

- (43) Trenbolone (17 $\beta$ -hydroxyestra-4,9,11-trien-3-one)
- 2 Zeranol (3,4,5,6,7,8,9,10,11,12-decahydro-7,14,16-trihydroxy-3-methyl-1H-2-benzoxacyclotetradecin-1-one)

SOR/78-427, s. 10; SOR/79-753, s. 1; SOR/81-84, s. 1; SOR/85-550, s. 14(F); SOR/86-678, s. 1; SOR/89-381, s. 1; SOR/92-386, s. 3; SOR/97-228, s. 21; SOR/99-425, s. 1; SOR/2003-34, ss. 2, 3; SOR/2003-413, s. 2; SOR/2015-210, s. 1; SOR/2016-106, s. 1; SOR/2017-12, ss. 1, 2(E); SOR/2017-43, s. 1; SOR/2017-250, s. 1; SOR/2019-171, s. 21.

## PART J

# Restricted Drugs

## Definitions

### Definitions

**J.01.001** The following definitions apply in this Part.

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

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

**compound** includes a preparation. (*composé*)

**designated criminal offence** means

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

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

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

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

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

**destroy**, in respect of a restricted drug, means to alter or denature it to such an extent that its consumption is rendered impossible or improbable. (*destruction*)

**hospital** means a facility that is

(a) licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of

disease or illness; or

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

**institution** means any institution engaged in research on drugs and includes a hospital, a university in Canada or a department or agency of the Government of Canada or of a government of a province or any part of them. (*établissement*)

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

**label** has the same meaning as in [section 2](#) of the *Food and Drugs Act*. (*étiquette*)

**licensed dealer** means the holder of a licence issued under section J.01.015. (*distributeur autorisé*)

**package** includes anything in which a restricted drug is wholly or partly contained, placed or packed. (*emballage*)

**pharmacist** [Repealed, SOR/2021-271, s. 1]

**prescription** [Repealed, SOR/2021-271, s. 1]

**proper name**, in respect of a restricted drug, means the name in English or French that

**(a)** is assigned to the drug in section C.01.002;

**(b)** appears in bold face type for the drug in these Regulations and, if the drug is dispensed in a form other than that described in Part C, the name of the dispensing form; or

**(c)** is assigned in any of the publications mentioned in Schedule B to the *Food and Drugs Act* in the case of a drug not included in paragraph (a) or (b). (*nom propre*)

**qualified investigator** means, in respect of a restricted drug, a person whose use and possession of that drug are authorized by the Minister under subsection J.01.059(4) and who is

**(a)** employed by or connected with an institution; or

**(b)** engaged in clinical testing or laboratory research in an institution in respect of that drug. (*chercheur compétent*)

**qualified person in charge** means the individual designated under subsection J.01.012(1). (*responsable qualifié*)

**restricted drug** means a controlled substance that is set out in the schedule to this Part. (*drogue d'usage restreint*)

**Security Directive** means the *Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis*, as amended from time to time

and published by the Government of Canada on its website. (*Directive en matière de sécurité*)

**senior person in charge** means the individual designated under section J.01.011. (*responsable principal*)

**test kit** means a kit

- (a) that contains a restricted drug and a reagent system or buffering agent;
- (b) that is used during the course of a chemical or analytical procedure to test for the presence or quantity of a restricted drug for a medical, laboratory, industrial, educational, law administration or enforcement, or research purpose; and
- (c) the contents of which are not intended or likely to be consumed by, or administered to, a person or an animal. (*nécessaire d'essai*)

SOR/97-228, s. 22; SOR/2004-238, s. 31; SOR/2013-172, s. 1; SOR/2019-171, s. 22; SOR/2021-271, s. 1.

## General

### Temporary accelerated scheduling

**J.01.002 (1)** The Minister may, by order, add to column 1 of Part III of the schedule to this Part any item or portion of an item listed in Schedule V to the Act for a period referred to in column 2 that is the same as that listed in Schedule V for that item.

### Deletion

**(2)** The Minister may, by order, delete any item or portion of an item from column 1 of Part III of the schedule to this Part.

### Deletion — Schedule V to Act

**(3)** An item or portion of an item listed in Part III of the schedule to this Part is deemed to be deleted on the day on which it is no longer listed in Schedule V to the Act.

SOR/97-228, s. 23; SOR/99-125, s. 7; SOR/2010-222, s. 23; SOR/2015-210, s. 2; SOR/2018-85, s. 1; SOR/2019-171, s. 22.

### Non-application — member of police force

**J.01.003** A member of a police force or a person acting under their direction and control who, in respect of the conduct of the member or person, is exempt from the application of [subsection 4\(2\)](#) or [section 5, 6 or 7](#) of the *Act* by virtue of the *Controlled Drugs and Substances Act (Police Enforcement) Regulations* is, in respect of that conduct, exempt from the application of this Part.

SOR/2004-238, s. 32; SOR/2019-171, s. 22.

**J.01.003.1** [Repealed, SOR/2019-171, s. 22]

**J.01.003.2** [Repealed, SOR/2019-171, s. 22]

# Possession

## Authorized persons

**J.01.004 (1)** The following persons are authorized to possess a restricted drug listed in Part I of the schedule to this Part:

- (a) a licensed dealer;
- (b) a qualified investigator who possesses the drug for the purpose of conducting clinical testing or laboratory research in an institution;
- (c) an inspector, member of the Royal Canadian Mounted Police, police constable, peace officer, member of the technical or scientific staff of the Government of Canada, the government of a province or a university in Canada who possesses the drug in connection with their employment;
- (d) a person exempted under section 56 of the [Act](#) with respect to the possession of that drug; and
- (e) the Minister.

## Agent or mandatary

**(2)** A person is authorized to possess a restricted drug listed in Part I of the schedule to this Part if they are acting as the agent or mandatary of a person referred to in paragraph (1)(a), (b), (d) or (e).

## Agent or mandatary — person referred to in paragraph (1)(c)

**(3)** A person is authorized to possess a restricted drug listed in Part I of the schedule to this Part if they

- (a) are acting as the agent or mandatary of a person who they have reasonable grounds to believe is a person referred to in paragraph (1)(c); and
- (b) possess the restricted drug for the purpose of assisting that person in the administration or enforcement of an Act or regulation.

SOR/2019-171, s. 22; SOR/2021-271, s. 2.

**J.01.004.1** [Repealed, SOR/2019-171, s. 22]

# Test Kits

## Authorized activities

**J.01.005** A person may sell, possess or otherwise deal in a test kit if the following conditions are met:

- (a) a registration number has been issued for the test kit under section J.01.007 and has not been cancelled under section J.01.008;
- (b) the test kit bears, on its external surface,

(i) the name of the manufacturer,

(ii) the trade name or trademark, and

(iii) the registration number; and

(c) the test kit will be used for a medical, laboratory, industrial, educational, law administration or enforcement, or research purpose.

