Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight): SOR/2025-260

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CONTROLLED DRUGS AND SUBSTANCES ACT

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

Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)

Amendments

1 (1) The portion of the definition *pharmacien* in section 1 of the French version of the *Precursor Control Regulations* [1] before paragraph (a) is replaced by the following:

pharmacien Personne physique qui :

(2) Section 1 of the Regulations is amended by adding the following in alphabetical order:

combination product containing ephedrine or pseudoephedrine
means

(a) a natural health product that contains ephedrine or any of its salts or pseudoephedrine or any of its salts, or any combination of those ingredients, in combination with one or more other substances set out in Schedule 1 to the *Natural Health Products Regulations*; or

(b) a drug for human use that

(i) contains ephedrine or any of its salts or pseudoephedrine or any of its salts, or any combination of those ingredients, in combination with one or more other drugs,

(ii) is not required under the *Food and Drugs Act* or the Act to be sold under a prescription,

(iii) is not a natural health product,

(iv) does not contain a drug that is listed in Schedule C or D to the *Food and Drugs Act*,

(v) does not contain a controlled substance, and

(vi) is not intended to be administered by injection via needle or by intravenous infusion. (*produit combiné contenant de l'éphédrine ou de la pseudoéphédrine*)

natural health product
means a natural health product within the meaning of the *Natural Health Products Regulations*. (*produit de santé naturel*)

non-combination product containing ephedrine or pseudoephedrine
means a natural health product that contains — as its only medicinal ingredients — ephedrine or any of its salts or pseudoephedrine or any of its salts, or any combination of those ingredients. (*produit non combiné contenant de l'éphédrine ou de la pseudoéphédrine*)

2 (1) The portion of section 5 of the Regulations before paragraph (a) is replaced by the following:

5 A person who only sells or provides, or possesses only for the purpose of sale or provision, a Class A precursor — other than a combination product containing ephedrine or pseudoephedrine or a non-combination product containing ephedrine or pseudoephedrine — is exempt from the requirements of these Regulations in respect of the activity if the person

(2) Subparagraph 5(b)(ii) of the English version of the Regulations is replaced by the following:

(ii) in the case of a precursor set out in column 1 of the schedule, only in a quantity, per transaction, that does not exceed the maximum quantity, expressed as an absolute amount or per package, specified for the precursor in column 2, and

3 Section 7 of the Regulations is amended by striking out "and" at the end of paragraph (c), by adding "and" at the end of paragraph (d) and by adding the following after paragraph (d):

(e) in the case of the sale or provision of a combination product containing ephedrine or pseudoephedrine or a non-combination product containing ephedrine or pseudoephedrine, the sale or provision is only to

(i) another licensed dealer,

(ii) a pharmacist,

(iii) a practitioner,

(iv) a hospital, or

(v) an individual working in a retail location where a pharmacist provides services.

4 (1) Subsection 8(2) of the Regulations is replaced by the following:

(2) If a licensed dealer intends to sell or provide, to a person who is not a licensed dealer, a Class A precursor that is a preparation or mixture containing a precursor set out in Part 1 of Schedule VI to the Act, an end-use declaration under subsection (1) is required if the quantity of the contained precursor, per transaction, is greater than the maximum quantity, expressed as an absolute amount or per package, specified for the contained precursor in column 2 of the schedule to the Regulations.

(2) Subsection 8(5) of the Regulations is replaced by the following:

(5) A licensed dealer required to obtain an end-use declaration must take all reasonable measures to verify the identity of the signatory to the declaration if that person or their signature is unfamiliar to the licensed dealer.

5 Subsection 9(2) of the Regulations is replaced by the following:

(2) A licensed dealer must, when transporting an imported Class A precursor between the port of entry and the site set out in the licence, or when sending, delivering or transporting a Class A precursor to a destination, including the port of exit, take all reasonable measures to ensure the security of the precursor during transportation in order to prevent the diversion of the precursor to an illicit market or use.

6 (1) Paragraph 14(3)(b) of the French version of the Regulations is replaced by the following:

b) comprend une attestation du signataire portant que :

(i) à sa connaissance les renseignements et documents fournis à l'appui de la demande sont exacts et complets,

(ii) il a le pouvoir d'obliger le demandeur,

(2) Paragraph 14(3)(b) of the Regulations is amended by striking out "and" at the end of subparagraph (i), by adding "and" at the end of subparagraph (ii) and by adding the following after subparagraph (ii):

(iii) the applicant has taken all reasonable measures to ensure that their employees do not contribute to the risk of a precursor being diverted to an illicit market or use.

7 Paragraph 15.1(d) of the Regulations is replaced by the following:

(d) examine, as part of the inspection, the books, registers, electronic data and other records kept in accordance with section 85.

8 The portion of subsection 17(1) of the Regulations before paragraph (a) is replaced by the following:

17 (1) Subject to subsection (2), the Minister shall refuse to issue, renew or amend a licence if

9 (1) Paragraph 18(a) of the English version of the Regulations is replaced by the following:

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

(2) Paragraph 18(b) of the Regulations is replaced by the following:

(b) the day on which the licence is revoked or suspended under section 22 or 23 or subsection 24(1).

10 The Regulations are amended by adding the following after section 21:

Changes to Conditions of Licence

21.1 (1) The Minister may, at any time other than at the issuance, renewal or amendment of a licence, add a condition to, or modify a condition of, the licence if the Minister gives prior written notice to the holder and has reasonable grounds to believe that the addition or modification is necessary to

(a) ensure that the international obligations of Canada are respected; or

(b) ensure compliance with the Act and these Regulations, including by reducing the risk of a Class A precursor being diverted to an illicit market or use.

(2) However, the Minister may add a condition to, or modify a condition of, a licence without prior notice if the Minister has reasonable grounds

(a) to believe that it is necessary to do so to protect public health, safety or security; or

(b) to suspect that it is necessary to do so to prevent a Class A precursor from being diverted to an illicit market or use.

21.2 The Minister may delete from a licence a condition that the Minister determines is no longer necessary. Any such deletion takes effect as soon as the Minister notifies the licensed dealer in writing of the deletion.

11 (1) The portion of subsection 23(1) of the Regulations before paragraph (a) is replaced by the following:

23 (1) Subject to subsection (2), the Minister shall revoke a licence if

(2) Subsection 23(3) of the Regulations is replaced by the following:

(3) The Minister may revoke a licence if the licensed dealer fails to comply with a decision of the Minister to suspend the licence under subsection 24(1) or if the situation giving rise to the suspension is not rectified.

12 (1) The portion of section 24 of the Regulations before paragraph (a) is replaced by the following:

24 (1) The Minister shall, without prior notice, suspend a licence in respect of any authorized activities in relation to any Class A precursor if the Minister has reasonable grounds

(2) Paragraph 24(1)(b) of the Regulations is replaced by the following:

(b) to suspect that the continuation of the activities presents a risk of a Class A precursor being diverted to an illicit market or use.

(3) Section 24 of the Regulations is amended by adding the following after subsection (1):

(2) The Minister shall reinstate the licence in respect of any activities affected by the suspension if the reasons for the suspension no longer exist or the holder demonstrates that the suspension is unfounded.

13 Paragraphs 26(2)(b) and (c) of the Regulations are replaced by the following:

(b) the day on which the licence pertaining to the permit is revoked or suspended under section 22 or 23 or subsection 24(1), and

(c) the day on which the permit is revoked or suspended under section 29 or 30 or subsection 31(1).

14 (1) The portion of subsection 30(1) of the Regulations before paragraph (a) is replaced by the following:

30 (1) Subject to subsection (2), the Minister shall revoke a Class A import permit if

(2) Subsection 30(3) of the Regulations is replaced by the following:

(3) The Minister may revoke a Class A import permit if the holder fails to comply with a decision of the Minister to suspend the permit under subsection 31(1) or if the situation giving rise to the suspension is not rectified.

15 Section 31 of the Regulations is renumbered as subsection 31(1) and is amended by adding the following:

(2) The Minister shall reinstate the Class A import permit if the reasons for the suspension no longer exist or the holder demonstrates that the suspension is unfounded.

16 Paragraphs 33(2)(b) and (c) of the Regulations are replaced by the following:

(b) the day on which the licence pertaining to the permit is revoked or suspended under section 22 or 23 or subsection 24(1), and

(c) the day on which the permit is revoked or suspended under section 36 or 37 or subsection 38(1).

17 (1) The portion of subsection 37(1) of the Regulations before paragraph (a) is replaced by the following:

37 (1) Subject to subsection (2), the Minister shall revoke a Class A export permit if

(2) Subsection 37(3) of the Regulations is replaced by the following:

(3) The Minister may revoke a Class A export permit if the holder fails to comply with a decision of the Minister to suspend the permit under subsection 38(1) or if the situation giving rise to the suspension is not rectified.

18 Section 38 of the Regulations is renumbered as subsection 38(1) and is amended by adding the following:

(2) The Minister shall reinstate the Class A export permit if the reasons for the suspension no longer exist or the holder demonstrates that the suspension is unfounded.

19 Section 40 of the Regulations is amended by striking out "and" at the end of paragraph (c), by adding "and" at the end of paragraph (d) and by adding the following after paragraph (d):

(e) any conditions that are necessary to

(i) ensure that the international obligations of Canada are respected,

(ii) ensure compliance with any requirement of the country of final destination or any country of transit or transhipment, or

(iii) ensure compliance with the Act and these Regulations, including by reducing the risk of a Class A precursor being diverted to an illicit market or use.

20 (1) The portion of subsection 45(1) of the Regulations before paragraph (a) is replaced by the following:

45 (1) Subject to subsection (2), the Minister shall revoke a permit for transit or transhipment if

(2) Subsection 45(3) of the Regulations is replaced by the following:

(3) The Minister may revoke a permit if the holder fails to comply with a decision of the Minister to suspend the permit under subsection 46(1) or if the situation giving rise to the suspension is not rectified.

21 Section 46 of the Regulations is renumbered as subsection 46(1) and is amended by adding the following:

(2) The Minister shall reinstate the permit for transit or transhipment if the reasons for the suspension no longer exist or the holder demonstrates that the suspension is unfounded.

22 Paragraph 47(4)(a) of the Regulations is replaced by the following:

(a) all reasonable measures are taken to ensure the security of the precursor during transit in order to prevent its diversion to an illicit market or use;

23 Section 53 of the Regulations is replaced by the following:

53 (1) The Minister shall revoke an authorization certificate if it was issued on the basis of false or misleading information or false or falsified documents.

(2) The Minister may revoke an authorization certificate if the holder fails to comply with a decision of the Minister to suspend the certificate under section 54 or if the situation giving rise to the suspension is not rectified.

24 The Regulations are amended by adding the following after section 54:

54.1 The Minister shall reinstate a suspended authorization certificate if the reasons for the suspension no longer exist or the holder demonstrates that the suspension is unfounded.

25 (1) Subsection 65(3) of the French version of the Regulations is replaced by the following:

(3) Si le changement porte sur une mention faite à son certificat d'inscription, le distributeur inscrit joint à l'avis l'original du certificat que lui a délivré le ministre.

(2) Subsection 65(4) of the Regulations is replaced by the following:

(4) Subject to section 67, if the requirements of subsections (1) to (3) are met, the Minister shall amend the registration certificate accordingly and may add any condition necessary to

(a) ensure that the international obligations of Canada are respected; or

(b) ensure compliance with the Act and these Regulations, including by reducing the risk of a Class B precursor being diverted to an illicit market or use.

26 The Regulations are amended by adding the following after section 65:

Changes to Conditions of Registration

65.1 (1) The Minister may, at any time other than at registration, renewal of a registration or amendment of a registration certificate, add a condition to, or modify a condition of, the registration certificate if the Minister gives prior written notice to the registered dealer and has

reasonable grounds to believe that the addition or modification is necessary to

(a) ensure that the international obligations of Canada are respected; or

(b) ensure compliance with the Act and these Regulations, including by reducing the risk of a Class B precursor being diverted to an illicit market or use.

(2) However, the Minister may add a condition to, or modify a condition of, the registration certificate without prior notice if the Minister has reasonable grounds

(a) to believe that it is necessary to do so to protect public health, safety or security; or

(b) to suspect that it is necessary to do so to prevent a Class B precursor from being diverted to an illicit market or use.

65.2 The Minister may delete from the registration certificate a condition that the Minister determines is no longer necessary. Any such deletion takes effect as soon as the Minister notifies the registered dealer in writing of the deletion.

27 Section 66 of the Regulations is replaced by the following:

66 The Minister shall revoke a registration at the request of the registered dealer or if the registered dealer informs the Minister that the certificate has been lost or stolen.

