Guidance Document for the *Precursor Control Regulations*

APPLICATION FOR CLASS A PRECURSOR LICENCES

Aussi disponible en français

This document is one of a series of guidance documents written as a companion to the *Precursor Control Regulations* to provide guidance on meeting the regulatory requirements under these Regulations.

Other documents in this series include:

Requirements and Responsibilities of Licensed Dealers of Class A Precursors Application for Import, Export and Transit/Transhipment Permits

To obtain these documents, or for further information about the *Precursor Control Regulations*, please contact the Chemical Precursors Section, Licences and Permits Division, Office of Controlled Substances (OCS), Drug Strategy and Controlled Substances Programme (DSCS), Healthy Environments and Consumer Safety Branch (HECS), Health Canada:

Website: www.healthcanada.gc.ca/precursors

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APPENDIX: List of Class A Precursors

1. PURPOSE

This document provides guidance to individuals applying for a licence under the *Precursor Control Regulations* (PCR) to produce, package, provide, sell, import and/or export any Class A precursor, as set out in Schedule VI of the *Controlled Drugs and Substances Act* (CDSA).

2. BACKGROUND

Precursors are chemicals that are frequently diverted from legitimate activities to the illegal manufacture of drugs. In 1988, the United Nations addressed the problem of the diversion of precursors to illegal markets or uses, by adopting provisions within the *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*. Canada signed this convention in 1990, committing itself to controlling the movement of precursors into, out of and within Canada.

In 1997, Canada enacted the CDSA, which allowed for the control of precursors and the development of regulations for their import, export, production and distribution.

The PCR provide a regulatory framework that allows Canada to fulfill its international obligations with respect to the monitoring and control of precursors used in the production of illegal drugs.

3. SCOPE

This document was developed as a companion to the PCR to provide guidance in meeting the regulatory requirements relating to Class A precursor licence applications. It is not intended to replace the PCR. The PCR shall, under all circumstances, take precedence over these guidelines should any apparent confusion or inconsistencies arise.

4. **DEFINITIONS**

Many terms used in this document are defined in the CDSA and in the PCR. Please refer to Section 2 of the CDSA and Section 1 of the PCR.

5. GENERAL INFORMATION

Copies of the CDSA and the PCR can be obtained by visiting the Justice Canada Web site at http://laws.justice.gc.ca/en/C-38.8/index.html.

Copies of guidance documents and application forms can be obtained from the Health Canada website at www.healthcanada.gc.ca/precursors or by contacting that Office at (613) 946-1142.

SECTION A: NEW LICENCE APPLICATION

6. APPLYING FOR A LICENCE

Please Note: Applications for a new licence may require up to 150 days for processing, due to the requirement for a criminal record check.

6.1 Who Requires a Licence

All individuals or corporations who wish to produce, package, provide or sell, import or export Class A precursors must apply for a licence. Certain Class A precursors and general retailers are exempted. Please refer to Sections 2 to 5 of the PCR.

6.2 Who is Eligible for a Licence

- (i) An individual who ordinarily resides in Canada; or
- (ii) a corporation that has its head office in Canada or operates a branch in Canada.

6.3 Licensing a Site

A separate licence application must be submitted for each site. The activities authorized on the licence are limited to one site; however, one site may comprise more than one building. Please refer to Section 1 of the PCR.

7. REQUIREMENTS FOR LICENCE APPLICATION

The following requirements must be met for each licence application:

7.1 Personnel

(Section 13 of PCR)

The following responsible persons must be engaged by the applicant to conduct authorized activities, and must be approved by Health Canada to perform those functions:

(i) <u>Senior Person in Charge (SPIC)</u>

This person:

(a) must have overall responsibility for the management of the licensed dealer's operations pertaining to the Class A precursor activity at the licensed site;

- (b) must be considered the representative of the applicant and have the authority to bind the applicant;
- (c) must be familiar with the provisions of the Act and the Regulations;
- (d) must not have been convicted within the previous 10 years of any designated drug offence, designated criminal offence or an offence committed outside of Canada that, if committed in Canada, would have constituted a designated drug or criminal offence;

Note: Simple possession is not included as a designated drug offence under Section 1 of the PCR.

- (e) may be the same person as the applicant; and
- (f) may be in charge of more than one site.

Note: The SPIC does not have to be physically present on the licensed site.

(ii) Responsible Person in Charge (RPIC).