SOR/2019-171, s. 22.

### **Application for registration number**

**J.01.006 (1)** The manufacturer of a test kit may obtain a registration number for it by submitting to the Minister an application containing

(a) a detailed description of the design and construction of the test kit;

(b) a detailed description of the restricted drug and other substances, if any, contained in the test kit, including the qualitative and quantitative composition of each component; and

(c) a description of the proposed use of the test kit.

### **Signature and attestation**

(2) The application must

(a) be signed and dated by the person authorized by the applicant for that purpose; and

(b) include an attestation by that person that all of the information submitted in support of the application is correct and complete to the best of their knowledge.

### **Additional information or document**

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

SOR/2019-171, s. 22.

### **Issuance of registration number**

**J.01.007** On completion of the review of the application for a registration number, the Minister must issue a registration number for the test kit, preceded by the letters "TK", if the Minister determines that the test kit will only be used for a medical, laboratory, industrial, educational, law administration or enforcement, or research purpose and that it contains

(a) a restricted drug and an adulterating or denaturing agent that are combined in such a manner and in such a quantity, proportion or concentration that the preparation or mixture has no significant drug abuse potential; or

(b) such small quantities or concentrations of any restricted drug as to have no significant drug abuse potential.

SOR/2004-238, s. 33; SOR/2010-222, s. 25; SOR/2014-260, ss. 9, 16(F); SOR/2019-171, s. 22.

**J.01.007.1** [Repealed, SOR/2019-171, s. 22]

**J.01.007.2** [Repealed, SOR/2019-171, s. 22]

**J.01.007.3** [Repealed, SOR/2019-171, s. 22]

**J.01.007.4** [Repealed, SOR/2019-171, s. 22]

**J.01.007.5** [Repealed, SOR/2019-171, s. 22]

**J.01.007.6** [Repealed, SOR/2019-171, s. 22]

**J.01.007.7** [Repealed, SOR/2019-171, s. 22]

**J.01.007.8** [Repealed, SOR/2019-171, s. 22]

**J.01.007.9** [Repealed, SOR/2019-171, s. 22]

**J.01.007.91** [Repealed, SOR/2019-171, s. 22]

### **Cancellation of registration number**

**J.01.008** The Minister must cancel the registration number for a test kit if

(a) the test kit is removed from the market by the manufacturer;

(b) the Minister has reasonable grounds to believe that the test kit is used or is likely to be used for any purpose other than a medical, laboratory, industrial, educational, law administration or enforcement, or research purpose; or

(c) the Minister has reasonable grounds to believe that the cancellation is necessary to protect public health or safety, including to prevent a restricted drug from being diverted to an illicit market or use.

SOR/2019-171, s. 22.

## Licensed Dealers

### **Authorized Activities**

#### **General**

**J.01.009 (1)** A licensed dealer may produce, assemble, sell, provide, transport, send, deliver, import or export a restricted drug if they comply with this Part and the terms and conditions of their dealer's licence and any permit issued under this Part.

#### **Qualified person in charge present**

**(2)** A licensed dealer may conduct an activity in relation to a restricted drug at their site only if the qualified person in charge or an alternate qualified person in charge is present at the site.

#### **Permit — import and export**

**(3)** A licensed dealer must obtain a permit to import or export a restricted drug.

### **Possession for export**

**(4)** A licensed dealer may possess a restricted drug for the purpose of exporting it if they have obtained it in accordance with this Part.

SOR/2019-171, s. 22.

## **Dealer's Licences**

### **Preliminary Requirements**

#### **Eligible persons**

**J.01.010** The following persons may apply for a dealer's licence:

- (a)** an individual who ordinarily resides in Canada;
- (b)** a corporation that has its head office in Canada or operates a branch office in Canada; or
- (c)** the holder of a position that includes responsibility for restricted drugs on behalf of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada.

SOR/2019-171, s. 22.

#### **Senior person in charge**

**J.01.011** An applicant for a dealer's licence must designate only one individual as the senior person in charge, who has overall responsibility for management of the activities with respect to restricted drugs that are specified in the licence application. The applicant may designate themselves if the applicant is an individual.

SOR/2004-238, s. 34; SOR/2019-171, s. 22.

#### **Qualified person in charge**

**J.01.012 (1)** An applicant for a dealer's licence must designate only one individual as the qualified person in charge, who is responsible for supervising the activities with respect to restricted drugs that are specified in the licence application and for ensuring that those activities comply with this Part. The applicant may designate themselves if the applicant is an individual.

#### **Alternate qualified person in charge**

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

### **Qualifications**

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

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

**(b)** they

**(i)** are a person entitled or, if applicable, registered and entitled by a provincial professional licensing authority or a professional association in Canada and entitled to practise a profession that is relevant to their duties, such as pharmacist, practitioner, pharmacy technician or laboratory technician,

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

**(iii)** hold a diploma, certificate or credential that is awarded by a foreign educational institution in a field or occupation referred to in subparagraph (ii) and hold

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

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

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

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

### **Exception**

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

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

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

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

SOR/2004-238, s. 34; SOR/2010-222, s. 30; SOR/2019-171, s. 22.

**J.01.012.1** [Repealed, SOR/2019-171, s. 22]

**J.01.012.2** [Repealed, SOR/2019-171, s. 22]

## Ineligibility

**J.01.013** An individual is not eligible to be a senior person in charge, a qualified person in charge or an alternate qualified person in charge if, during the 10 years before the day on which the dealer's licence application is submitted,

(a) in respect of a designated substance offence or a designated criminal offence or a *designated offence* as defined in [subsection 2\(1\)](#) of the *Cannabis Act*, the individual

(i) was convicted as an adult, or

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

(b) in respect of an offence committed outside Canada that, if committed in Canada, would have constituted a designated substance offence or a designated criminal offence or a *designated offence* as defined in [subsection 2\(1\)](#) of the *Cannabis Act*,

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

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

SOR/2004-238, s. 34; SOR/2019-171, s. 22.