28 (1) The portion of subsection 67(1) of the Regulations before paragraph (a) is replaced by the following:

67 (1) Subject to subsection (2), the Minister shall revoke a registration if

(2) Paragraph 67(1)(c) of the Regulations is replaced by the following:

(c) the registered dealer has failed to comply with a provision of the Act or any regulation made under the Act or with a condition of a registration certificate, licence or import or export permit issued under any regulation made or continued under the Act;

(3) The portion of subsection 67(2) of the Regulations before paragraph (a) is replaced by the following:

(2) The Minister is not required to revoke a registration under paragraph (1)(b) or (c) if the registered dealer

(4) Subsection 67(3) of the Regulations is replaced by the following:

(3) The Minister may revoke a registration if the registered dealer fails to comply with a decision of the Minister to suspend the registration under subsection 68(1) or if the situation giving rise to the suspension is not rectified.

29 (1) The portion of section 68 of the Regulations before paragraph (a) is replaced by the following:

68 (1) The Minister shall, without prior notice, suspend a registration in respect of any authorized activities in relation to any Class B precursor if the Minister has reasonable grounds

(2) Paragraph 68(1)(b) of the Regulations is replaced by the following:

(b) to suspect that the continuation of the activities presents a risk of a Class B precursor being diverted to an illicit market or use.

(3) Section 68 of the Regulations is amended by adding the following after subsection (1):

(2) The Minister shall reinstate the registration in respect of any activities affected by the suspension if the reasons for the suspension no longer exist or the holder demonstrates that the suspension is unfounded.

30 (1) Subparagraph 70(1)(d)(ii) of the Regulations is replaced by the following:

(ii) the date of expiry of the registration certificate of the applicant, and

(2) Paragraphs 70(2)(b) and (c) of the Regulations are replaced by the following:

(b) the day on which the registration is revoked or suspended under section 66 or 67 or subsection 68(1); and

(c) the day on which the export permit is revoked or suspended under section 73 or 74 or subsection 75(1).

31 Paragraph 71(a) of the English version of the Regulations is replaced by the following:

(a) the applicant is not a registered dealer or is a registered dealer whose registration certificate will expire prior to the proposed date of export;

32 (1) The portion of subsection 74(1) of the Regulations before paragraph (a) is replaced by the following:

74 (1) Subject to subsection (2), the Minister shall revoke a Class B export permit if

(2) Subsection 74(3) of the Regulations is replaced by the following:

(3) The Minister may revoke a Class B export permit if the holder fails to comply with the decision of the Minister to suspend a permit under subsection 75(1) or if the situation giving rise to the suspension is not rectified.

33 (1) Paragraph 75(a) of the Regulations is replaced by the following:

(a) the registration certificate of the holder of the permit has expired or their registration has been suspended or revoked;

(2) Section 75 of the Regulations is renumbered as subsection 75(1) and is amended by adding the following:

(2) The Minister shall reinstate the Class B export permit if the reasons for the suspension no longer exist or the holder demonstrates that the suspension is unfounded.

34 Section 81 of the Regulations is replaced by the following:

81 (1) The Minister shall revoke an authorization certificate if it was issued on the basis of false or misleading information or false or falsified documents.

(2) The Minister may revoke an authorization certificate if the holder fails to comply with a decision of the Minister to suspend the certificate under section 82 or if the situation giving rise to the suspension is not rectified.

35 The Regulations are amended by adding the following after section 82:

82.1 The Minister shall reinstate a suspended authorization certificate if the reasons for the suspension no longer exist or the holder demonstrates that the suspension is unfounded.

36 Section 84 of the Regulations and the heading before it are replaced by the following:

Notice

84 The following decisions of the Minister do not take effect until the Minister has provided the applicant or holder of an affected licence, certificate or permit with a written notice that sets out the reasons for the decision and the applicant or holder has been given an opportunity to be heard within the period specified in the notice:

(a) a decision to revoke or to refuse to issue, amend or renew a licence;

(b) a decision to revoke or to refuse to renew a registration or to refuse to issue or amend a registration certificate;

(c) a decision to revoke or to refuse to issue an authorization certificate; and

(d) a decision to revoke or to refuse to issue an import or export permit or a permit for transit or transhipment.

84.1 (1) The following decisions of the Minister take effect as soon as the Minister provides the holder of an affected licence, certificate or permit with a written notice that sets out the reasons for the decision:

(a) a decision to suspend a licence in respect of any authorized activities in relation to any Class A precursor;

(b) a decision to suspend a registration in respect of any authorized activities in relation to any Class B precursor;

(c) a decision to suspend an authorization certificate; and

(d) a decision to suspend an import or export permit or a permit for transit or transhipment.

(2) The written notice must specify a period within which the holder is given an opportunity to be heard, as well as any corrective measures to be carried out and the date by which they must be carried out.

84.2 A decision of the Minister under subsection 21.1(1) or 65.1(1) to add a condition to, or modify a condition of, a licence or registration certificate does not take effect until the Minister has provided the holder with a written notice that sets out the reasons for the decision and the holder has been given an opportunity to be heard within the period specified in the notice.

84.3 (1) A decision of the Minister under subsection 21.1(2) or 65.1(2) to add a condition to, or modify a condition of, a licence or registration certificate takes effect as soon as the Minister provides the holder with a written notice that sets out the reasons for the decision.

(2) The written notice must specify a period within which the holder is given an opportunity to be heard, as well as any corrective measures to be carried out and the date by which they must be carried out.

37 (1) Section 85 of the Regulations is amended by adding the following after subsection (4):

(4.1) The licensed dealer shall keep at their site all documents showing the measures taken under section 90.1 and shall keep them for at least two years after the day on which the documents were made.

(2) Subsections 85(5) to (7) of the Regulations are replaced by the following:

(5) The licensed dealer shall

(a) keep any record referred to in subsections (1) and (3) for at least two years after the day on which information was last recorded in the record; and

(b) keep an end-use declaration for at least two years after the end of the calendar year for which it was obtained.

(6) The registered dealer shall keep any record referred to in subsection (4) for at least two years after the day on which information was last recorded in the record.

(7) The licensed dealer and registered dealer shall

(a) keep the record referred to in section 86 for at least two years after the day on which it is made;

(b) keep the notice referred to in paragraph 90(2)(a) for at least two years after the day on which it is provided to a member of a police force;

(c) keep the notice referred to in paragraph 90(2)(b) for at least two years after the day on which it is provided to the Minister; and

(d) keep the notice referred to in subsection 90(3) for at least two years after the day on which it is provided to the Minister.

(8) The licensed dealer and registered dealer shall make the records that they are required to keep under this Part available for examination by the Minister.

(9) The licensed dealer and registered dealer, if requested by the Minister in writing, shall provide to the Minister a copy of any record that they are required to keep under this Part.

(3) Paragraph 85(7)(a) of the Regulations is replaced by the following:

(a) keep the report referred to in section 86.1 for at least two years after the day on which it is made to the Minister;

38 Section 85.1 of the Regulations is replaced by the following:

85.1 If a licence or a registration certificate expires without being renewed or is revoked, the former holder shall

(a) retain the records that they were required to keep under section 85 for at least two years after the expiry or revocation; and

(b) at the written request of the Minister, provide the Minister with a copy of any record required to be retained under paragraph (a).

39 Section 86 of the Regulations is amended by adding the following after subsection (6):

(7) This section ceases to have effect on the day on which this subsection comes into force.

40 The Regulations are amended by adding the following after section 86:

86.1 (1) A licensed dealer or registered dealer that becomes aware of a transaction occurring in the course of their activities that they have reasonable grounds to suspect may be related to the diversion of a precursor to an illicit market or use shall, within 72 hours after becoming aware of the transaction, make a written report to the Minister containing the following information:

(a) with respect to the licensed dealer or registered dealer,

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

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

(b) the name and municipal address of the other party to the transaction;

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

(d) the name and quantity of the precursor involved and, in the case of a preparation or mixture, the names and quantities of all precursors that it contains; and

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

(2) A licensed dealer or registered dealer shall not disclose that they have made the report or disclose details of it with the intent to prejudice a criminal investigation, whether or not a criminal investigation has begun.

(3) No civil proceedings lie against a licensed dealer or registered dealer for having made the report in good faith.

(4) The report, or any evidence derived from it, is not to be used or received to incriminate the licensed dealer or registered dealer, or the dealer's agent or mandatary, in any criminal proceeding against them other than a prosecution under section 132, 136 or 137 of the *Criminal Code*.

41 The portion of section 87 of the Regulations before paragraph (a) is replaced by the following:

87 A licensed dealer shall make a written report to the Minister, within three months after the end of each calendar year, showing

42 (1) Subsection 89(1) of the French version of the Regulations is replaced by the following:

89 (1) Le titulaire dont la licence ou le certificat d'inscription ou d'autorisation est renouvelé doit, dès que possible après la date de prise d'effet du document de remplacement, remettre au ministre le document remplacé.

(2) Subsection 89(2) of the Regulations is replaced by the following:

(2) If a licence, a registration or authorization certificate, an import or export permit or a permit for transit or transhipment issued under these Regulations expires without being renewed or is revoked, the former holder shall, within 30 days after the expiry or revocation, return the document to the Minister.

43 Subsection 90(1) of the Regulations is replaced by the following:

90 (1) The holder of a licence, a registration or authorization certificate or an import or export permit issued under these Regulations shall take all reasonable measures to ensure the security of any precursor in their possession, as well as of the licence, certificate or permit.

44 The Regulations are amended by adding the following after section 90:

90.1 A licensed dealer must take all reasonable measures to ensure that their employees do not contribute to the risk of a precursor being diverted to an illicit market or use.

45 (1) Paragraph 91(5)(a) of the English version of the Regulations is replaced by the following:

(a) information pertaining to an activity authorized by a licence, registration or authorization certificate or permit issued to a person under these Regulations, including the person's name, the nature of the authorized activity and any applicable conditions; and

(2) Subparagraph 91(5)(b)(i) of the Regulations is replaced by the following:

(i) information contained in the records mentioned in subsections 85(1) to (4),

46 Section 91.1 of the Regulations is replaced by the following:

91.1 (1) The prohibitions set out in paragraph 6(1)(c) and subsection 6(2) on the sale or provision of a Class A precursor and on the possession of a Class A precursor for the purpose of sale or provision do not apply to

(a) a practitioner or hospital that sells or provides, only on a retail basis, preparations or mixtures containing Class A precursors;

(b) a pharmacist who sells or provides, only on a retail basis, preparations or mixtures containing Class A precursors, other than combination products containing ephedrine or pseudoephedrine or non-combination products containing ephedrine or pseudoephedrine;

(c) a pharmacist who sells or provides, only on a retail basis, non-combination products containing ephedrine or pseudoephedrine, if those products are not accessible to the public for self-selection; or

(d) in the case of combination products containing ephedrine or pseudoephedrine that are sold or provided, only on a retail basis,

(i) a pharmacist who sells or provides the products, if those products are accessible to the public for self-selection and a pharmacist is available at the request of a purchaser or consumer to discuss the products prior to purchase,

(ii) a pharmacist who sells or provides the products, if those products are not accessible to the public for self-selection, or

(iii) an individual working in a retail location where a pharmacist provides services, if

(A) those products are accessible to the public for self-selection and a pharmacist is available at the request of a purchaser or consumer to discuss the products prior to purchase, and

(B) the quantity, per transaction, of each precursor contained in the product and set out in column 1 of the schedule does not exceed the maximum quantity, expressed as an absolute amount or per package, specified for the precursor in column 2.

(2) The prohibitions set out in subsection 9(1) on transporting a Class A precursor and possessing a Class A precursor for the purpose of transport do not apply to a practitioner or hospital referred to in paragraph (1)(a) or a pharmacist referred to in any of paragraphs (1)(b) to (d).

47 Paragraph 91.96(a) of the Regulations is replaced by the following:

(a) take all reasonable measures to ensure the security of the Class A precursors;

48 The schedule to the Regulations is amended by replacing the references after the heading "SCHEDULE" with the following:

(Paragraph 5(b), section 8, subsection 9(1.1), clause 91.1(1)(d)(iii)(B), subsection 91.3(1), section 91.9, subsection 91.92(1), paragraph 91.96(c) and section 92)

49 The Regulations are amended by replacing "reducing" with "by reducing" in the following provisions:

(a) subparagraph 16(h)(ii);

(b) paragraph 19(3)(b);

(c) subparagraph 26(1)(e)(ii);

(d) subparagraph 33(1)(e)(iii);

(e) subparagraph 49(1)(e)(ii);

(f) subparagraph 62(f)(ii);

(g) subparagraph 70(1)(e)(iii); and

(h) subparagraph 77(1)(e)(ii).

50 The English version of the Regulations is amended by replacing "absolute quantity" and "column 2 of the schedule" with "absolute amount" and "column 2", respectively, in the following provisions:

(a) subparagraph 5(b)(iii);

(b) subsection 8(1);

(c) the portion of subsection 9(1.1) before paragraph (a);

(d) subsection 91.3(1);

(e) section 91.9; and

(f) subsection 91.92(1).