This person must work on the licensed site and:

- (a) is responsible for supervising the activity on-site, as mentioned in the licence, and ensuring that the activity complies with the Regulations;
- (b) must be familiar with the provisions of the Act and the Regulations;
- (c) must not have been convicted within the previous 10 years of any designated drug offence, designated criminal offence or an offence committed outside of Canada that, if committed in Canada, would have constituted a designated drug or criminal offence;

Note: Simple possession is not included as a designated drug offence under Section 1 of the PCR.

- (d) must have sufficient knowledge concerning the use and handling of Class A precursors;
- (e) must be aware of the risk of those precursors being diverted to illicit market or use; and
- (f) may be the same person as the SPIC.

Note: If the applicant already holds a Controlled Drug licence and has a Qualified Person in Charge (QPIC), that person can be designated as the RPIC, if he/she meets the criteria stated above for RPIC.

(iii) Alternate Responsible Person in Charge (A/RPIC).

The applicant may engage one or more persons at the licensed site who meet the requirements for RPIC and can replace the RPIC when that person is absent.

Note: If the applicant already holds a Controlled Drug licence and has Alternate Qualified Person(s) in Charge (A/QPIC), these persons can be designated as the A/RPICs, if they meet the criteria stated above for RPIC.

7.2 Security Measures

(Sections 9, 83 and 90 of PCR)

The applicant must establish appropriate measures for storage safety at the site and for transportation security when a precursor is sent, transported or delivered.

7.3 Internal Controls

(Section 14 of PCR)

The applicant must provide a description of the internal controls for the precursor activities at the site.

Note: For further information on security, internal controls, and other requirements, please refer to the guidance document, *Requirements and Responsibilities of Licensed Dealers of Class A Precursors*.

8. APPLICATION SUBMISSION

(Section 14 of PCR)

A submission includes the following documents:

- (i) A completed Application for a Class A Precursor Licence Form;
 - (a) to be considered complete, the application form must include all the required information;
 - (b) if a criminal record check certificate is not included, Section 7D of the application form must be completed. This is to allow Health Canada to initiate the criminal record check;
 - (c) Section 10 of the form must be signed by the SPIC, RPIC, and A/RPIC, if any; and
 - (d) Section 11 of the form must be signed by the Senior Person in Charge for the site.
- (ii) If Section 7D of the application form was not completed, an original criminal record check certificate issued by a Canadian police force, and/or a police force in another country if the individual has resided in that country in the previous 10 years;
- (iii) If applicable, a copy of the certificate of incorporation, or any document filed with the province stating the applicant's corporate name and any other name registered with a province.

Note: As per Section 14(5)(c) of PCR, any cost for criminal record check will be the applicant's responsibility.

The application package must be sent to the address stated in Section 14 of this document.

9. PRE-LICENCE INSPECTION

(Section 15.1 of PCR)

The applicant may be required to undergo an inspection before being approved for a licence.

10. ISSUANCE OF LICENCE

(Section 16 of PCR)

- (i) If all requirements are met, Health Canada will issue a licence to authorize the applicant to conduct activities with Class A precursors as specified on the licence.
- **Note**: (a) Not all information provided on the application will be specified on the licence.
 - (b) The licence must be kept at the licensed site.
 - (c) The licence will generally be valid for a period of one year. The expiry date for all licences will be varied to facilitate a staggered renewal process.
- (ii) Under the circumstances defined in Sections 17, 22-24 of the PCR, Health Canada can refuse to issue, amend, or renew a licence, or can suspend or revoke an existing licence.

SECTION B: AMENDMENTS

11. AMENDMENT OF LICENCE

(Section 19 of PCR)

11.1 Conditions for an Amendment

A licensed dealer must make a request in writing for any of the following changes pertaining to the information indicated on the licence:

- (i) Licensed dealer's name;
- (ii) Address of the licensed site;
- (iii) Precursor(s); or
- (iv) Activities for each precursor.

11.2 Amendment Request Submission

The request for amendment of licence information must include:

- (i) a request in writing signed by the Senior Person in Charge describing the proposed amendment, along with a statement that all information and documents provided are correct and complete;
- (ii) any supporting documents that are relevant to the proposed amendment; and
- (iii) the original licence (The licensed dealer must retain a photocopy of the original licence at the site until the amended licence is received).

11.3 Issuance of Licence

If all requirements are met, Health Canada will issue an amended licence.