## Issuance of Licence

### Application

**J.01.014 (1)** A person who intends to conduct an activity referred to in section J.01.009 must obtain a dealer's licence for each site at which they intend to conduct activities by submitting an application to the Minister that contains the following information:

(a) if the licence is requested by

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

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

(iii) the holder of a position mentioned in paragraph J.01.010(c), the applicant's name and the title of the position;

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

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

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

- (i)** their name, date of birth, telephone number and email address,
  - (ii)** the title of their position at the site,
  - (iii)** the name and title of the position of their immediate supervisor at the site,
  - (iv)** if applicable, the profession they practise that is relevant to their duties, the name of the province that authorizes them to practise it and their authorization number, and
  - (v)** their education, training and work experience that are relevant to their duties;
- (e)** the activities that are to be conducted and the restricted drugs in respect of which each of the activities is to be conducted;
- (f)** if the licence is requested to manufacture or assemble a product or compound that contains a restricted drug, other than a test kit, a list that includes, for each product or compound,
- (i)** the brand name of the product or the name of the compound,
  - (ii)** the name of the restricted drug in the product or compound,
  - (iii)** the strength per unit of the restricted drug in it, the number of units per package and the number of packages,
  - (iv)** if it is to be manufactured or assembled by or for another licensed dealer under a custom order, the name, municipal address and dealer's licence number of the other licensed dealer, and
  - (v)** if the applicant's name appears on the label of the product or compound, a copy of the inner label;
- (g)** if the licence is requested in order to produce a restricted drug other than a product or compound that contains a restricted drug,
- (i)** the name of the restricted drug,
  - (ii)** the quantity that the applicant expects to produce under their licence and the period during which that quantity would be produced, and
  - (iii)** if it is to be produced for another licensed dealer under a custom order, the name, municipal address and licence number of the other licensed dealer;
- (h)** if the licence is requested for an activity that is not described in paragraph (f) or (g), the name of the restricted drug for which the activity is to be conducted and the purpose of the activity;
- (i)** a detailed description of the security measures in place at the site, determined in accordance with the Security Directive; and
- (j)** a detailed description of the method for recording information that the applicant proposes to use for the purpose of section J.01.075.

## **Documents**

**(2)** An application for a dealer's licence must be accompanied by the following documents:

- (a)** if the applicant is a corporation, a copy of
  - (i)** the certificate of incorporation or other constituting instrument, and
  - (ii)** any document filed with the province in which its site is located that states its corporate name and any other name registered with the province under which the applicant intends to conduct the activities specified in its dealer's licence or by which it intends to identify itself;
- (b)** individual declarations signed and dated by each of the proposed senior person in charge, and qualified person in charge and any proposed alternate qualified person in charge, attesting that the person is not ineligible for a reason specified in section J.01.013;
- (c)** a document issued by a Canadian police force in relation to each person referred to in paragraph (b), indicating whether, during the 10 years before the day on which the application is submitted, the person was convicted as specified in subparagraph J.01.013(a)(i) or received a sentence as specified in subparagraph J.01.013(a)(ii);
- (d)** if any of the persons referred to in paragraph (b) has ordinarily resided in a country other than Canada during the 10 years before the day on which the application is submitted, a document issued by a police force of that country indicating whether in that period that person was convicted as specified in subparagraph J.01.013(b)(i) or received a sentence as specified in subparagraph J.01.013(b)(ii);
- (e)** declaration, signed and dated by the proposed senior person in charge, attesting that the proposed qualified person in charge and any proposed alternate qualified person in charge have the knowledge and experience required under paragraphs J.01.012(3)(c) and (d); and
- (f)** if the proposed qualified person in charge or any proposed alternate qualified person in charge does not meet the requirement of subparagraph J.01.012(3)(b)(i), either
  - (i)** a copy of the person's diploma, certificate or credential referred to in subparagraph J.01.012(3)(b)(ii) or (iii), or
  - (ii)** a detailed description of the education, training and work experience that is required under paragraph J.01.012(4)(c), together with supporting evidence, such as a copy of a course transcript or an attestation by the person who provided the training.

### **Signature and attestation**

**(3)** The application must

- (a)** be signed and dated by the proposed senior person in charge; and
- (b)** include an attestation by that person that

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

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

### **Additional information and documents**

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

SOR/2019-171, s. 22.

### **Issuance**

**J.01.015** Subject to section J.01.017, on completion of the review of the licence application, the Minister must issue a dealer's licence, with or without terms and conditions, that contains

**(a)** the licence number;

**(b)** the name of the licensed dealer, their corporate name or the title of the position they hold;

**(c)** the activities that are authorized and the names of the restricted drugs in respect of which each activity may be conducted;

**(d)** the municipal address of the site at which the dealer may conduct the authorized activities;

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

**(f)** the effective date of the licence;

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

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

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

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

**(iii)** reduce a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use; and

**(i)** if the licensed dealer produces a restricted drug, the quantity that they may produce and the authorized production period.

SOR/2019-171, s. 22.

### **Validity**

**J.01.016** A dealer's licence is valid until the expiry date set out in the licence or, if it is earlier, the date of the suspension or revocation of the licence under section J.01.035 or J.01.036.

SOR/2019-171, s. 22.

## **Refusal**

**J.01.017 (1)** The Minister must refuse to issue a dealer's licence if

- (a)** the applicant may not apply for a licence under section J.01.010;
- (b)** during the 10 years before the day on which the licence application is submitted, the applicant has contravened
  - (i)** a provision of the Act, the *Cannabis Act* or their regulations, or
  - (ii)** a term or condition of a licence or permit issued to the applicant under any regulations made under the Act or issued to the applicant under the *Cannabis Act* or its regulations;
- (c)** during the 10 years before the day on which the licence application is submitted the proposed senior person in charge or qualified person in charge or any proposed alternate qualified person in charge was convicted as specified in subparagraph J.01.013(a)(i) or (b)(i) or received a sentence as specified in subparagraph J.01.013(a)(ii) or (b)(ii);
- (d)** an activity for which the licence is requested would contravene an international obligation;
- (e)** the applicant does not have in place at the site the security measures set out in the Security Directive in respect of an activity for which the licence is requested;
- (f)** the method referred to in paragraph J.01.014(1)(j) does not permit the recording of information as required under section J.01.075;
- (g)** the applicant has not complied with the requirements of subsection J.01.014(4) or the information and documents that they have provided are not sufficient to complete the review of the licence application;
- (h)** the Minister has reasonable grounds to believe that the applicant has submitted false or misleading information or false or falsified documents in or in support of the licence application;
- (i)** information received from a competent authority or the United Nations gives the Minister reasonable grounds to believe that the applicant has been involved in the diversion of a restricted drug to an illicit market or use or has been involved in an activity that contravened an international obligation; or
- (j)** the Minister has reasonable grounds to believe that the issuance of the licence would likely create a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

## **Exceptions**

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

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

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

## **Notice**

**(3)** Before refusing to issue a licence, the Minister must send the applicant a notice that sets out the Minister's reasons and gives the applicant an opportunity to be heard.

SOR/2019-171, s. 22.

## Renewal of Licence

### **Application**

**J.01.018 (1)** To apply to renew a dealer's licence, a licensed dealer must submit to the Minister an application that contains the information and documents referred to in subsections J.01.014(1) and (2).

### **Signature and attestation**

**(2)** The application must

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

**(b)** include an attestation by that person that

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

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

### **Additional information and documents**

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

SOR/2019-171, s. 22.