51 The English version of the Regulations is amended by replacing "term or condition" and "terms and conditions" with "condition" and "conditions", respectively, in the following provisions:

(a) subparagraph 17(1)(g)(ii);

(b) paragraph 23(1)(c);

(c) paragraph 45(1)(b);

(d) the portion of subsection 57(4) before paragraph (a); and

(e) subparagraph 63(1)(f)(ii).

52 The French version of the Regulations is amended by replacing "se conformer" with "que soit assurée la conformité à" in the following provisions:

(a) subparagraph 33(1)(e)(ii); and

(b) subparagraph 70(1)(e)(ii).

Coming into Force

53 (1) Subject to subsection (2), these Regulations come into force on the day on which they are published in the *Canada Gazette*, Part II.

(2) Section 6, subsections 37(1) and (3) and sections 39, 40 and 44 come into force on the 180th day after the day on which these Regulations are published in the *Canada Gazette*, Part II.

REGULATORY IMPACT ANALYSIS STATEMENT

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

Executive summary

Issues: The toxic illegal drug and overdose crisis remains a significant and complex public health and public safety issue in Canada that impacts individuals, families and communities. Most of the overdose deaths in Canada involve illegally produced fentanyl. Canadian law enforcement agencies have noticed an increase in illegal domestic production of fentanyl and fentanyl analogues in clandestine laboratories by organized crime groups, as well as the illegal importation and diversion of chemical ingredients (precursors) and drug manufacturing equipment (designated devices) used to support said production. In response, Canadian law and border enforcement agencies have targeted precursors and designated devices entering Canada. However, there is a need for increased regulatory oversight of precursors and designated devices and additional tools to support these efforts.

Description: The amendments to the *Precursor Control Regulations* (PCR), made by the Governor in Council, do the following: increase regulatory oversight through mandatory reporting of suspicious transactions involving precursors; mitigate the risk of employees diverting precursors to an illicit market or use by requiring licensed dealers to take reasonable measures to prevent this potential occurrence; strengthen existing regulatory controls for precursors by expanding condition-of-sale restrictions for certain health products containing ephedrine and/or pseudoephedrine, which are precursors that could be used to illegally produce methamphetamine; and increase Health Canada's regulatory flexibility and agility by enabling the Minister of Health (the Minister) to add conditions to a licence or registration at any time (not just at the time of issuance or renewal), to add conditions to transit and transhipment permits at the time of issuance and to partially suspend a licence or registration.

To decrease the availability of designated devices in clandestine laboratories, import registration requirements for designated devices have been expanded to also apply to certain component parts suitable for use in pill presses or encapsulators by adding them to Schedule IX to the *Controlled Drugs and Substances Act* (CDSA). This amendment is made by order of the Governor in Council.

In addition, the *Order Establishing Supplementary Rules Respecting the Sale of Natural Health Products Containing Ephedrine or Pseudoephedrine* is repealed by order of the Minister (the Repeal Order) to help ensure there is no duplication of federal regulations regarding retail sale of ephedrine and pseudoephedrine.

Rationale: Organized crime groups are continually evolving their illegal drug operations in attempts to evade the strict controls established under the CDSA and its regulations. In response, the Government of Canada must continually take concrete action to adapt its own strategies and approaches to address the risks posed to public health and public safety. As one action being taken under Canada's Border Plan, the amendments will help disrupt illegal domestic drug production by organized crime groups, not only decreasing the risk that these harmful drugs are present in Canada, but also decreasing the risk that they would be illegally exported to other countries.

The amendments to the PCR and to Schedule IX to the CDSA impose costs on licensed and registered dealers, importers of component parts suitable for use in pill presses or encapsulators and Health Canada. The total costs are estimated to be $1.01 million in present value (PV) over 10 periods of 12 months or an annualized value of $143,274. Benefits are discussed qualitatively.

Given that there is no change in requirements for natural health products from the Repeal Order, no change in impacts to affected stakeholders is anticipated.

The one-for-one rule applies. The amendments to the PCR and to Schedule IX to the CDSA impose an administrative burden resulting in incremental administrative costs of $89,509 in PV over 10 years or an annualized value of $12,744 (in 2012 dollars). Although the Repeal Order will not result in any change in the administrative burden to regulated parties, it results in one regulatory title OUT for the purpose of the one-for-one rule.

Issues

A dangerous and unpredictable illegal drug supply made up of powerful synthetic opioids like fentanyl and other emerging synthetic drugs is driving overdose deaths and harms, and having devastating impacts on people, families, and communities. Between January 2016 and March 2025, there were 53 821 opioid-related deaths, 49 445 opioid-related hospitalizations and 203 577 opioid-related emergency department visits. The toxicity and unpredictability of the illegal drug supply continue to be a major driver of the overdose crisis, with 63% of all opioid toxicity deaths so far in 2025 (January to March) involving fentanyl and 51% involving fentanyl analogues.

Canada has a robust legal framework to mitigate the public health and public safety risks posed by controlled substances. Controlled substances are drugs, such as fentanyl and other synthetic opioids, that the federal government has categorized as having a higher-than-average potential for misuse and diversion, ranging from illegal street drugs to certain prescription medications.

The framework not only includes controls on controlled substances themselves, but also on certain chemical building blocks essential to the production of controlled substances (precursors), and on some of the equipment used in their production (designated devices).

Since 2019, Canadian law enforcement agencies have observed a move away from trafficking fentanyl made elsewhere to producing it domestically in clandestine laboratories along with fentanyl analogues (i.e. alterations of drugs that have a different but similar chemical structure that imitate the same pharmacological effects). For example, parafluorofentanyl is an analogue of fentanyl. With this shift, there is an increased risk of smuggling precursors into Canada or illegally obtaining them from legitimate domestic sources (diversion).

In response, Canadian law and border enforcement agencies have adapted their efforts to target precursors and designated devices entering Canada and have also made it more difficult to divert precursors from legitimate domestic sources. However, there is a need for additional tools to support law and border enforcement agencies, as well as Health Canada, in the federal government's collective efforts to address the illegal importation of precursors and designated devices and the illegal importation, production and trafficking of fentanyl and other synthetic drugs (e.g. methamphetamine). Timely action is required by the Government of Canada to respond to the threat to public health and public safety, in which the illegal drug supply is constantly evolving and in which organized crime groups attempt to evade Canada's strict controls under the CDSA and its regulations.

Background

Overview of Canada's legal framework for controlled substances

The CDSA is one of the legislative frameworks through which the Government of Canada fulfills its international obligations under the

- United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988;
- Single Convention on Narcotic Drugs, 1961; and
- Convention on Psychotropic Substances, 1971.

These conventions form the basis for the current international drug control system, and require signatories to, among other things, establish national controls on legitimate activities conducted by authorized persons (including organizations) with substances listed in the schedules to the conventions.

The CDSA and its regulations provide a legal framework for the control of drugs that can alter mental processes and pose risks to public health and public safety when misused or diverted to an illicit market.

In general, the CDSA prohibits persons from conducting various activities with substances listed in the schedules to the CDSA, such as production, sale/provision, importation and exportation, unless authorized by regulation or by an exemption granted by the Minister, if either necessary for a medical or scientific purpose, or otherwise in the public interest. The CDSA specifies a range of offences and penalties for unauthorized activities with controlled substances and precursors. Regulated parties include licensed and registered dealers, pharmacists, health care practitioners and hospitals.

The CDSA and its regulations have the dual purpose of protecting public health and maintaining public safety by balancing the need for access to these substances for legitimate commercial, industrial, medical or scientific purposes, and the mitigation of risks of misuse and potential diversion to support the illegal production of drugs by organized crime groups.

Overview of Canada's regulatory framework for precursors

In Canada, precursors are controlled under Schedule VI to the CDSA and are subject to the PCR. The purpose of the PCR is to ensure that precursors are handled effectively in the course of legitimate commercial, industrial, medical and scientific activities and remain within closed legal distribution channels. It is the regulatory framework through which otherwise prohibited activities with precursors are authorized, for example, through issuance of a licence, registration or import/export permit.

Precursors are essential to the production of a controlled substance. Authorized persons conducting activities with precursors include licensed and registered dealers, pharmacists, health care practitioners and hospital staff. While precursors have legitimate uses, such as in the production of certain goods and products (e.g. pharmaceuticals, fragrances, flavouring agents, petroleum products, fertilizers, paints), they can also be used in the production of illegal drugs, like fentanyl and methamphetamine.

There are two classes of precursors under the PCR. Class A precursors are essential ingredients or building blocks used in the production of controlled substances such as fentanyl, methamphetamine and methylenedioxymethamphetamine (MDMA). Class B precursors are common essential reagents such as solvents, acids and bases.

Under the PCR, anyone who wishes to produce, package, provide/sell, export, or possess for those purposes, or import Class A precursors must be licensed with Health Canada. There are also registration requirements for anyone seeking to produce, import or export Class B

precursors. There are security, record keeping and reporting requirements for both Class A and Class B precursors. The PCR also establish a permit scheme for the import, export and transit or transhipment of Class A precursors and a permit scheme for the export of Class B precursors to countries that have requested a pre-export notification of these precursors through the International Narcotics Control Board.

Overview of controls related to ephedrine and pseudoephedrine — two precursors used in the illegal production of methamphetamine

Ephedrine and pseudoephedrine are two precursors that have an established history of misuse and diversion to the illegal production of methamphetamine. While natural health products (NHPs) and non-prescription drugs (NPDs) containing these precursors have been authorized for sale with approved conditions of use as decongestants, there is evidence that some of these products, specifically NHPs containing ephedrine, have been promoted and sold for unintended uses outside the pharmacy setting, often to consumers wishing to enhance athletic performance and increase weight loss and energy.

There is also an established history of these products, in particular single ingredient 8 milligram (mg) ephedrine formulations, being diverted and used to illegally produce methamphetamine in clandestine laboratories by organized crime groups in Canada and internationally. The Royal Canadian Mounted Police (RCMP) and Health Canada's Drug Analysis Service have recorded instances of clandestine laboratories using ephedrine tablets to synthesize methamphetamine between 2011 and 2020. Evidence demonstrates that pseudoephedrine can also be extracted from a variety of NPDs including cold and flu, allergy and decongestant preparations, and in various forms (tablets, coated tablets, soft gelatin capsules, liquids, etc.). [2]

In 2006, in response to evidence from law enforcement demonstrating the diversion of ephedrine and pseudoephedrine to the illegal market, the National Association of Pharmacy Regulatory Authorities (NAPRA) added ephedrine and pseudoephedrine to its National Drug Schedules, which imposed certain condition-of-sale restrictions on NHPs and NPDs containing these substances. Products containing ephedrine or pseudoephedrine as their only medicinal ingredient were listed in Schedule II; this required professional intervention from a pharmacist for their sale (i.e. only available behind the counter). Products containing ephedrine and/or pseudoephedrine, as well as other medicinal ingredients, were listed in Schedule III; they could only be sold in pharmacies but could be available in an area that was readily accessible to the public (e.g. in the open self-selection area of the pharmacy). However, in 2024, NAPRA removed ephedrine and pseudoephedrine from its National Drug Schedules as part of an updated policy on NHPs, which outlines that NHPs approved for sale under the *Natural Health Products*

Regulations are not considered products for scheduling within the National Drug Schedules. This policy also impacted some NPDs containing ephedrine and/or pseudoephedrine, as NAPRA schedules are based on ingredients, not whether the product is an NHP or NPD.

Since many provinces and territories incorporate NAPRA's National Drug Schedules by reference in their respective laws, the NAPRA scheduling change resulted in the removal of the associated condition-of-sale restrictions in pharmacy settings for all NHPs and many NPDs containing ephedrine and/or pseudoephedrine. This had the potential to increase risks of misuse and diversion of these products.

Overview of the Order Establishing Supplementary Rules Respecting the Sale of Natural Health Products Containing Ephedrine or Pseudoephedrine

In response to NAPRA's removal of ephedrine and pseudoephedrine from the National Drug Schedules, the Minister made a temporary (ARCHIVED) *Interim Order Concerning the Sale of Certain Natural Health Products Containing Ephedrine or Pseudoephedrine* (the Interim Order), which was replaced by the *Order Establishing Supplementary Rules Respecting the Sale of Natural Health Products Containing Ephedrine or Pseudoephedrine* (the Ministerial Order) under the *Food and Drugs Act* (FDA). The Ministerial Order was published in the *Canada Gazette*, Part II, on March 26, 2025, and came into force on May 18, 2025.