12. AMENDMENT OF APPLICATION INFORMATION

(Section 20 of PCR)

12.1 Changes Requiring Prior Approval

A licensed dealer must obtain prior approval for any of the following changes:

- (i) designated personnel, including the SPIC, and the RPIC or the A/RPIC; or
- (ii) the security measures; or
- (iii) the internal controls.

12.2 Timing of Notification

The licensed dealer must notify the Minister:

- (i) within 10 days if the SPIC, RPIC or A/RPIC ceases to act in that capacity; and
- (ii) not later than the next business day if the RPIC for the site ceases to act in that capacity and there is no person designated to act in the capacity.

Note: In the event that the SPIC ceases to act in that capacity as set out in Section 20(4) of the PCR, another individual who meets the requirements in Section 13(4) of the PCR may be appointed, on an interim basis, by the licensed dealer as the SPIC until approval for a new SPIC is granted by Health Canada.

12.3 Request for Amendment

The request for amendment of application information must include:

- (i) a request in writing signed by the SPIC describing the proposed amendment, along with a statement that all information and documents provided are correct and complete; and
- (ii) any supporting documents that are relevant to the proposed amendment. In the case of responsible personnel changes, documents described in Sections 8(i)(b) to (c) and (ii) of this guidance document must be attached to the request.

This package must be sent to the address stated in Section 14 of this document.

12.4 Notification of Approval

Health Canada will notify the Licensed Dealer when the proposed changes are approved.

SECTION C: LICENCE RENEWAL

13. APPLICATION FOR LICENCE RENEWAL

(Section 14 of PCR)

13.1 Renewal of Licence

A licensed dealer who wishes to renew a licence should submit an application form for renewal **at least 60 days** before the expiry date of the licence.

13.2 Application Submission

The *Application for a Class A Precursor Licence* form is also used to renew a licence.

If additions or deletions of a precursor or activity are required, complete the table in Section 6A of the application.

The application package must be sent to the address in Section 14 of this guidance document.

13.3 Return of Document

The licensed dealer must return the expired original licence immediately after the effective date of the new licence to the address in Section 14 of this guidance document.

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14. ADDRESS

Chemical Precursors Section
Licences and Permits Division
Office of Controlled Substances
Drug Strategy and Controlled Substances Programme
Healthy Environments and Consumer Safety Branch
Health Canada
AL 3502A
123 Slater St, 2nd Floor
Ottawa ON K1A 1B9

APPENDIX

List of Class A Precursors

- 1. Acetic anhydride
- 2. **N-Acetylanthranilic acid** (2-acetamidobenzoic acid) and its salts
- 3. **Anthranilic acid** (2-aminobenzoic acid) and its salts
- 4. **Ephedrine** (l-erythro-2-(methylamino)-1-phenyl-propan-1-ol), its salts and any plant containing ephedrine or any of its salts
- 5. **Ergometrine** (9,10-didehydro-N-(2-hydroxy-1-methylethyl)-6-methylergoline-8-carboxamide) and its salts
- 6. **Ergotamine** (12'-hydroxy-2'-methyl-5'-(phenylmethyl)ergotaman-3',6', 18-trione) and its salts
- 7. **Isosafrole** (5-(1-propenyl)-1,3-benzodioxole)
- 8. **Lysergic acid** (9,10-didehydro-6-methylergoline-8-carboxylic acid) and its salts
- 9. **3,4-Methylenedioxyphenyl-2-propanone** (1-(1,3-benzodioxole)-2-propanone)
- 10. **Norephedrine** (Phenylpropanolamine) and its salts
- 11. 1-Phenyl-2-propanone
- 12. **Phenylacetic acid** and its salts
- 13. **Piperidine** and its salts
- 14. **Piperonal** (1,3-benzodioxole-5-carboxaldehyde)
- 15. **Potassium permanganate**
- 16. **Pseudoephedrine** (d-threo-2-(methylamino)-1-phenyl-propan-1-ol) and its salts
- 17. **Safrole** (5-(2-propenyl)1,3-benzodioxole) and any essential oil containing more than 4% safrole
- 18. **Gamma-butyrolactone** (dihydro-2(3H)-furanone)
- 19. **1,4-butanediol**
- 20. Red Phosphorus
- 21. White Phosphorus
- 22. **Hypophosphorous acid**, its salts and derivatives
- 23. Hydriodic acid

Note: Each Class A precursor includes synthetic and natural forms