### **Renewal**

**J.01.019 (1)** Subject to section J.01.021, on completion of the review of the renewal application, the Minister must issue a renewed dealer's licence that contains the information specified in section J.01.015.

## Terms and conditions

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

- (a)** ensure that an international obligation is respected;
- (b)** ensure conformity with the requirements associated with the security level specified in the licence or the new level required as a result of the licence renewal; or
- (c)** reduce a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

SOR/2019-171, s. 22.

## Validity

**J.01.020** A renewed dealer's licence is valid until the expiry date set out in the licence or, if it is earlier, the date of the suspension or revocation of the licence under section J.01.035 or J.01.036.

SOR/2019-171, s. 22.

## Refusal

**J.01.021 (1)** The Minister must refuse to renew a dealer's licence if

- (a)** the licensed dealer may no longer apply for a licence under section J.01.010;
- (b)** during the 10 years before the day on which the renewal application is submitted, the licensed dealer has contravened
  - (i)** a provision of the Act, the *Cannabis Act* or their Regulations, or
  - (ii)** a term or condition of a licence or permit issued to the dealer under a regulation made under the Act or issued to the dealer under the *Cannabis Act* or its regulations;
- (c)** during the 10 years before the day on which the renewal application is submitted, the proposed senior person in charge or qualified person in charge or any proposed alternate qualified person in charge was convicted as specified in subparagraph J.01.013(a)(i) or (b)(i) or received a sentence as specified in subparagraph J.01.013(a)(ii) or (b)(ii);
- (d)** an activity for which the renewal is requested would contravene an international obligation;
- (e)** the licensed dealer does not have in place at the site the security measures set out in the Security Directive in respect of an activity for which the renewal is requested;
- (f)** the method referred to in paragraph J.01.014(1)(j) does not permit the recording of information as required under section J.01.075;

**(g)** the licensed dealer has not complied with the requirements of subsection J.01.018(3) or the information or documents that they have provided are not sufficient to complete the review of the renewal application;

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

**(i)** information received from a competent authority or the United Nations gives the Minister reasonable grounds to believe that the licensed dealer has been involved in the diversion of a restricted drug to an illicit market or use or has been involved in an activity that contravened an international obligation; or

**(j)** the Minister has reasonable grounds to believe that the renewal of the licence would likely create a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

### **Exceptions**

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

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

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

### **Notice**

**(3)** Before refusing to renew a licence, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard.

SOR/85-550, s. 15; SOR/2019-171, s. 22.

## **Amendment of Licence**

### **Application**

**J.01.022 (1)** Before making a change affecting any information referred to in section J.01.015 that is contained in their dealer's licence, a licensed dealer must submit to the Minister an application to amend the licence that contains a description of the proposed amendment, as well as the information and documents referred to in section J.01.014 that are relevant to the proposed amendment.

### **Signature and attestation**

**(2)** The application must

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

**(b)** include an attestation by that person that

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

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

### **Additional information and documents**

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

SOR/2019-171, s. 22.

### **Amendment**

**J.01.023 (1)** Subject to section J.01.025, on completion of the review of the amendment application, the Minister must amend the dealer's licence.

### **Terms and conditions**

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

**(a)** ensure that an international obligation is respected;

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

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

SOR/2004-238, s. 35; SOR/2010-222, s. 31(F); SOR/2019-171, s. 22.

### **Validity**

**J.01.024** An amended dealer's licence is valid until the expiry date set out in the licence or, if it is earlier, the date of the suspension or revocation of the licence under section J.01.035 or J.01.036.

SOR/2019-171, s. 22.

### **Refusal**

**J.01.025 (1)** The Minister must refuse to amend a dealer's licence if

**(a)** an activity for which the licence amendment is requested would contravene an international obligation;

**(b)** the licensed dealer does not have in place at the site the security measures set out in the Security Directive in respect of an activity for which the licence amendment

is requested;

**(c)** the method referred to in paragraph J.01.014(1)(j) does not permit the recording of information as required by section J.01.075;

**(d)** the licensed dealer has not complied with the requirements of subsection J.01.022(3) or the information or documents that they have provided are not sufficient to complete the review of the amendment application;

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

**(f)** the Minister has reasonable grounds to believe that the amendment of the licence would likely create a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

## Exceptions

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

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

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

## Notice

**(3)** Before refusing to amend a licence, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard.

SOR/2004-238, s. 36; SOR/2010-222, s. 32; SOR/2019-171, s. 22.

## Changes Requiring Prior Approval by Minister

### Application

**J.01.026 (1)** A licensed dealer must obtain the Minister's approval before making any of the following changes by submitting a written application to the Minister:

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

**(b)** the replacement of the senior person in charge;

**(c)** the replacement of the qualified person in charge; or

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

## **Information and documents**

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

- (a)** in the case of a change affecting the security measures in place at the site specified in the dealer's licence, details of the change;
- (b)** in the case of the senior person in charge,
  - (i)** the information specified in paragraph J.01.014(1)(c), and
  - (ii)** the declaration specified in paragraph J.01.014(2)(b) and the documents specified in paragraphs J.01.014(2)(c) and (d); and
- (c)** in the case of the qualified person in charge or an alternate qualified person in charge,
  - (i)** the information specified in paragraph J.01.014(1)(d), and
  - (ii)** the declarations specified in paragraphs J.01.014(2)(b) and (e) and the documents specified in paragraphs J.01.014(2)(c), (d) and (f).

## **Additional information and documents**

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

SOR/2004-238, s. 37; SOR/2019-171, s. 22.

## **Approval**

**J.01.027 (1)** Subject to section J.01.028, on completion of the review of the application for approval of the change, the Minister must approve the change.

## **Terms and conditions**

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

- (a)** ensure that an international obligation is respected;
- (b)** ensure conformity with the requirements associated with the security level specified in the licence; or
- (c)** reduce a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

SOR/2004-238, s. 38; SOR/2010-222, s. 33; SOR/2019-171, s. 22.

## **Refusal**

**J.01.028 (1)** The Minister must refuse to approve the change if

**(a)** during the 10 years before the day on which the application for approval of the change is submitted, the proposed senior person in charge or qualified person in charge or any proposed alternate qualified person in charge was convicted as specified in subpara/ragraph J.01.013(a)(i) or (b)(i) or received a sentence as specified in subparagraph J.01.0013(a)(ii) or (b)(ii);

**(b)** the licensed dealer has not complied with the requirements of subsection J.01.026(3) or the information or documents that they have provided are not sufficient to complete the review of the application for approval of the change;

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

**(d)** the Minister has reasonable grounds to believe that the change would likely create a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

### **Exception**

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

### **Notice**

**(3)** Before refusing to approve a change, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard in respect of them.

SOR/2015-210, s. 3; SOR/2018-85, s. 2; SOR/2019-171, s. 22.