The Ministerial Order maintains the requirements set out in the Interim Order (which ceased to have effect on May 17, 2025) for NHPs containing ephedrine and/or pseudoephedrine as their only medicinal ingredients. The Ministerial Order also introduced condition-of-sale restrictions for NHPs containing ephedrine and/or pseudoephedrine in combination with other NHPs. These requirements align with how ephedrine and pseudoephedrine were previously scheduled under NAPRA's National Drug Schedules. The Interim Order and Ministerial Order, however, did not introduce condition-of-sale restrictions for NPDs containing ephedrine and/or pseudoephedrine. Thus, there was a gap concerning the retail sale of certain NPDs containing ephedrine and/or pseudoephedrine, which posed a risk of misuse and diversion.

Overview of Schedule IX to the Controlled Drugs and Substances Act

In 2017, amendments were made to the CDSA to prohibit the unregistered importation of certain equipment (designated devices) that can be used in the illegal production of drugs. The list of designated devices subject to import controls is set out in Schedule IX to the CDSA and captures pill presses and capsule filling machines (i.e. encapsulators), but not their component parts. These designated devices are also used in pharmaceutical, food and other consumer product industries.

Objective

Organized crime groups are continually evolving their illegal drug operations in an attempt to evade the strict controls established under the CDSA and its regulations. In response, the Government of Canada must continually take concrete action to adapt its own strategies and approaches to mitigate risks to public health and public safety. The amendments aim to protect public health and public safety by providing Health Canada and the Canada Border Services Agency (CBSA) with additional tools to support law enforcement in their efforts to detect and disrupt the illegal fentanyl trade and the supply of other illegal synthetic drugs. Targeted amendments in relation to precursors and designated devices further reduce risks of their misuse or diversion while continuing to support their legitimate use for commercial, industrial, medical or scientific purposes. They address commitments made in Canada's Border Plan, strengthen border security and help keep individuals, families and communities safe.

Description

The amendments to the PCR and to Schedule IX to the CDSA target the following five priority areas: mandatory reporting of suspicious transactions; reasonable measures taken by licensed dealers to prevent the potential diversion of Class A precursors; condition-of-sale restrictions for NHPs and NPDs containing ephedrine and/or pseudoephedrine; increased regulatory flexibility for Health Canada; and expansion of import registration requirements for designated devices to include the importation of component parts. The amendments come into force immediately, with the exception of provisions related to the reporting of suspicious transactions and taking reasonable measures, which are delayed by six months. These amendments are made by the Governor in Council. The Repeal Order is made by the Minister to help ensure there is no duplication of federal regulatory requirements related to retail sale for NHPs containing ephedrine and/or pseudoephedrine.

Mandatory reporting of suspicious transactions to Health Canada

To help ensure that precursors remain in legal distribution channels and are used for legitimate purposes, the amendments to the PCR require mandatory reporting of suspicious transactions involving precursors. Licensed and registered dealers will need to provide a written report to Health Canada within 72 hours of becoming aware of a transaction occurring where they have reasonable grounds to suspect it may be related to the diversion of a precursor to an illicit market or use. Prior to this regulatory change, reporting to Health Canada was voluntary and licensed and registered dealers were required to make a record of every suspicious transaction and retain it for at least two years.

The mandatory report will need to include a detailed description of the reasons for the suspicions and be retained for two years after it was made. The retention requirement also applies to entities who are no longer licensed or registered. Further, licensed and registered dealers are not permitted to disclose that they have made a report or disclose details in the report with the intent to prejudice a criminal investigation, whether or not a criminal investigation has begun.

Mandatory reporting will enable prompt action by Health Canada to verify and triage information on suspicious transactions. Where warranted, Health Canada will proactively disclose this information to law enforcement agencies. Mandatory reporting also provides a proactive mechanism for collecting information instead of relying on inspections and encourages early detection of suspicious activities that could be related to diversion of precursors to an illicit market or use.

In addition, to protect licensed and registered dealers who may have felt at risk when reporting suspicious transactions voluntarily, protective measures will be provided for licensed and registered dealers for mandatory reporting. They will be protected against civil proceedings if the suspicious transaction report was made in good faith. In addition, there will be partial protection against self-incrimination for them, and their agents or mandataries, when reporting suspicious transactions.

To respond to consultation feedback, mandatory reporting requirements will come into force on the 180th day after the day the amendments to the PCR are published in the *Canada Gazette*, Part II. During this transition period, voluntary reporting is encouraged and record keeping remains mandatory.

Reasonable measures taken by licensed dealers to prevent the potential diversion of Class A precursors

Concerns have been raised that organized crime groups might look to infiltrate legitimate businesses conducting permitted activities with precursors. To address this concern, Health Canada had proposed amendments to the PCR that would require both licensed and registered dealers to take reasonable measures to ensure their employees do not contribute to the risk of a precursor being diverted to an illicit market or use, including taking into consideration whether employees with access to precursors in the course of their duties have been convicted as an adult within the previous 10 years of a designated drug offence or a designated criminal offence (e.g. production of substances in the schedules to the CDSA), or an equivalent offence outside of Canada.

In response to consultation feedback, Health Canada has altered the proposed amendments to apply only to licensed dealers handling Class A precursors and applicants seeking a licence to conduct activities with Class A precursors. The amendments will not apply to registered dealers handling Class B precursors. Further, the amendments will not require licensed dealers to take into consideration criminal records or prior convictions for employees with access to precursors (though they may choose to do so as part of their reasonable measures, should they see fit).

The amendments require licensed dealers handling Class A precursors to take reasonable measures to ensure their employees do not contribute to a risk of diverting precursors to an illicit market or use. Applicants seeking a Class A precursor licence or its renewal will need to provide a statement, signed by the senior person in charge of a licence, to Health Canada to acknowledge that reasonable measures have been taken.

Any documents or records related to implementing reasonable measures will need to be retained by the licensed dealer for at least two years after the information was last recorded. These record keeping requirements will also apply to licensed dealers who are no longer licensed.

The final amendments will continue to meet Health Canada's public health and public safety objective of preventing the diversion of precursors to an illegal market or use, while allowing flexibility to consider implementation of measures to their operations based on risk factors such as volume and type of precursors, size of business and number of employees.

To respond to consultation feedback, a six-month transitional provision has been added to facilitate compliance by licensed dealers. The requirement to take reasonable measures will come into force on the 180th day after the day the amendments to the PCR are published in the *Canada Gazette*, Part II.

Condition-of-sale restrictions for natural health products and non-prescription drugs containing ephedrine and/or pseudoephedrine

To address the risk of misuse and diversion of ephedrine and pseudoephedrine, the amendments to the PCR replicate the requirements set out in the Ministerial Order for NHPs, while introducing condition-of-sale restrictions for NPDs containing these ingredients.

Since ephedrine and pseudoephedrine are Class A precursors and the PCR is the regulatory framework by which Health Canada controls precursors, Health Canada recognizes that the PCR is a more appropriate place for these condition-of-sale restrictions to reside than the Ministerial Order.

These restrictions align with the previous restrictions under NAPRA's National Drug Schedules. The aim is to ensure NHPs and NPDs containing ephedrine and/or pseudoephedrine remain strictly regulated, while also ensuring individuals can continue to have access to these products for the treatment of approved indications (e.g. nasal congestion).

The PCR previously allowed for the sale or provision (or possession for the purpose of sale or provision) of a Class A precursor on a retail basis under certain conditions by persons other than licensed dealers and other regulated parties, such as in health food stores. Under the amendment, this exception no longer applies to NHPs and NPDs containing ephedrine and/or pseudoephedrine, and their retail sale will only be permitted in pharmacies, in hospitals and via health care practitioners.

Furthermore, the amendments prohibit licensed dealers from selling or providing these products to anyone other than other licensed dealers, pharmacists (and individuals working in a retail location where a pharmacist provides services), health care practitioners and hospitals.

Health Canada heard from stakeholders who responded to the consultation that the ordering of these health products is typically done by individuals other than the pharmacist. Therefore, to continue supporting pharmacy operations, Health Canada has amended the proposed provision to allow licensed dealers to sell or provide these products to individuals working in a pharmacy other than the pharmacist.

This regulatory change allows for continued intra-industry sale of these products (e.g. between manufacturers and distributors), but limits the ability to provide or sell them to an end user (e.g. consumers) anywhere other than in pharmacies, in hospitals or via a health care practitioner.

Health Canada recognizes that NPDs containing ephedrine and/or pseudoephedrine are being distributed in a closed-loop, highly regulated supply chain where distributors sell exclusively to pharmacies, hospitals and health care practitioners and never to other retailers or the public. Nevertheless, all licensed dealers selling or providing NHPs or NPDs containing ephedrine and/or pseudoephedrine should continue to be familiar with their customers to ensure these products are sold only to persons who are permitted to sell these substances, including verifying that an individual placing an order is authorized to do so on behalf of a pharmacy that is serviced by a pharmacist.

The amendments do not impact clinical trials involving these products and the distribution of product samples by a practitioner or pharmacist.

Conditions of sale at the retail level

The following condition-of-sale restrictions apply to pharmacists selling these products on a retail basis:

- Non-combination NHPs can only be sold behind the counter in a pharmacy — The amendments permit a pharmacist to sell NHPs containing ephedrine and/or pseudoephedrine as their only medicinal ingredients (referred to as non-combination products containing ephedrine or pseudoephedrine in the regulations; e.g. decongestants) in a pharmacy setting, but these products cannot be accessible to the public (i.e. they need to be sold behind the counter in a pharmacy).
- There is no requirement for combination NHPs or NPDs to be sold behind the counter — For NHPs and NPDs that contain ephedrine and/or pseudoephedrine in combination with other NHPs or drugs (referred to as combination products containing ephedrine or pseudoephedrine in the regulations; e.g. cough, cold and allergy relief medication), the amendments permit a pharmacist (or individuals working in a retail location where a pharmacist provides services) to sell them in an area that is readily accessible to the public (e.g. in the open self-selection area of a pharmacy). However, a pharmacist must be available at the request of a purchaser or consumer to discuss the products prior to purchase.

The amendments are minimum federal standards that apply to the sale of NHPs and NPDs containing ephedrine and/or pseudoephedrine. It is possible that these products are also subject to additional requirements via provincial or territorial regulations, or contain other ingredients that are subject to NAPRA's National Drug Schedules.

The amendments are technologically neutral in that the sale prohibitions and exceptions apply to both physical and online retail settings. For example, combination products containing ephedrine or pseudoephedrine could be sold by an online pharmacy retailer; however, a pharmacist must be available (e.g. by telephone, video, text or other means of communication) at the request of the purchaser or consumer to discuss the products prior to purchase.

The amendments do not include any new restrictions on the sale of veterinary drugs or veterinary health products containing ephedrine and/or pseudoephedrine or NHPs or drugs containing the plant ephedra (as long as they do not also contain isolated and extracted ephedrine or pseudoephedrine in addition to the ephedra), which is typically used in traditional Chinese medicines. While there are a limited number of approved pharmaceutical drugs containing ephedrine that are administered by injection via needle or by intravenous infusion and do not require a prescription, the amendments do not apply to these drugs due to their lower risk of diversion. Should Health Canada or law enforcement detect instances of misuse or diversion of any of these other products, additional condition-of-sale restrictions may be considered in the future.

For greater clarity and precision for regulated parties, Health Canada has made two minor amendments to the definitions of "combination product" and "non-combination product." The words "containing ephedrine or pseudoephedrine" have been added to the respective definitions of both terms (e.g. combination product containing ephedrine or pseudoephedrine). Additionally, the "combination product" definition has been amended to clarify that products administered by injection via needle or by intravenous infusion are out of scope. A minor adjustment has also been made to the condition-of-sale provisions to ensure that retail staff in pharmacies continue to be prohibited from selling products to consumers in a quantity that exceeds the maximum quantity set out in the Schedule to the PCR. This means that NHPs and NPDs containing ephedrine and/or pseudoephedrine cannot be sold in package sizes that contain more than 0.4 grams of ephedrine and/or 3 grams of pseudoephedrine. This limit is to prevent the retail sale of bulk amounts of precursors.

Increased regulatory flexibility so that Health Canada can respond to public health or public safety risks in a more agile and timely manner

The following amendments to the PCR provide Health Canada, acting on behalf of the Minister, with increased flexibility to respond to new and emerging public health or public safety risks related to precursors in a timely manner. In addition, they increase efficiency by enabling Health Canada to target specific activities instead of fully suspending a licence or registration, thereby reducing potential operational impacts to businesses.

Licence and registration conditions

The amendments introduce new regulatory tools and flexibility for Health Canada. Namely, they allow Health Canada to add, modify or delete conditions to a licence (for Class A precursors) or registration (for Class B precursors) at any time if there are reasonable grounds to believe that the conditions are necessary to ensure that international obligations are respected or to ensure compliance with the CDSA or PCR, including by reducing the risk of a precursor being diverted to an illicit market or use.

For example, Health Canada could add conditions to a licence in response to an issue of non-compliance identified during an inspection. Prior to this regulatory change, Health Canada was limited to adding, modifying or removing conditions to a licence or registration at the time of issuance or renewal (or, in the case of a licence for Class A precursors, when an amendment was initiated by the licensed dealer).

