required and the inventory limitation allowed at the premises.

#### Grounds for Refusal

Sets out the circumstances under which the Minister would refuse to issue, renew or amend a dealer's licence. Another new feature of the licensing framework is that it explicitly states the measures that the Minister must take if he proposes to refuse to issue, amend or renew or proposes to revoke a dealer's licence. These include a requirement to set out the reasons for the refusal or revocation in writing, and to provide an opportunity for the applicant or the dealer's licence holder to

be heard in respect of the refusal or revocation.

#### Application for renewal or amendment

Establishes the requirements that licensed dealers must meet for the renewal of their dealer's licence, which are similar to those encountered when submitting their original applications. It also describes the information that licensed dealers must submit to the Minister to have the content of their dealer's licence amended.

#### Revocation or Suspension of a Dealer's Licence

States the circumstances where the Minister would revoke or suspend a dealer's licence if, for example, false or misleading information was submitted regarding the licence application or the applicant no longer meets the eligibility requirements set out in the regulations.

#### Duration of a Dealer's Licence

Currently a dealer's licence for narcotics, controlled and restricted drugs expires on December 31st of each year, and has to be renewed annually. This licensing framework would now provide flexibility with respect to the effective date and the expiry date of the dealer's licence. A licence will generally be valid for one year, although a maximum of three years is provided for. The length of validity may vary during the transition period in order to accommodate implementation of a staggered renewal schedule.

#### Clarification regarding inspections

Allows for an inspection of an applicant for a dealer's licence or a licensed dealer. This reflects current practices, and is consistent with similar provisions found in the Targeted Substances Regulations.

#### Consequential Amendments

In addition, a number of consequential amendments are required. Some changes are necessary to harmonize the terminology used in the NCR and Parts G and J of the FDR with that used in the CDSA, the Targeted Substances Regulations, and the PCR. Also, as a result of the licensing framework, regulatory provisions within the NCR and Parts G

and J of the FDR have been renumbered. Consequently, changes in numerical references within the *Marihuana Medical Access Regulations* (MMAR), and the *Industrial Hemp Regulations* (IHR), in which the renumbered provisions of the NCR are cross referenced, are required.

### ***Alternatives***

The SJCSR has the authority to direct that amendments be made to regulations. Failure to comply with the Committee's recommendations can result in disallowance of the regulations in question. Leaving the regulations as they were written was therefore not an alternative.

It was decided to model the amendments to the NCR and the FDR after similar provisions in the Targeted Substances Regulations and the PCR as:

- the concerns of the SJCSR were addressed in these newer regulations;
- many licensed dealers are already subject to, and familiar with, the licensing provisions of the Targeted Substances Regulations and the PCR;
- these two sets of regulations are recent, having come into force in 2000 and 2002 respectively;
- extensive consultations were conducted, and issues identified by stakeholders were addressed during the development of these Regulations; and
- they largely reflect current administrative processes for issuance of licences respecting narcotics, controlled and restricted drugs.

### ***Benefits and Costs***

These amendments provide a more transparent licensing framework, which should be of benefit to licensed dealers and Health Canada in terms of clearer statements of rights and obligations. These changes, to a large extent, align the licensing processes set out in four sets of regulations under the CDSA that govern the activities of licensed dealers (i.e., the NCR, the FDR, the Targeted Substances Regulations, and the PCR), which will minimize confusion, increase efficiency, and

facilitate compliance and enforcement for the parties involved.

Because the licensing framework largely reflects the current administrative processes in Health Canada, costs of implementation to both licensed dealers and Health Canada should be minimal. Licensed dealers may incur minimal costs to obtain the newly required criminal record check. This measure, which is a requirement under other regulations within the CDSA, will be beneficial to Canadians as it will minimize the risk of diversion of narcotics, controlled and restricted drugs to the illicit market, and therefore decrease public health risks and increase community security.

The change in the licence renewal cycle will have a positive impact. Renewal applications will be processed more efficiently by Health Canada as they will be distributed over the course of a year, which should eliminate the end of calendar year backlog. To minimize impacts on licensed dealers, Health Canada will make every effort to ensure that the renewal cycles for the various dealer's licences will be synchronized with their business activities.

In summary, there are minimal impacts associated with this initiative.

## ***Consultation***

### Previous Consultations

These amendments are modelled after the provisions of the Targeted Substances Regulations and the PCR, which were the subject of extensive consultations.

Prior to the promulgation of the Targeted Substances Regulations in September 2000, stakeholders were afforded three separate opportunities to comment. The first, followed publication of the Notice of Intent in the *Canada Gazette*, Part I. The second, followed the posting on the internet of a policy proposal outlining the considered alternatives and the preferred options and direct distribution to over 200 stakeholders. The third comment period of 60 days, followed the pre-publication of the Regulations in *Canada Gazette*, Part I.

Prior to pre-publication of the PCR in the *Canada Gazette*, Part I, extensive consultation with other government departments and industry took place during 2001 through various avenues.

A Notice of Intent was published in the *Canada Gazette*, Part I, in March of 2001 followed with a discussion document. A consultation workshop was held that summer and attended by various stakeholders from Canada, the United States and the European Union. Publication in the *Canada Gazette*, Part I, took place in April 2002 and resulted in 12 responses, which overall supported the regulatory framework. The PCR were promulgated in September 2002.

### Canada Gazette, Part I, Consultations

These proposed regulatory amendments were pre-published in the *Canada Gazette*, Part I, on September 20, 2003, with a 75-day comment period. All stakeholders on the distribution list were notified directly and invited to provide comments. Only one response was received from a multinational pharmaceutical company regarding the educational requirements of the QPIC.

Issue: The pharmaceutical company suggested that additional educational backgrounds be considered as acceptable types of educational requirements to those indicated in the amendments. This comment specifically referred to paragraph G.02.001.2(2)(b) which states:

"The qualified person in charge and, if applicable, the alternate qualified person in charge 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".

Response: Paragraph G.02.001.2(2)(b) is not intended to be an exhaustive list of acceptable types of educational requirements. The backgrounds listed are intended to be an indication of the fields of study that are generally considered acceptable. Other educational backgrounds will be considered on an individual basis; therefore, no changes to the regulatory amendment are required.

### **Compliance and Enforcement**

The licensing framework does not alter existing compliance

mechanisms under the provisions of the CDSA and its related regulations. The licensing framework sets out licensing practices in clearer statements of rights and obligations for the licensed dealer, which will help to facilitate compliance and enforcement activities. Persons failing to comply with the licensing framework could have their licence or permit revoked. A person conducting activities outside of those authorized by the licensing framework could be subject to the punishments defined in the CDSA.

### **Contact**

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### [Footnote a](#)

S.C. 1996, c. 19

### [Footnote 1](#)

C.R.C., c. 1041

### [Footnote 2](#)

SOR/98-156

### [Footnote 3](#)

SOR/2001-227

#### **NOTICE:**

The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.