## **Changes Requiring Notice to Minister**

### **Prior notice**

**J.01.029 (1)** A licensed dealer must notify the Minister in writing before

**(a)** making or assembling a product or compound that is not set out in the most recent version of the list referred to in paragraph J.01.014(1)(f) that has been submitted to the Minister; or

**(b)** making a change to a product or compound that is set out in the list, if the change affects any of the information that has previously been submitted.

### **Information and list**

**(2)** The notice must contain the information referred to in paragraph J.01.014(1)(f) that is necessary to update the list and be accompanied by the revised version of the list.

### **Notice — five days**

**J.01.030** A licensed dealer must notify the Minister in writing within five days after a person ceases to act as the qualified person in charge or an alternate qualified person in charge.

### **Notice — 10 days**

**J.01.031 (1)** A licensed dealer must notify the Minister in writing within 10 days after one of the following changes occurs:

- (a) a person ceases to act as the senior person in charge; or
- (b) the licensed dealer ceases to manufacture or assemble a product or compound that is set out in the most recent version of the list referred to in paragraph J.01.014(1)(f) that has been submitted to the Minister.

### **Information and list**

**(2)** A notice submitted under paragraph (1)(b) must specify which information referred to in paragraph J.01.014(1)(f) is being changed and be accompanied by the revised version of the list.

### **Notice of cessation of activities**

**J.01.032 (1)** A licensed dealer that intends to cease conducting activities at their site — whether on or before the expiry of their licence — must notify the Minister in writing to that effect at least 30 days before ceasing those activities.

### **Content of notice**

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

- (a) the expected date of the cessation of activities at the site;
- (b) a description of the manner in which any remaining restricted drugs on the site as of that date will be disposed of by the licensed dealer, including
  - (i) if some or all of them will be sold or provided to another licensed dealer that will be conducting activities at the same site, the name of that dealer,
  - (ii) if some or all of them will be sold or provided to another licensed dealer that will not be conducting activities at the same site, the name of that dealer and the municipal address of their site, and
  - (iii) if some or all of them will be destroyed, the date on which and the municipal address of the location at which the destruction is to take place;

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

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

## **Update**

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

SOR/2004-238, s. 39; SOR/2019-171, s. 22.

**J.01.032.1** [Repealed, SOR/2019-171, s. 22]

## **Changes to Terms and Conditions of Licence**

### **Addition of or modification to term or condition**

**J.01.033 (1)** The Minister may, at any time other than at the issuance, renewal or amendment of a dealer's licence, add a term or condition to it or modify one if the Minister has reasonable grounds to believe that it is necessary to do so to

(a) ensure that an international obligation is respected;

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

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

## **Notice**

(2) Before adding a term or condition to a licence or modifying one, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard.

### **Urgent circumstances**

(3) Despite subsection (2), the Minister may add a term or condition to a licence or modify one without prior notice if the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a restricted drug from being diverted to an illicit market or use.

### **Urgent circumstances — notice**

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

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

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

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

SOR/99-125, s. 8; SOR/2004-238, s. 40; SOR/2018-69, ss. 67, 69; SOR/2019-171, s. 22.

**J.01.033.1** [Repealed, SOR/2019-171, s. 22]

**J.01.033.2** [Repealed, SOR/2019-171, s. 22]

**J.01.033.3** [Repealed, SOR/2019-171, s. 22]

**J.01.033.4** [Repealed, SOR/2019-171, s. 22]

### **Deletion of term or condition**

**J.01.034 (1)** The Minister may delete a term or condition of a dealer's licence that the Minister determines is no longer necessary.

### **Notice**

**(2)** The deletion takes effect as soon as the Minister sends the licensed dealer a notice to that effect.

SOR/2019-171, s. 22.

## **Suspension and Revocation of Licence**

### **Suspension**

**J.01.035 (1)** The Minister must suspend a dealer's licence without prior notice if the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a restricted drug from being diverted to an illicit market or use.

### **Notice**

**(2)** The suspension takes effect as soon as the Minister sends the licensed dealer a notice that

**(a)** sets out the reasons for the suspension;

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

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

### **Reinstatement of licence**

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

SOR/97-228, s. 24; SOR/2019-171, s. 22.

### **Revocation**

**J.01.036 (1)** Subject to subsection (2), the Minister must revoke a dealer's licence if

- (a) the licensed dealer may no longer apply for a licence under section J.01.010;
- (b) the licensed dealer requests the Minister to do so or informs the Minister of the loss or theft of the licence or the actual or potential unauthorized use of the licence;
- (c) the licensed dealer ceases to conduct activities at their site before the expiry of their licence;
- (d) the licensed dealer does not take the corrective measures specified in an undertaking or notice;
- (e) the licensed dealer has contravened
  - (i) a provision of the Act, the *Cannabis Act* or their regulations, or
  - (ii) a term or condition of a licence or permit issued to the dealer under a regulation made under the Act or issued to the dealer under the *Cannabis Act* or its regulations;
- (f) during the 10 years before the day on which the licence is revoked, the senior person in charge, the qualified person in charge or any alternate qualified person in charge was convicted as specified in subparagraph J.01.013(a)(i) or (b)(i) or received a sentence as specified in subparagraph J.01.013(a)(ii) or (b)(ii);
- (g) the Minister has reasonable grounds to believe that the licensed dealer submitted false or misleading information or false or falsified documents in or in support of an application relating to the licence; or
- (h) information received from a competent authority or the United Nations gives the Minister reasonable grounds to believe that the licensed dealer has been involved in the diversion of a restricted drug to an illicit market or use.

### **Exceptions**

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

- (a) the licensed dealer does not have a history of non-compliance with the Act, the *Cannabis Act* or their regulations; and
- (b) the licensed dealer has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act, the *Cannabis Act* and their regulations.

### **Notice**

**(3)** Before revoking a licence, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard.

## **Return of licence**

**J.01.037** The licensed dealer must return the original of the licence to the Minister within 15 days after the effective date of the revocation.

SOR/2018-85, s. 3; SOR/2019-171, s. 22.

## **Import Permits**

### **Application**

**J.01.038 (1)** A licensed dealer must submit to the Minister, before each importation of a restricted drug, an application for an import permit that contains the following information:

- (a)** their name, municipal address and dealer's licence number;
- (b)** with respect to the restricted drug to be imported,
  - (i)** its name, as specified in the dealer's licence,
  - (ii)** if it is a salt, the name of the salt,
  - (iii)** its quantity, and
  - (iv)** in the case of a raw material, its purity and its anhydrous content;
- (c)** if the restricted drug is contained in a product to be imported,
  - (i)** the brand name of the product,
  - (ii)** the drug identification number that has been assigned to the product under section C.01.014.2, if any, and
  - (iii)** the strength per unit of the restricted drug in the product, the number of units per package and the number of packages;
- (d)** the name and municipal address, in the country of export, of the exporter from whom the restricted drug is being obtained;
- (e)** the name of the customs office where the importation is anticipated; and
- (f)** each proposed mode of transportation and any proposed country of transit or transshipment.