To ensure transparency and fairness, a licensed or registered dealer will be provided written notice before new conditions are added to a licence or registration or existing conditions are modified. This written notice will set out Health Canada's reasons for doing so. Licensed and registered dealers will have an opportunity to be heard and to comment on the changes.

The amendments provide an exception in urgent circumstances, where Health Canada may add a condition or modify one without prior written notice if there are reasonable grounds to believe that it is necessary to do so to protect public health or public safety or reasonable grounds to suspect that it is necessary to prevent a precursor from being diverted to an illicit market or use. In such situations, a licensed or registered dealer has an opportunity to be heard after the decision has taken effect.

In the context of removing a condition on a licence or registration, the change takes effect as soon as Health Canada provides the licensed or registered dealer with a written notice to that effect.

Partial suspensions

Consistent with federal regulations such as the *Cannabis Regulations* and the *Controlled Substances Regulations*, the amendments authorize Health Canada to partially suspend a licence or registration with respect to any authorized activity relating to any precursor, without prior notice, if there are reasonable grounds to believe that such suspension is necessary to protect public health, safety or security or reasonable grounds to suspect that continuing the activity presents a risk of a precursor being diverted to an illicit market or use. Prior to this regulatory change, Health Canada's authority under the PCR was limited to fully suspending a licence or registration.

In such cases, the partial suspension takes effect as soon as Health Canada provides the licensed or registered dealer with a notice in writing. The notice will specify the reasons for the partial suspension, set out the corrective measures that must be carried out (if applicable) and provide the licensed or registered dealer with an opportunity to be heard. Reinstatement will occur if the reasons for the partial suspension no longer exist or the licensed or registered dealer demonstrates that the suspension is unfounded.

Transit and transhipment permits

The amendments allow Health Canada to add conditions to transit and transhipment permits; however, Health Canada is not authorized to add, modify or delete conditions after the permit is issued nor to partially suspend it once it has been issued. Prior to this regulatory change, there were no authorities for Health Canada to add conditions to transit and transhipment permits at the time of issuance.

Expansion of import registration requirements for designated devices to include the importation of component parts

Law and border enforcement agencies have raised concerns that organized crime groups are breaking down designated devices (e.g. pill presses and encapsulators) into component parts prior to importation to evade existing import registration requirements under the CDSA.

The *Order Amending Schedule IX to the Controlled Drugs and Substances Act*

- Clarifies that designated devices listed in Schedule IX must be registered with Health Canada prior to importation regardless of whether this equipment is imported as a whole or in parts (i.e. unassembled or fully or partially assembled or disassembled); and
- Adds certain component parts (i.e. punches, moulds and dies) suitable for use in a pill press or encapsulator to Schedule IX to prohibit their importation unless the importation has been registered with Health Canada.

When importing a designated device, importers are not required to register both the device and the component parts (punches, moulds and dies) that already form part of that device. They are only required to register scheduled component parts if they are being imported as separate parts from the device itself (e.g. a replacement part for an existing device or if importing multiple different punches, moulds or dies along with a designated device).

Prior to importation, importers are required to provide the information set out in the CDSA to Health Canada. This enables the Minister to register the importation and provide proof of the registration to the person importing the scheduled items. The importer is required to provide proof of the import registration to the customs office at the time of importation.

The Minister is authorized to disclose this information to the CBSA for the purpose of verifying compliance and also to a Canadian police force who requests the information in the course of an investigation under the CDSA.

Health Canada has the option to refuse to register or to cancel the import registration of scheduled component parts if the Minister believes on reasonable grounds that false or misleading information was provided, or it is necessary to do so to protect public health or public safety.

Order Repealing the Order Establishing Supplementary Rules Respecting the Sale of Natural Health Products Containing Ephedrine or Pseudoephedrine

The repeal of the Ministerial Order ensures that similar requirements to control the sale of NHPs containing ephedrine and/or pseudoephedrine are not applied under two different federal legislative frameworks.

Unlike the other regulatory instruments covered by this Regulatory Impact Analysis Statement, which are made under the authority of the Governor in Council, the Repeal Order is made under the authority of the Minister. Given that the amendments to the PCR and the Repeal Order are

linked, presenting both instruments in this Regulatory Impact Analysis Statement offers a more transparent and coherent picture.

Consequential and coordinating amendments

Bill C-12, An Act respecting certain measures relating to the security of Canada's borders and the integrity of the Canadian immigration system and respecting other related security measures also proposes amendments to the PCR. As a consequence, certain provisions in the final amendments of this regulatory package are renumbered to align with the numbering in Bill C-12.

Proposed amendments to the PCR that relate to loss and theft reporting for precursors will no longer be addressed in this regulatory package. They have been addressed as part of the *Controlled Substances Regulations* regulatory package to align requirements for precursors and controlled substances and to ensure consistency among regulations made under the CDSA.

Regulatory development

Consultation

Notice of intent

On February 1, 2025, Health Canada published a notice of intent in the *Canada Gazette*, Part I, and launched a public consultation on the proposed amendments to the PCR and to Schedule IX to the CDSA that would increase oversight of precursors, strengthen Canada's regulatory framework and increase Health Canada's regulatory flexibility and agility. The consultation was open for public comment for 30 days and closed on March 3, 2025.

Health Canada received 23 responses to the notice of intent, largely from industry or industry associations that use precursors such as manufacturers, distributors, importers and exporters in the pharmaceutical, chemical and fragrance industries. Other responses were from law enforcement and the general public. The proposal was generally well received. Most respondents were supportive of Health Canada's efforts to curb illegal activities related to the importation, production, diversion and trafficking of precursors and designated devices.

Consultation following prepublication of the amendments in the *Canada Gazette*, Part I

On June 28, 2025, Health Canada published the proposed *Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)* and the proposed *Order Amending Schedule IX to the Controlled Drugs and Substances Act* in the *Canada Gazette*, Part I. The publication opened a 45-day consultation period, which ended on August 12, 2025. Health Canada received 22 submissions from licensed dealers, industry associations, health care professional associations,

an association representing provincial and territorial regulators, law enforcement and individuals. Overall, stakeholders were generally opposed to the proposed regulatory changes. The majority (59%) expressed opposition, with 20% in favour and 20% neutral.

The majority of submissions (14) came from industry, including industry associations and licensed dealers. Many expressed support for the overall objective of combatting the illegal drug trade but had concerns that the proposed regulatory changes would not actually accomplish that goal. Instead, many were concerned that the amendments would punish compliant, law-abiding companies by increasing the regulatory burden on legitimate businesses, increasing costs for companies and negatively impacting the legitimate precursor supply chain. It was noted that many of the precursors being used in illegal drug production do not have legitimate uses and are therefore not being used by licensed and registered companies. They also predicted that implementation of the proposed amendments would create undue burden on pharmacy operations, resulting in negative impacts to health care services and patient outcomes.

Two health care professional associations and one association representing provincial and territorial regulatory bodies responded to the consultation. The latter was in favour of the proposed amendments, whereas the health care professional associations had differing views on the proposed changes.

Two law enforcement agencies provided feedback and while they had neutral views, they did offer suggestions to target additional drug manufacturing equipment regularly used in the production of illegal drugs and asked for further specifics on how the proposal would be implemented.

Three individuals, who did not claim association with any particular type of stakeholder, responded to the consultation. Their comments were either neutral or opposed to the regulatory proposal.

Key highlights of the consultation feedback received are summarized thematically below.

Mandatory reporting of suspicious transactions to Health Canada

Overall, stakeholders opposed the proposal to replace voluntary reporting of suspicious transactions involving precursors with mandatory reporting due to concerns about increased costs to the legal industry, administrative burden and lack of clarity in criteria for identifying suspicious transactions.

Stakeholders advocated for a standardized, industry-backed approach with clear rules and defined thresholds to reduce administrative burden and over-reporting. They recommended that reporting be risk and sector-specific (e.g. require only non-licensed entities to report).

Further, they encouraged simplifying the reporting process, potentially by implementing a digital reporting system.

Stakeholders also highlighted that diversion of controlled precursors from the legal industry is not a significant contributor to illegal fentanyl production in Canada.

Health Canada response

In considering these concerns, Health Canada concluded that mandatory reporting of suspicious transactions involving precursors is an important control measure to increase oversight for precursors and to further minimize diversion risks. This change will align with mandatory reporting requirements for controlled substances.

Health Canada anticipates limited cost and burden with this regulatory change; the number of suspicious transactions involving precursors is expected to be low, given extensive controls already in place under the PCR to minimize potential diversion risks.

In response to industry concerns, Health Canada has added a six-month transition period for implementing mandatory reporting to allow licensed and registered dealers to review and update their internal processes to promote compliance.

Reasonable measures by licensed dealers to prevent the potential diversion of precursors

There were significant concerns raised by stakeholders in response to Health Canada's proposal to require licensed and registered dealers to take reasonable measures to prevent the diversion of precursors by employees, with the majority of respondents opposed. In general, stakeholders had concerns about the high level of burden (time and costs) for a legitimate business with little to no evidence of diversion. There were concerns about potential labour law, human rights and privacy implications and some noted that Health Canada's proposal was disproportional to the risks and runs counter to the government's priority of reducing red tape. Stakeholders also noted that many companies already have policies and procedures in place to mitigate diversion risks (e.g. verification of legitimate buyers such as pharmacies) and how the proposed amendments would unjustly punish compliant, law-abiding companies for the damage caused by those operating outside the law.

Some industry associations and licensed dealers were strongly opposed to the proposed requirement that licensed or registered dealers must consider if their employees with access to precursors have been convicted of certain offences within the past 10 years (thus requiring criminal record and background checks, or other access to this information). They argued that such measures are excessive and unjustified, given the absence of incidents of diversion and existing requirements related to inventory controls, audit protocols and restrictions on access to Class A precursors. They noted that it would impose high costs (over $10,000 annually for

certain distribution centres), and that it would create a significant administrative and operational burden, including hiring delays to confirm verification requirements of criminal record checks and increased staffing needs to support the process to obtain, manage and regularly update the required documentation.

There were also concerns raised about the legal implications of retroactively screening long-serving employees and contractors, including possible contraventions of labour, human rights and privacy laws. The feasibility of verifying foreign criminal records was also questioned.

Stakeholders emphasized the need for a risk-based, proportionate approach that distinguishes between Class A and Class B precursors, as well as employees with incidental and direct access to precursors. They advocated for clear guidance, including practical tools such as checklists and decision matrixes, to support consistent implementation across the industry. They emphasized the importance of industry working collaboratively with Health Canada to develop best practices that balance public safety with operational feasibility and fairness for the legitimate industry.

Additionally, they noted that the proposed amendments could have unintended consequences for the broader pharmaceutical supply chain, potentially affecting product availability and patient access.

Health Canada response

In response to stakeholder concerns, Health Canada's proposal has been altered considerably to respond proportionally to the degree and type of risk, and to reduce the burden on industry. Health Canada acknowledges that there are existing control measures in the PCR to help prevent the potential diversion of precursors, and that many licensed dealers already have strict hiring practices in place (e.g. hiring policies, employment background checks).

Health Canada has narrowed the scope of the amendments to apply only to licensed dealers conducting activities with Class A precursors, as these precursors are essential to the production of controlled substances and pose a greater risk of being diverted to an illicit market or use. Class B precursors are considered lower risk (e.g. one cannot illegally produce drugs solely with Class B precursors) and have broader industrial uses and therefore registered dealers are not subject to the new requirements.

Additionally, the regulations will not require licensed dealers to consider criminal records and prior convictions for employees with access to precursors. This will reduce cost and regulatory burden for regulated parties. Instead, licensed dealers are encouraged to identify and implement reasonable measures that are appropriate to the level of risk associated with their particular circumstances. Health Canada has determined that shifting to a statement at the time

of applying for or renewing a licence, where the applicant indicates that reasonable measures have been taken, along with record keeping requirements related to reasonable measures, will achieve Health Canada's objective of further minimizing diversion risks.

To support implementation, Health Canada has added a six-month transition period for licensed dealers and will develop guidance.

Condition-of-sale restrictions for natural health products and non-prescription drugs containing ephedrine and/or pseudoephedrine

The majority of stakeholders opposed this proposal for various reasons, including the fear that the condition-of-sale restrictions would limit patients' access to important medications, place undue burden on pharmacists, and/or increase regulatory burden on products they feel pose a low risk of misuse and diversion. Those in favour or neutral were from a law enforcement agency, a health care professional association and an association representing provincial and territorial regulators.

Stakeholders representing manufacturers and distributors of health products voiced opposition to Health Canada's proposal to expand the scope of the Ministerial Order to include condition-of-sale restrictions on NPDs containing ephedrine and/or pseudoephedrine, citing a lack of evidence that these products are being used in clandestine laboratories. There were concerns that restricting the sale of combination NPDs to pharmacies would impact access for patients and that the impacts would be significant in rural and remote communities where access to a pharmacy may be limited.