### **Signature and attestation**

**(2)** The application must

- (a)** be signed and dated by the qualified person in charge or an alternate qualified person in charge; and
- (b)** include an attestation by that person that all of the information submitted in support of the application is correct and complete to the best of their knowledge.

## **Additional information and documents**

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

SOR/2019-171, s. 22.

## **Issuance**

**J.01.039** Subject to section J.01.042, on completion of the review of the import permit application, the Minister must issue to the licensed dealer an import permit that contains

- (a)** the permit number;
- (b)** the information set out in subsection J.01.038(1);
- (c)** the effective date of the permit;
- (d)** the expiry date of the permit, being the earlier of
  - (i)** a date specified by the Minister that is not more than 180 days after its effective date, and
  - (ii)** the expiry date of the dealer's licence; and
- (e)** any terms and conditions that the Minister has reasonable grounds to believe are necessary to
  - (i)** ensure that an international obligation is respected, or
  - (ii)** reduce a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

SOR/2019-171, s. 22.

## **Validity**

**J.01.040** An import permit is valid until the earliest of

- (a)** the expiry date set out in the permit,
- (b)** the date of the suspension or revocation of the permit under section J.01.045 or J.01.046,
- (c)** the date of the suspension or revocation of the dealer's licence under section J.01.035 or J.01.036, and
- (d)** the date of the suspension or revocation of the export permit that applies to the restricted drug to be imported and that is issued by the competent authority in the country of export.

SOR/2019-171, s. 22.

## **Return of permit**

**J.01.041** If an import permit expires, the licensed dealer must return the original of the permit to the Minister within 15 days after its expiry.

## Refusal

**J.01.042 (1)** The Minister must refuse to issue an import permit if

- (a) the licensed dealer is not authorized by their dealer's licence to import the relevant restricted drug or their licence will expire before the date of importation;
- (b) the Minister has reasonable grounds to believe that the importation would contravene an international obligation;
- (c) the licensed dealer does not have in place at the site the security measures set out in the Security Directive in respect of the importation;
- (d) the licensed dealer has not complied with the requirements of subsection J.01.038(3) or the information or documents that they have provided are not sufficient to complete the review of the permit application;
- (e) the Minister has reasonable grounds to believe that the licensed dealer has submitted false or misleading information or false or falsified documents in or in support of the permit application;
- (f) the licensed dealer has been notified that their application to renew or amend their licence will be refused;
- (g) the Minister has reasonable grounds to believe that the importation would contravene the laws of the country of export or any country of transit or transshipment;  
or
- (h) the Minister has reasonable grounds to believe that the issuance of the permit would likely create a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

## Notice

**(2)** Before refusing to issue the import permit, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard.

## Providing copy of permit

**J.01.043** The holder of an import permit must provide a copy of the permit to the customs office at the time of importation.

## Declaration

**J.01.044** The holder of an import permit must provide the Minister, within 15 days after the day of release of the restricted drug specified in the permit in accordance with the [Customs Act](#), with a declaration that contains the following information:

- (a)** their name and the numbers of their dealer's licence and the import permit that applies to the restricted drug;
- (b)** with respect to the restricted drug,
  - (i)** its name, as set out in the dealer's licence,
  - (ii)** if it is a salt, the name of the salt, and
  - (iii)** its quantity;
- (c)** if the restricted drug is contained in a product that they have imported,
  - (i)** the brand name of the product,
  - (ii)** the drug identification number that has been assigned to the product under section C.01.014.2, if any, and
  - (iii)** the strength per unit of the restricted drug in the product, the number of units per package and the number of packages; and
- (d)** the name of the customs office from which the restricted drug was released and the date of the release.

SOR/2019-171, s. 22.

## **Suspension**

**J.01.045 (1)** The Minister must suspend an import permit without prior notice if

- (a)** the dealer's licence is suspended;
- (b)** the Minister has reasonable grounds to believe that the suspension is necessary to protect public health or safety, including to prevent a restricted drug from being diverted to an illicit market or use; or
- (c)** the importation would contravene the laws of the country of export or any country of transit or transshipment.

## **Notice**

**(2)** The suspension takes effect as soon as the Minister sends the licensed dealer a notice that

- (a)** sets out the reasons for the suspension;
- (b)** gives the dealer an opportunity to be heard; and
- (c)** if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.

## **Reinstatement of permit**

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

SOR/2019-171, s. 22.

## Revocation

**J.01.046 (1)** Subject to subsection (2), the Minister must revoke an import permit if

- (a) the licensed dealer requests the Minister to do so or informs the Minister of the loss or theft of the permit or the actual or potential unauthorized use of the permit;
- (b) the licensed dealer does not carry out the corrective measures specified by the Minister under paragraph J.01.045(2)(c) by the specified date;
- (c) the licensed dealer has contravened a term or condition of the permit;
- (d) the Minister has reasonable grounds to believe that the licensed dealer submitted false or misleading information or false or falsified documents in or in support of the application for the permit;
- (e) information received from a competent authority or the United Nations gives the Minister reasonable grounds to believe that the licensed dealer has been involved in the diversion of a restricted drug to an illicit market or use; or
- (f) the dealer's licence has been revoked.

## Exceptions

**(2)** The Minister must not revoke an import permit for a ground set out in paragraph (1) (d) or J.01.036(1)(e) or (g) if the licensed dealer meets the following conditions, unless the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a restricted drug from being diverted to an illicit market or use:

- (a) the licensed dealer does not have a history of non-compliance with the Act, the [Cannabis Act](#) or their regulations; and
- (b) the licensed dealer has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act, the [Cannabis Act](#) and their regulations.

## Notice

**(3)** Before revoking an import permit, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard.

SOR/2019-171, s. 22.

## Return of permit

**J.01.047** If an import permit is revoked, the licensed dealer must return the original of the permit to the Minister within 15 days after the effective date of the revocation.

SOR/2019-171, s. 22.

## Export Permits

### Application

**J.01.048 (1)** A licensed dealer must submit to the Minister, before each exportation of a restricted drug, an application for an export permit that contains the following information and document:

- (a)** their name, municipal address and dealer's licence number;
- (b)** with respect to the restricted drug to be exported,
  - (i)** its name, as specified in the dealer's licence,
  - (ii)** if it is a salt, the name of the salt,
  - (iii)** its quantity, and
  - (iv)** in the case of a raw material, its purity and its anhydrous content;
- (c)** if the restricted drug is contained in a product to be exported,
  - (i)** the brand name of the product,
  - (ii)** the drug identification number that has been assigned to the product under section C.01.014.2, if any, and
  - (iii)** the strength per unit of the restricted drug in the product, the number of units per package and the number of packages;
- (d)** the name and municipal address of the importer in the country of final destination;
- (e)** the name of the customs office where the exportation is anticipated;
- (f)** each proposed mode of transportation and any proposed country of transit or transshipment; and
- (g)** a copy of the import permit issued by the competent authority in the country of final destination that sets out the name of the importer and the municipal address of their site in that country.

### **Signature and attestation**

- (2)** The application must
  - (a)** be signed and dated by the qualified person in charge or an alternate qualified person in charge; and
  - (b)** include an attestation by that person that, to the best of their knowledge,
    - (i)** the exportation does not contravene the laws of the country of final destination or any country of transit or transshipment, and
    - (ii)** all of the information and documents submitted in support of the application are correct and complete.

### **Additional information and documents**

- (3)** The licensed dealer must, not later than the date specified in the Minister's written request to that effect, provide the Minister with any information or document that the

Minister determines is necessary to complete the review of the application.  
SOR/2019-171, s. 22.

## **Issuance**

**J.01.049** Subject to section J.01.052, on completion of the review of the export permit application, the Minister must issue to the licensed dealer an export permit that contains

- (a) the permit number;
- (b) the information set out in paragraphs J.01.048(1)(a) to (f);
- (c) the effective date of the permit;
- (d) the expiry date of the permit, being the earliest of
  - (i) a date specified by the Minister that is not more than 180 days after its effective date,
  - (ii) the expiry date of the dealer's licence, and
  - (iii) the expiry date of the import permit issued by the competent authority in the country of final destination; and
- (e) any terms and conditions that the Minister has reasonable grounds to believe are necessary to
  - (i) ensure that an international obligation is respected, or
  - (ii) reduce a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

SOR/2019-171, s. 22.

## **Validity**

**J.01.050** An export permit is valid until the earliest of

- (a) the expiry date set out in the permit,
- (b) the date of the suspension or revocation of the permit under section J.01.055 or J.01.056,
- (c) the date of the suspension or revocation of the dealer's licence under section J.01.035 or J.01.036, and
- (d) the date of the expiry, suspension or revocation of the import permit that applies to the restricted drug to be exported and that is issued by the competent authority in the country of final destination.

SOR/2019-171, s. 22.

## **Return of permit**

**J.01.051** If an export permit expires, the licensed dealer must return the original of the permit to the Minister within 15 days after its expiry.

SOR/2019-171, s. 22.

## **Refusal**

**J.01.052 (1)** The Minister must refuse to issue an export permit if

- (a)** the licensed dealer is not authorized by their dealer's licence to export the relevant restricted drug or their dealer's licence will expire before the date of export;
- (b)** the Minister has reasonable grounds to believe that the exportation would contravene an international obligation;
- (c)** the licensed dealer has not complied with the requirements of subsection J.01.048(3) or the information or documents that they have provided are not sufficient to complete the review of the permit application;
- (d)** the Minister has reasonable grounds to believe that the licensed dealer has submitted false or misleading information or false or falsified documents in or in support of the permit application;
- (e)** the licensed dealer has been notified that their application to renew or amend their licence will be refused;
- (f)** the Minister has reasonable grounds to believe that the exportation would not be in conformity with the import permit issued by the competent authority of the country of final destination;
- (g)** the Minister has reasonable grounds to believe that the exportation would contravene the laws of the country of final destination or any country of transit or transshipment; or
- (h)** the Minister has reasonable grounds to believe that the issuance of the permit would likely create a risk to public health or safety, including the risk of a restricted drug being diverted to an illicit market or use.

## **Notice**

**(2)** Before refusing to issue the export permit, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard.

SOR/2019-171, s. 22.

## **Providing copy of permit**

**J.01.053** The holder of an export permit must provide a copy of the permit to the customs office at the time of exportation.

SOR/2019-171, s. 22.

## **Declaration**

**J.01.054** The holder of an export permit must provide the Minister, within 15 days after the day of export of the restricted drug specified in the permit, with a declaration that contains the following information:

- (a)** their name and the numbers of their dealer's licence and the export permit that applies to the restricted drug;
- (b)** with respect to the restricted drug,
  - (i)** its name, as specified in the dealer's licence,
  - (ii)** if it is a salt, the name of the salt, and
  - (iii)** its quantity;
- (c)** if the restricted drug is contained in a product that they have exported,
  - (i)** the brand name of the product,
  - (ii)** the drug identification number that has been assigned to the product under section C.01.014.2, if any, and
  - (iii)** the strength per unit of the restricted drug in the product, the number of units per package and the number of packages; and
- (d)** the name of the customs office from which the restricted drug was exported and the date of export.

SOR/2019-171, s. 22.

## **Suspension**

**J.01.055 (1)** The Minister must suspend an export permit without prior notice if

- (a)** the dealer's licence is suspended;
- (b)** the Minister has reasonable grounds to believe that the suspension is necessary to protect public health or safety, including to prevent a restricted drug from being diverted to an illicit market or use; or
- (c)** the exportation would contravene the laws of the country of final destination or any country of transit or transshipment.

## **Notice**

**(2)** The suspension takes effect as soon as the Minister sends the licensed dealer a notice that

- (a)** sets out the reasons for the suspension;
- (b)** gives the dealer an opportunity to be heard; and
- (c)** if applicable, specifies the corrective measures that must be carried out and the date by which they must be carried out.

## **Reinstatement of permit**

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

SOR/2019-171, s. 22.

## Revocation

**J.01.056 (1)** Subject to subsection (2), the Minister must revoke an export permit if

- (a) the licensed dealer requests the Minister to do so or informs the Minister of the loss or theft of the permit or the actual or potential unauthorized use of the permit;
- (b) the licensed dealer does not carry out the corrective measures specified by the Minister under paragraph J.01.055(2)(c) by the specified date;
- (c) the licensed dealer has contravened a term or condition of the permit;
- (d) the Minister has reasonable grounds to believe that the licensed dealer submitted false or misleading information or false or falsified documents in or in support of the application for the permit;
- (e) information received from a competent authority or the United Nations gives the Minister reasonable grounds to believe that the licensed dealer has been involved in the diversion of a restricted drug to an illicit market or use; or
- (f) the dealer's licence has been revoked.