Several stakeholders misunderstood certain elements of the proposal, raising concerns that the restrictions on combination NPDs would limit access to cough, cold and allergy-relief products. For example, some stakeholders assumed that all NHPs and NPDs containing ephedrine and/or pseudoephedrine would be required to be sold behind the counter in pharmacies. They noted this would place a significant burden on pharmacists and reduce customers' awareness of these products.

Other stakeholders acknowledged the proposed amendments would align with the previous place-of-sale restrictions that applied to combination NPDs when they were listed on NAPRA's National Drug Schedules. However, they felt Health Canada's regulatory proposal should not revert back to the restrictions that were in place under NAPRA's National Drug Schedules prior to the making of the Interim Order.

Some felt that NPDs containing ephedrine and/or pseudoephedrine posed little to no risk of misuse or diversion to an illegal market or use and that adding condition-of-sale restrictions would unfairly penalize generally law-abiding companies for illegal activities conducted by bad actors. It was also noted that single-ingredient ephedrine pills, which can only legally be sold

behind the counter in pharmacies, are still being sold illegally online, and that such products continue to pose a greater risk of diversion than NPDs containing ephedrine and/or pseudoephedrine.

Traditional Chinese medicine (TCM) practitioners, who are regulated in some provinces, do not meet the definition of “practitioner” under the CDSA and its regulations. Thus, certain stakeholders expressed concern that TCM practitioners were being unfairly excluded from the ability to purchase and use these products in a therapeutic context, particularly if products containing whole plant preparations of ephedra (also referred to as “Ma Huang”) would be impacted.

Some stakeholders urged Health Canada to develop materials that would help regulated parties better understand the requirements in light of the iterative changes made over the years. Further, some stakeholders pointed out the importance of clarifying how the proposed restrictions on NPDs would align with corresponding provincial and territorial regulations in this space.

Health Canada response

The regulatory amendments only require that non-combination NHPs be sold behind the counter in pharmacies. Combination NHPs and NPDs can continue to be made available for self-selection within a pharmacy.

To ensure that products that are not required to be sold behind the counter can continue to be ordered by pharmacies, the regulations have been adjusted to enable the ordering and purchasing of NHPs and NPDs containing ephedrine and/or pseudoephedrine by additional persons, namely, individuals working in a retail location where a pharmacist provides services. This change supports current pharmacy operations, where various retail staff may be involved in the ordering of NHPs and NPDs and thus will reduce the burden on pharmacists.

Recognizing broader issues about access to drugs in rural and remote communities, Health Canada acknowledges that while the amendments limit access to NPDs containing ephedrine and/or pseudoephedrine to a pharmacy, a hospital or via a health care practitioner, there is no indication that such products are available for sale in other retail settings (e.g. gas stations) despite the Ministerial Order not prohibiting this type of sale. Therefore, the amendments are not expected to have an impact on access in rural and remote communities. Finally, by including NPDs in these amendments, Health Canada reduces the potential risk of diversion of these products at retail.

Health Canada notes that NHPs and NPDs containing ephedrine and/or pseudoephedrine in combination with other medical ingredients are permitted to be sold in the open self-selection area of a pharmacy. However, Health Canada acknowledges that these products may continue

to be subject to additional condition-of-sale requirements in provincial and territorial legal frameworks and/or more place-of-sale restrictions due to NAPRA's scheduling of other ingredients that these products may contain. Thus, the condition-of-sale restrictions in the amendments should be considered minimum federal standards.

As stated during the prepublication of the amendments, Health Canada does not intend to include any new restrictions on the sale of NHPs or drugs containing the plant ephedra, which is typically used in traditional Chinese medicines, as long as the product does not also contain isolated and extracted ephedrine or pseudoephedrine in addition to the ephedra. Health Canada will continue to assess whether additional controls are needed as new information becomes available to continue to meet the objectives of the CDSA and the FDA.

Health Canada will work closely with partners and stakeholders to ensure regulated parties understand the new condition-of-sale requirements and how they interact with requirements in place in some provinces and territories and to promote compliance.

Increased regulatory flexibility to allow Health Canada to respond to public health or public safety risks in a more agile and timely manner

Some stakeholders interpreted the proposed amendments as applying in isolation without existing provisions in the PCR that relate to providing a written notice and providing an opportunity to be heard and time to take corrective action. As such, they believed the proposed changes lacked transparency and procedural fairness.

Licence and registration conditions

There were specific concerns raised around the registration of Class B precursors and the enabling of Health Canada to add, modify or delete conditions to a registration at any time if there are "reasonable grounds" to believe that the conditions are necessary. Stakeholders were concerned about the lack of transparency and parameters for determining "reasonable grounds." They proposed Health Canada develop evidence-based criteria to support implementation, including to ensure consistent interpretation by inspectors.

Partial suspensions

There was support for Health Canada to partially suspend a registration with respect to any authorized activity relating to any precursor but no specific mention of support for partially suspending a licence. The majority of respondents suggested that the ability to partially suspend export permits also be added to the PCR.

Transit and transhipment permits

Health Canada received one comment that was in favour of adding, modifying or deleting conditions of an issued transit or transhipment permit.

Health Canada response

In response to the mixed feedback received, Health Canada's proposed amendments remain unchanged. Health Canada will continue to take a risk-based approach to its compliance and enforcement actions, including selecting the most appropriate tool to monitor compliance and mitigate risks to public health or public safety as circumstances warrant.

Regarding concerns about transparency and procedural fairness, Health Canada clarifies that the amendments require Health Canada to provide a written notice of the changes being made to a licence or registration and that licensed and registered dealers will have an opportunity to be heard and to comment on the changes.

Health Canada further clarifies that while export permits cannot be partially suspended (as they are standalone authorizations for one activity), Health Canada has the ability to partially suspend an export activity authorized under a licence or registration.

Expansion of import registration requirements for designated devices to include the importation of component parts

There was mixed feedback on the proposal to extend import registration requirements for designated devices to include certain component parts. Law enforcement agencies were generally supportive or neutral and encouraged Health Canada to extend the requirements further. They recommended additional pieces of equipment (e.g. rotary evaporator) be added to the Schedule and the tracking of the domestic sale of designated devices once imported into the country.

Those not in favour of the regulatory change had concerns that the language was too broad and would inadvertently capture component parts that have multi-use purposes (e.g. funnels, screws, etc.).

Others were concerned that the expansion to include certain component parts could result in the domestic production of these parts by the illegal drug industry using tools such as 3D printers.

One stakeholder recommended Health Canada exempt NHP manufacturers from all import registration requirements.

Health Canada response

No changes have been made to the proposed amendments in response to these comments. Health Canada is of the view that adding punches, moulds and dies to Schedule IX will strengthen Canadian efforts to prevent the illegal domestic production of fentanyl and fentanyl analogues in clandestine laboratories by organized crime groups as well as the illegal importation and diversion of drug manufacturing equipment used to support illegal production.

Health Canada clarifies that pill presses and encapsulators must be registered with Health Canada prior to importation regardless of whether this equipment is imported as a whole or in parts (i.e. unassembled or fully or partially assembled or disassembled).

Health Canada further clarifies that importers are not required to register both a pill press or encapsulator and any component parts (i.e. punches, moulds and dies) that already form part of that device. Importers are only required to register punches, moulds and dies when they are being imported as separate parts from the device itself (e.g. a replacement part for an existing device or if importing multiple different punches, moulds or dies along with a designated device).

Order Repealing the Order Establishing Supplementary Rules Respecting the Sale of Natural Health Products Containing Ephedrine or Pseudoephedrine

There were mixed reactions about repealing the Ministerial Order. There was support for Health Canada's rationale (i.e. eliminating duplicative requirements across two legal frameworks) and opposition because doing so would mean new condition-of-sale restrictions for NPDs containing ephedrine and/or pseudoephedrine. There was a suggestion that Health Canada create a side-by-side overview of the Ministerial Order and the regulations to help stakeholders better understand the changes in requirements, thereby supporting compliance.

Health Canada response

Health Canada acknowledges that the amendments to the PCR include condition-of-sale restrictions for NPDs containing ephedrine and/or pseudoephedrine, thereby expanding the condition-of-sale restrictions in the Ministerial Order that only applied to NHPs. This addition will ensure the approach remains in line with previous restrictions under NAPRA's National Drug Schedules. Health Canada will work with partners and stakeholders to help regulated parties better understand the requirements for both NHPs and NPDs containing ephedrine and/or pseudoephedrine.

Indigenous engagement, consultation and modern treaty obligations

An assessment of modern treaty implications was conducted and concluded that the amendments do not trigger a duty to consult with Indigenous Peoples. Separately, an assessment of intersections with the *United Nations Declaration on the Rights of Indigenous Peoples Act* (UNDRIPA) was conducted and determined that the amendments would not affect the rights and interests of Indigenous Peoples, including the right to determine and develop priorities for health as set out in the articles on health in the UNDRIPA.

The amendments advance public health and public safety objectives, particularly those related to curbing illegal activities related to fentanyl and other synthetic drugs and the potential diversion of precursors. Since the amendments do not specifically target Indigenous Peoples, they are not expected to impact the rights of Indigenous Peoples recognized and affirmed under section 35 of the *Constitution Act, 1982*, and the assessments did not identify any implications for modern treaties or self-government agreements.

There were no responses received from Indigenous Peoples regarding the amendments prepublished in the *Canada Gazette*, Part I, for public comment.

Instrument choice

The threat that the illegal fentanyl trade and other illegal synthetic drugs pose to public health and public safety, and the means by which organized crime groups seek to evade current controls, indicate that guidance, directives or other non-regulatory approaches would not be efficient or effective in curbing illegal activities with precursors and designated devices. Regulatory amendments, on the other hand, enable the Government of Canada to respond proportionally to the degree and type of risk and provide law and border enforcement agencies, as well as Health Canada, with additional tools to target the diversion of precursors and designated devices that support the illegal domestic production of fentanyl and other synthetic drugs by organized crime groups.

Regulatory analysis

Benefits and costs

Analytical approach

To estimate impacts of the amendments to the PCR and to Schedule IX to the CDSA, a cost-benefit analysis (CBA) was undertaken that identified and, to the extent possible, quantified and monetized the incremental impacts on affected stakeholders. These incremental impacts were derived by comparing a baseline scenario to a regulatory scenario that reflects key aspects of the regulatory amendments. To quantify impacts, Health Canada used internal administrative data, as well as information collected from stakeholders through a questionnaire and during the *Canada Gazette*, Part I, public consultation period. Where quantification was not possible, the incremental impacts were evaluated in qualitative terms.

Since condition-of-sale restrictions for NHPs containing ephedrine and/or pseudoephedrine already exist in the Ministerial Order, these restrictions are not within the scope of this CBA. Incorporating the restrictions that are in the Ministerial Order into the PCR will constitute a transfer of requirements from one regulatory instrument to another, with no incremental

impacts on relevant stakeholders. The impacts identified and assessed for the Ministerial Order exist in the baseline scenario and will remain in the regulatory scenario. Thus, the estimated impacts are with respect to combination NPDs only (i.e. NPDs that contain ephedrine and/or pseudoephedrine along with additional drugs).

All monetized impacts are estimated over 10 periods of 12 months and expressed in constant 2024 Canadian dollars. The present values (PV) of these estimates are discounted to period one using a 7% discount rate.

The CBA has been updated following prepublication of the regulatory proposal in the *Canada Gazette*, Part I, to reflect revisions made when finalizing the amendments to the PCR. In particular,

- the costs previously attributed to registered dealers in the *Canada Gazette*, Part I, analysis have been removed given that the final amendments no longer require them to implement reasonable measures;
- the estimated time that each affected company will spend on compliance activities has been reduced given that the final amendments no longer require licensed dealers to consider conducting criminal record checks or prior convictions for employees with access to Class A precursors;
- the costs to licensed dealers to account for the submission of statements demonstrating that reasonable measures have been taken when applying for or renewing their licences have been added; and
- the cost estimates have been revised to reflect the transition period that now applies to certain amendments to the PCR.

Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)

Costs

Costs to licensed and registered dealers

One-time costs to licensed and registered dealers to familiarize themselves with the amendments

All licensed and registered dealers will need to spend time reviewing the amendments to become familiar with the regulatory requirements and to ensure compliance. Health Canada assumes that each of the 429 licensed and registered dealers will have four employees (i.e. one manager and three staff) reviewing the amendments, and that each employee will spend

approximately 30 minutes reviewing the amendments. [3] Using hourly wages of $75.60 (manager) [4] and $41.52 (staff), [5] the total cost [6] to all licensed and registered dealers is estimated to be $40,127 in PV over 10 periods of 12 months or $5,713 in annualized value.

Cost of mandatory reporting of suspicious transactions to Health Canada

Under the baseline scenario, licensed and registered dealers must make a record of a suspicious transaction; however, they do not have to report these suspicious transactions to Health Canada. Nevertheless, some licensed and registered dealers have been reporting transactions they deemed suspicious to Health Canada on a voluntary basis. Over the past three years, Health Canada received a cumulative total of about 580 suspicious transactions reports involving precursors.

Under the regulatory scenario, licensed and registered dealers who have not been voluntarily reporting suspicious transactions to Health Canada will now have to do so. The final amendment for mandatory reporting provides those affected with a 180-day transition period. It is estimated that about 120 suspicious transactions reports (that would not have been submitted to Health Canada under the baseline scenario) will now be submitted every year going forward. It is assumed that a licensed or registered dealer will spend approximately 30 minutes to prepare and submit a suspicious transactions report and, if necessary, respond to Health Canada's subsequent inquiry. This assumption is based on internal assessment of the information requirements on the reporting form as well as estimates provided by industry from previous feedback on similar forms. Using an hourly wage rate of $41.52 (staff), the total administrative costs to licensed and registered dealers are estimated to be $16,470 in PV over 10 periods of 12 months or $2,345 in annualized value.

Cost associated with reasonable measures

Under the baseline scenario, many licensed dealers already have measures in place to minimize the risk of employee involvement in the diversion of Class A precursors. These measures commonly include conducting criminal record checks for some employees (particularly for a senior person in charge, responsible person in charge and alternate responsible person in charge), or involve verifying prior convictions.

Under the regulatory scenario, the amendments to the PCR will require licensed dealers to take reasonable measures to ensure that employees do not contribute to the diversion of Class A precursors to an illicit market or use. As part of this requirement, licensed dealers will be required to submit a signed statement to Health Canada demonstrating that reasonable measures have been implemented when applying for or renewing their Class A precursor licence.

Many licensed dealers already have various measures in place to mitigate diversion risks; Health Canada expects that most will continue with their existing practices. However, those licensed dealers who do not currently have measures in place to fully meet this new regulatory requirement will need to implement additional measures. These may include developing a standard operating procedure for hiring employees with access to Class A precursors, conducting employment or identity verification or performing an online search for information about the applicant (e.g. government website, social media).

In the *Canada Gazette*, Part I, Health Canada initially estimated that each affected company would spend 96 hours annually implementing the reasonable measures requirement. These measures could include activities such as verifying prior convictions. The requirement was expected to apply to both Class A precursor licensed dealers and Class B precursor registered dealers. It was assumed that 10% of the 355 companies operating a total of 429 licensed or registered sites would be affected. However, subsequent to stakeholders' feedback, Health Canada has revised the final provisions.

The requirement to implement reasonable measures will not apply to registered dealers, and licensed dealers will not be required to conduct criminal record checks or consider prior convictions for employees with access to precursors. Additionally, affected companies will be granted a six-month transition period to adjust to the requirement. With these revisions, it is now assumed that 10% of the 180 companies holding 215 licences will be affected. Each of these companies is expected to spend 48 hours annually to carry out the necessary additional measures. Using an hourly wage rate of $58.56 [7], the total costs to these companies are estimated to be $0.33 million in PV over 10 periods of 12 months or $47,230 in annualized value.

In addition to implementing reasonable measures, licensed dealers will need to prepare and sign a statement to demonstrate compliance. This statement is estimated to take approximately 15 minutes for a senior person in charge to prepare. Based on Health Canada's administrative data, an average of 90 new licence applications and renewals are expected each year. Using an hourly wage rate of $75.60, the estimated administrative cost to prepare these statements is approximately $11,152 in PV over 10 periods of 12 months or $1,588 in annualized value.

Costs of imposing condition-of-sale restrictions for combination NPDs

Currently, according to the Drug Product Database, there are approximately 90 combination NPDs listed as marketed. Technically, under the baseline scenario, these products can be sold by any retailer (e.g. a gas station). However, given that these combination NPDs were previously included in NAPRA's National Drug Schedules, to the best of Health Canada's knowledge, these combination NPDs are not currently sold or expected to be sold or provided by anyone other than pharmacists, individuals working in a retail location where a pharmacist provides services,

health care practitioners and hospitals. Feedback received as part of the consultation on the proposed amendments confirms that these products are typically sold only in pharmacies and hospitals.

Under the amendments, licensed dealers are prohibited from selling or providing these NPDs to anyone other than other licensed dealers, pharmacists and individuals working in a retail location where a pharmacist provides services, health care practitioners and hospitals. It should be noted that, in the absence of the sale restrictions, it is possible that some licensed dealers may have planned to start selling combination NPDs to businesses other than pharmacies. The amendments may therefore limit this opportunity, thus impacting industry in the form of limited access to the market and resulting in profit losses. However, given the uncertainty about future sales to businesses other than pharmacies, and due to a lack of data, it is not possible to quantify this impact. Nonetheless, Health Canada acknowledges that these amendments could lead to an economic impact for some businesses, should they have had such plans.

Record-keeping costs

Under the baseline scenario, former registered dealers are not required to retain documents once their registration expires or is revoked. However, with the amendments, former registered dealers are required to retain documents after their registration is no longer active.

Under the regulatory scenario, all existing 429 licensed and registered dealers will be required to retain reports submitted to Health Canada regarding suspicious transactions, and these licensed dealers will need to retain any documents related to taking reasonable measures. All of these documents must be kept for at least two years. It is assumed that all licensed and registered dealers have migrated to keeping records electronically. In addition to retaining about 120 suspicious transaction reports, it is also assumed that each year there will be two former registered dealers, each retaining 50 documents, while each of the 215 existing licensed dealers will retain 200 documents related to reasonable measures to meet the record-keeping requirement. Assuming that the cost of storing a digital document is approximately 2.16 cents per 100 documents, [8] the total administrative cost of retaining these documents is estimated to be $65 in PV over 10 periods of 12 months or $9 in annualized value.

Costs to government

Health Canada will incur costs associated with processing suspicious transactions reports. Additionally, Health Canada will incur costs to conduct compliance promotion and enforcement activities to support the implementation of the regulatory amendments. These activities will include developing and publishing web-based compliance promotion materials to raise awareness about the amendments to the PCR, as well as revising guidance, relevant forms and

internal standard operating procedures, responding to stakeholder inquiries and conducting inspections to promote and verify compliance. These costs are expected to be $295,178 in PV over 10 periods of 12 months or $42,027 in annualized value.

Benefits

Requiring licensed and registered dealers to report suspicious transactions to Health Canada, including high-volume transactions or unusual payment methods, will strengthen existing controls and oversight for precursors under the PCR. This will help further reduce the potential diversion of these precursors to an illicit market and prevent their use in the illicit production of fentanyl and other synthetic drugs, as well as disrupt related actions in support of these illicit activities. Mandatory reporting of suspicious transactions will align the PCR with the regulatory scheme for controlled substances and with similar requirements with respect to precursors in the United States.

Requiring licensed dealers to take reasonable measures to ensure their employees do not contribute to the diversion of Class A precursors to an illicit market or use will help reduce the potential for legitimate businesses to be inadvertently involved in supplying precursors for use in illicit activities and will help deter organized crime groups from accessing legitimate channels for the purpose of diverting precursors to an illicit market or use.

The amendments will help protect public health and public safety by preventing the sale and provision of combination NPDs to anyone other than licensed dealers, pharmacists and individuals working in a retail location where a pharmacist provides services, health care practitioners and hospitals. This will minimize a potential risk of diversion while maintaining continued access for legitimate purposes. This benefit is considered minimal given that most, if not all, of the impacted combination NPDs are already being sold or provided to consumers primarily by pharmacists, health care practitioners and hospitals.

Enabling Health Canada to add, modify or delete conditions to a licence or registration at any time or to partially suspend certain activities authorized on a licence or registration will provide Health Canada with greater flexibility to respond to non-compliance and emerging risks. These amendments will enable Health Canada to take timely action to protect public health or public safety, including by helping to reduce the risk of misuse and diversion of precursors to an illicit market or use. Such flexibility will enable Health Canada to act swiftly and proportionately when necessary.

Order Amending Schedule IX to the Controlled Drugs and Substances Act

Costs

Costs to importers associated with registration of component parts

Under the baseline scenario, any person can import component parts (i.e. punches, moulds and dies) that are intended to be used in a pill press or encapsulator without having to register these parts with Health Canada.

Under the regulatory scenario, any person importing these component parts [9] must register them with Health Canada prior to their importation.

Registering the targeted component parts will result in costs to affected importers. These costs are associated with time spent preparing and submitting a registration form to Health Canada prior to the component part arriving at the border. Since the registration form is similar to the one used for registering designated devices, which takes approximately 45 minutes to complete, it is assumed that affected importers will require the same amount of time per registration form. Additionally, based on updated analysis, it is estimated that about 1 200 component parts will be imported annually. Assuming an average hourly wage of $41.52, the total administrative cost to importers associated with the import registration application is estimated to be $257,657 in PV over 10 periods of 12 months or $36,685 in annualized value.

Costs to government

Health Canada will bear costs associated with processing import registration requests for component parts. Additionally, Health Canada will bear costs to conduct compliance promotion and enforcement activities to support the implementation of the amendments. These activities include developing and publishing web-based compliance promotion materials to raise awareness about changes to Schedule IX to the CDSA, revising guidance, developing the registration form, responding to stakeholder inquiries and conducting inspections to promote and verify compliance. These costs are expected to be $53,917 in PV over 10 periods of 12 months or $7,677 in annualized value.

Benefits

Amending Schedule IX to the CDSA to add component parts (i.e. punches, moulds and dies) suitable for use in a pill press or encapsulator will help prevent the use of designated devices in the illegal production of fentanyl and other synthetic drugs and enable law and border enforcement to take action to address the illegal importation of these parts into Canada.

Order Repealing the Order Establishing Supplementary Rules Respecting the Sale of Natural Health Products Containing Ephedrine or Pseudoephedrine

The Repeal Order does not result in any change in impacts because the requirements in the Ministerial Order have been incorporated in the PCR.

Cost-benefit statement

Number of years: 10 periods of 12 months (2025–2026 to 2034–2035)

Price year: 2024

Present value base year: 2025

Discount rate: 7%

Table 1.1: Monetized costs — *Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)*

Impacted stakeholders	Description of cost	Base year	2nd year	Final year	Total (undiscounted)	Total (PV)	Annualized value
Licensed and registered dealers	**Becoming familiar with the amendments**	$42,936	$0	$0	$42,936	$40,127	$5,713
	Reporting suspicious transactions	$1,256	$2,512	$2,512	$23,865	$16,470	$2,345
	Submitting statements	$851	$1,701	$1,701	$16,160	$11,152	$1,588
	Taking reasonable measures	$23,643	$44,193	$25,721	$480,668	$331,726	$47,230
	Record keeping	$9	$9	$9	$93	$65	$9
	Total costs to industry	**$68,695**	**$48,415**	**$29,943**	**$563,721**	**$399,541**	**$56,886**
Government	**Implementation of compliance and enforcement**	$109,868	$51,359	$18,328	$373,768	$295,178	$42,027
	Total costs to government	**$109,868**	**$51,359**	**$18,328**	**$373,768**	**$295,178**	**$42,027**
All stakeholders	**Total costs**	**$178,563**	**$99,775**	**$48,271**	**$937,489**	**$694,719**	**$98,912**

Table 1.2: Monetized costs — *Order Amending Schedule IX to the Controlled Drugs and Substances Act*

Impacted stakeholders	Description of costs	Base year	2nd year	Final year	Total (undiscounted)	Total (PV)	Annualized value

Importers of component parts	Preparing and submitting import registration forms for component parts	$36,685	$36,685	$36,685	$366,846	$257,657	$36,685
Government	Processing import registration forms for component parts	$7,677	$7,677	$7,677	$76,766	$53,917	$7,677
All stakeholders	**Total costs**	**$44,361**	**$44,361**	**$44,361**	**$443,612**	**$311,575**	**$44,361**

Table 1.3: Aggregate monetized costs

Impacted stakeholders	Base year	2nd year	Final year	Total (undiscounted)	Total (PV)	Annualized value
Industry	$105,379	$85,100	$66,628	$930,567	$657,198	$93,570
Government	$117,545	$59,036	$26,004	$450,534	$349,096	$49,703
TOTAL	**$222,924**	**$144,136**	**$92,632**	**$1,381,101**	**$1,006,294**	**$143,274**

Qualitative impacts

Negative impacts

Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)

- Requiring licensed dealers to take reasonable measures to ensure their employees do not contribute to the risk of diversion of Class A precursors to an illicit market or use will result in incremental compliance costs for those that currently do not have sufficient measures in place to fully meet this new regulatory requirement. They will need to implement additional measures and the extent of these costs will vary depending on the size of each business and the scope of the additional measures implemented.
- Restricting licensed dealers from selling combination NPDs to persons other than those set out in the regulations, such as gas stations, could limit future market opportunities for some retailers and result in potential profit losses for these affected businesses.

Positive impacts

Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)

- Requiring licensed and registered dealers to report suspicious transactions to Health Canada will help reduce the diversion of precursors to an illicit market or use.
- Requiring licensed dealers to take reasonable measures to ensure their employees do not contribute to the diversion of Class A precursors to an illicit market or use will help reduce the potential for legitimate businesses to be inadvertently involved in supplying precursors for use in illicit activities and will help deter organized crime groups from accessing legitimate channels for the purpose of diverting precursors to an illicit market or use.
- Imposing condition-of-sale restrictions on combination NPDs will further protect public health and maintain public safety.
- Providing increased regulatory flexibility will enable Health Canada to respond to emerging risks and to take timely action to protect public health and public safety.

Order Amending Schedule IX to the Controlled Drugs and Substances Act

- Requiring the import registration of component parts (i.e. punches, moulds and dies) will help prevent the illegal production of fentanyl and other synthetic drugs.

Small business lens

Analysis under the small business lens concluded that the amendments to the PCR and to Schedule IX to the CDSA will impact small businesses. Most impacted businesses are small, accounting for 90% of all businesses. The costs to impacted small businesses related to the compliance and administrative burden are described in the CBA section. In total, monetized costs to small businesses to undertake the above-mentioned activities are expected to be $0.57 million in PV over 10 periods of 12 months or $81,624 in annualized value. Cost per small business is estimated at $1,485 in PV over 10 periods of 12 months or $211 in annualized value.

Impacts to small businesses are not expected to be disproportionate compared to other businesses. Further, as the amendments to the PCR and to Schedule IX to the CDSA are instrumental for achieving the stated objectives and effectively administering and enforcing the regulations, providing flexibility to small businesses in meeting those requirements is not feasible.

Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)

There will be a burden associated with becoming familiar with the amendments, reporting suspicious transactions to Health Canada, submitting a statement and retaining records for at least two years. In addition, there could be a compliance burden associated with taking

reasonable measures to ensure employees do not contribute to the risk of a Class A precursor being diverted to an illicit market or use.

Order Amending Schedule IX to the Controlled Drugs and Substances Act

There will be an administrative burden associated with registering the importation of component parts with Health Canada.

Small business lens summary

Number of small businesses impacted: 386

Number of years: 10 periods of 12 months (2025–2026 to 2034–2035)

Price year: 2024

Present value base year: 2025

Discount rate: 7%

Table 2.1: Costs — *Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)*

Administrative or compliance	Description of cost	Present value	Annualized value
Administrative	**Becoming familiar with the amendments** [a]	$10,834	$1,543
	Reporting suspicious transactions [b]	$8,235	$1,172
	Submitting statements	$10,037	$1,429
	Record keeping	$59	$8
	Total administrative costs	$29,165	$4,152
Compliance	**Becoming familiar with the amendments** [c]	$25,280	$3,599
	Taking reasonable measures	$298,554	$42,507
	Total compliance costs	$323,834	$46,107
Total	**Total costs**	**$352,999**	**$50,259**

[a] The provisions related to administrative requirements (e.g. submitting reports) total approximately six pages in length.

[b] It is expected that most reports will come from medium-sized or large businesses. To avoid underestimating costs for small businesses, it is assumed that 50% of the reports will come from small businesses.

[c] The provisions related to compliance requirements (e.g. taking reasonable measures) total approximately 14 pages in length.

Table 2.2: Costs — *Order Amending Schedule IX to the Controlled Drugs and Substances Act*

Administrative or compliance	Description of cost	Present value	Annualized value
Administrative	Preparing and submitting import registrations for component parts [a]	$220,297	$31,365
Total	**Total costs**	**$220,297**	**$31,365**

[a] Of all registrations, 95% are anticipated to come from industry, and of those, approximately 90% are expected to be from small businesses.

Table 3: Net impacts

Amount	Present value	Annualized value
Costs to impacted small businesses	$573,296	$81,624
Costs per impacted small business	$1,485	$211

One-for-one rule

For the purpose of the one-for-one rule, the administrative costs are estimated over 10 years and expressed in constant 2012 Canadian dollars and discounted to year 2012 using a 7% discount rate.

Regulations Amending the Precursor Control Regulations (Increased Regulatory Oversight)

The one-for-one rule applies, since there will be an increase in administrative burden on business, and the amendments are considered a burden IN under the rule.

As described in the CBA section, licensed and registered dealers will face an administrative burden associated with time spent becoming familiar with the amendments, submitting statements when applying for or renewing licences, [10] reporting suspicious transactions to Health Canada and fulfilling other reporting and record keeping obligations.

The time spent by responsible persons in charge or alternate responsible persons in charge on becoming familiar with the amendments and reporting suspicious transactions was monetized using an hourly wage of $31.41. For senior persons in charge, the time spent reviewing the amendments and submitting statements was monetized using an hourly wage of $57.18. Based on these estimates, the total incremental administrative costs to all affected businesses are estimated to be $12,683 in PV over 10 years or $1,806 in annualized value.

Order Amending Schedule IX to the Controlled Drugs and Substances Act

The one-for-one rule applies, since there will be an increase in administrative burden on business, and the amendments are considered a burden IN under the rule.

As described in the CBA section, affected businesses will face administrative burden associated with registering component parts with Health Canada before they are imported.

Using an hourly wage of $31.41 for submitting the import registration form, the total incremental administrative costs to all affected businesses are estimated to be $76,826 in PV over 10 years or $10,938 in annualized value.

Order Repealing the Order Establishing Supplementary Rules Respecting the Sale of Natural Health Products Containing Ephedrine or Pseudoephedrine

The one-for-one rule applies, since a regulatory title was repealed, and the Repeal Order is considered a title OUT.

Regulatory cooperation and alignment

The amendments respond to operational concerns raised by Canadian law and border enforcement agencies. The changes strengthen Canada's existing regulatory framework for precursors and designated devices that can be used to illegally produce fentanyl, fentanyl analogues and other synthetic drugs and align with approaches taken in the United States and other jurisdictions. Additionally, the condition-of-sale restrictions for NHPs and NPDs containing ephedrine and/or pseudoephedrine align with the previous restrictions under NAPRA's National Drug Schedules, which all provinces and territories either incorporated by reference or mirrored in their own legislation.

The amendments are minimum federal standards that apply to the sale of NHPs and NPDs containing ephedrine and/or pseudoephedrine. As noted, it is possible that these products are also subject to requirements via provincial or territorial regulations or contain other ingredients

which are subject to NAPRA's National Drug Schedules. Health Canada will continue to consider opportunities to align with requirements under other frameworks, as appropriate.

International obligations

Canada and other parties to the United Nations drug control conventions are concerned about synthetic drug-related harms to individuals and society, including the illegal importation and production, diversion and trafficking of synthetic drugs and their precursors. These changes strengthen Canada's compliance with international drug control conventions. They are in line with Canada's commitment to strengthen the coordinated global response to the international public health and public safety challenges posed by synthetic drugs, as outlined in the Ministerial Declaration on Accelerating and Strengthening the Global Response to Synthetic Drugs.

As a member of the World Trade Organization (WTO), Canada has an obligation under the WTO Agreement on Technical Barriers to Trade to ensure that any new regulations do not create unnecessary obstacles to trade. A notice and link to the proposed amendments published in the *Canada Gazette*, Part I, was provided to members, including the nature of the problem that Canada is aiming to address. Members were given an opportunity to provide their comments in writing and to discuss these comments upon request. No comments were received through the WTO notification process. Members will be provided a notice and a link to the final amendments published in the *Canada Gazette*, Part II.

Effects on the environment

In accordance with the *Cabinet Directive on Strategic Environmental and Economic Assessment*, a preliminary scan concluded that a strategic environmental and economic assessment is not required. There are no anticipated effects on the environment, positive or negative, as a result of the amendments.

Gender-based analysis plus

No gender-based analysis plus impacts have been identified as the primary stakeholders affected by this regulatory proposal are licensed and registered dealers conducting authorized activities with precursors and designated devices. The amendments apply equally to different population subgroups; there are no disproportionate impacts based on identity factors such as gender, sex, age, language and geography. No adverse outcomes to Canadians are anticipated from these changes.

Implementation, compliance and enforcement, and service standards

Implementation

Coming into force

The amendments to the PCR and to Schedule IX to the CDSA are approved by the Governor in Council and come into force immediately upon publication in the *Canada Gazette*, Part II, with the exception of mandatory reporting for suspicious transactions involving precursors and licensed dealers taking reasonable measures to prevent the diversion of Class A precursors, which are delayed for six months. These two requirements come into force on the 180th day after the day the amendments are published in the *Canada Gazette*, Part II.

The Minister has approved the Repeal Order. The Repeal Order will come into force when the PCR amendments are published in the *Canada Gazette*, Part II, unless the Repeal Order is registered after the PCR amendments are published, in which case the Repeal Order will come into force on the date it is registered.

Communications and guidance

In addition to the current publication of the final amendments in the *Canada Gazette*, Part II, Health Canada will notify stakeholders immediately of the amendments via email and through the Consultation and Stakeholder Information Management System.

Health Canada is committed to continuing to provide industry, provinces and territories, and other stakeholders with relevant and timely information. Based on consultation feedback, guidance documents and the import registration form have been developed or updated to increase awareness of the regulatory changes and to assist regulated parties in achieving compliance. Questions about how precursors and designated devices are controlled should be directed to precursors-precurseurs@hc-sc.gc.ca.

Compliance and enforcement

Compliance and enforcement measures under the CDSA and the PCR will continue to be available to Health Canada. These measures support the legitimate use of precursors and designated devices and reduce risks of misuse and diversion. They range from activities intended to educate and to prevent non-compliance through compliance promotion, to measures intended to bring a regulated party back into compliance or to address a risk to public health or public safety.

In alignment with the Health Canada compliance and enforcement policy framework and the Compliance and Enforcement Policy for Controlled Substances and Precursors, and informed by the circumstances of each case, Health Canada will continue to take a risk-based approach to its compliance and enforcement actions and will choose the most appropriate tool to achieve compliance, including adding conditions to a licence or suspending certain activities on a licence, and to mitigate risks as circumstances warrant.

In the conduct of compliance and enforcement activities, the level of risk to public health, public safety and security would be taken into consideration, as well as the risks presented by potential diversion to an illegal market or use, and the likelihood thereof when addressing identified risks. In certain circumstances, Health Canada could disclose relevant information obtained under the CDSA or PCR, for example, when it considers that the disclosure is necessary to protect public health or public safety.

To support its compliance objectives, Health Canada will continue to collaborate with partners, including law and border enforcement agencies and the provinces and territories. Federal, provincial and local law enforcement agencies are responsible for taking enforcement action in response to contraventions of the CDSA and its regulations. Provincial and territorial governments regulate the practice of medicine, and their legislated bodies regulate health professionals.

Service standards

The current service standards that already exist for issuing licences, registrations and permits remain in place; no additional service standards are provided.

Contact

Office of Legislative and Regulatory Affairs
Controlled Substances and Overdose Response Directorate
Controlled Substances and Cannabis Branch
Health Canada
Email: csd.regulatory.policy-politique.reglementaire.dsc@hc-sc.gc.ca

Footnotes

a S.C. 2024, c. 17, s. 413(1) to (3)

b S.C. 1996, c. 19

1 SOR/2002-359

2 Toske S., Extraction of Methamphetamine Precursor Material from Medicinal Preparations and Methamphetamine Profiling Results (PDF). U.S. Department of Justice Drug Enforcement Administration (DEA), May 2009.

[3] Based on feedback received from the National Association of Pharmacy Regulatory Authorities, it is estimated that a reader will take on average 1.5 minutes per page to read a regulatory document. Given that the amendments consist of approximately 20 pages, each affected employee is expected to take approximately 30 minutes to complete the review.

[4] Hourly wage for management occupation, adjusted for overhead. Sourced from Statistics Canada Table 14-10-0417-01 Employee wages by occupation, annual.

[5] The wage is derived based on wages of four occupational groups (technical occupations in health, technical roles in natural and applied sciences, service representatives and other customer and personal service positions, as well as technical trades and transportation officers and controllers), and adjusted for overhead. Sourced from Statistics Canada Table 14-10-0417-01, Employee wages by occupation, annual.

[6] Of the total time spent reviewing the amendments to the PCR, approximately 30% is associated with administrative burden, while the remaining 70% relates to compliance burden.

[7] Average of the wages for both managerial ($75.60) and staff ($41.52) levels.

[8] MCCi (2025) *The Dollars and Cents of Paper vs. Digital*

[9] Health Canada assumes that 95% of component parts are imported by businesses.

[10] This task is for licensed dealers only.