## Exceptions

**(2)** The Minister must not revoke an export permit for a ground set out in paragraph (1) (d) or J.01.036(1)(e) or (g) if the licensed dealer meets the following conditions, unless the Minister has reasonable grounds to believe that it is necessary to do so to protect public health or safety, including to prevent a restricted drug from being diverted to an illicit market or use:

- (a) the licensed dealer does not have a history of non-compliance with the Act, the [Cannabis Act](#) or their regulations; and
- (b) the licensed dealer has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act, the [Cannabis Act](#) and their regulations.

## Notice

**(3)** Before revoking an export permit, the Minister must send the licensed dealer a notice that sets out the Minister's reasons and gives the dealer an opportunity to be heard.

SOR/2019-171, s. 22.

## Return of permit

**J.01.057** If an export permit is revoked, the licensed dealer must return the original of the permit to the Minister within 15 days after the effective date of the revocation.

SOR/2019-171, s. 22.

## Identification

### Name

**J.01.058** A licensed dealer must include their name, as set out in their dealer's licence, on all the means by which they identify themselves in regard to their activities in relation to restricted drugs, including labels, orders, shipping documents, invoices and advertising.

SOR/2019-171, s. 22.

## **Sale of Restricted Drugs**

### **Sale to institution**

**J.01.059 (1)** Despite section C.08.002 and subject to subsections (3) and (4), a licensed dealer may sell a restricted drug to an institution for one of the following purposes if the institution submits to the dealer or the Minister an application to purchase the drug and the Minister issues a prior written authorization for the sale:

- (a) clinical testing in the institution by qualified investigators for the purpose of determining the hazards and efficacy of the drug; or
- (b) laboratory research in the institution by qualified investigators.

### **Content of application**

**(2)** The application must contain the following information:

- (a) the name and the municipal address of the institution;
- (b) the names and qualifications of the qualified investigators;
- (c) the name, form, quantity and strength per unit of the restricted drug being requested;
- (d) details of the proposed use of the drug; and
- (e) the name and municipal address of the licensed dealer from whom the institution proposes to purchase the drug.

### **Application to licensed dealer**

**(3)** If the institution submits the application to the licensed dealer, the dealer must provide a copy of it to the Minister.

### **Authorization by Minister**

**(4)** After reviewing the application received from the institution or the copy of it received from the licensed dealer, the Minister may, subject to any terms and conditions that the Minister has reasonable grounds to believe are necessary, authorize in writing

- (a) the sale by the licensed dealer to the institution of the restricted drug applied for in the form, quantity and strength per unit specified by the Minister; and
- (b) the possession of the restricted drug by qualified investigators for clinical testing of the drug in the institution for the purpose of determining its hazards and efficacy or to conduct laboratory research with the drug in the institution.

## **Authorized use only**

**(5)** The institution must use the restricted drug only in accordance with the written authorization.

SOR/2019-171, s. 22.

## **Sale to Minister**

**J.01.060** A licensed dealer may sell or provide a restricted drug to the Minister.

SOR/2019-171, s. 22.

## **Provision for identification or analysis**

**J.01.061 (1)** Despite anything in this Part, a person may, for the purpose of identification or analysis of a restricted drug, provide or deliver it to

**(a)** a practitioner of medicine; or

**(b)** an agent or mandatary of a practitioner of medicine, if the agent or mandatary has been exempted under section 56 of the [Act](#) with respect to the possession of that restricted drug for that purpose.

## **Agent or mandatary of practitioner of medicine**

**(2)** An agent or mandatary of a practitioner of medicine who receives the restricted drug must immediately provide or deliver it to

**(a)** the practitioner; or

**(b)** the Minister.

## **Practitioner of medicine**

**(3)** A practitioner of medicine who receives the restricted drug must immediately provide or deliver it

**(a)** for the purpose of its identification or analysis, to a person exempted under section 56 of the [Act](#) with respect to the possession of that restricted drug for that purpose; or

**(b)** to the Minister.

SOR/2019-171, s. 22.

## **Packaging, Labelling and Transportation**

### **Packaging — sale and provision**

**J.01.062 (1)** A licensed dealer that sells or provides a restricted drug must securely package it in its immediate container, which must be sealed in such a manner that the container cannot be opened without breaking the seal.

### **Packaging — transport and export**

**(2)** A licensed dealer that transports or exports a restricted drug must ensure that its package is sealed in such a manner that the package cannot be opened without breaking the seal.

### **Exception**

**(3)** Subsection (1) does not apply to a test kit that contains a restricted drug and that has a registration number.

SOR/2019-171, s. 22.

### **Labelling**

**J.01.063 (1)** A licensed dealer that sells or provides a restricted drug must ensure that its package is labelled so that its inner and outer labels show

- (a)** the proper name or, if there is no proper name, the name of the drug;
- (b)** the net contents of the package;
- (c)** the unit strength of the drug and the number of units per package, if applicable;
- (d)** the lot number of the drug;
- (e)** the expression "Restricted Drug"; and
- (f)** the name and municipal address of the manufacturer or assembler of the drug.

### **Exception**

**(2)** Subsection (1) does not apply to a test kit that contains a restricted drug and that has a registration number.

### **Non-application**

**(3)** The labelling requirements set out in section C.01.004 do not apply to a restricted drug.

SOR/2019-171, s. 22.

### **Transport**

**J.01.064** A licensed dealer must, in taking delivery of a restricted drug that they have imported or in making delivery of a restricted drug,

- (a)** take any measures that are necessary to ensure the security of the drug while it is being transported;
- (b)** use a method of transportation that permits an accurate record to be kept of all handling of the drug as well as of the signatures of every person handling it until it is delivered to the consignee;
- (c)** in the case of an imported drug, transport it directly to the site specified in their licence after it is released under the *Customs Act*; and
- (d)** in the case of a drug to be exported, transport it directly from the site specified in their licence to the customs office where it will be exported.

# Thefts, Losses and Suspicious Transactions

## **Protective measures — licences and permits**

**J.01.065** A licensed dealer must take any measures that are necessary to ensure the security of any licence or permit in their possession.

SOR/2019-171, s. 22.

## **Protective measures — restricted drugs**

**J.01.066** The following persons must take any measures that are necessary to ensure the security of any restricted drugs in their possession:

- (a) a licensed dealer;
- (b) an institution;
- (c) a qualified investigator who possesses the restricted drug for the purpose of clinical testing or laboratory research in an institution; and
- (d) a person exempted under section 56 of the [Act](#) with respect to the possession of the restricted drug.

SOR/2019-171, s. 22.

## **Theft or loss — licences and permits**

**J.01.067** A licensed dealer that becomes aware of a theft or loss of their licence or permit must provide a written report to the Minister within 72 hours after becoming aware of it.

SOR/2019-171, s. 22.

## **Theft or loss — restricted drugs**

**J.01.068 (1)** Subject to subsection (2), any person referred to in section J.01.066 who becomes aware of a theft or loss of a restricted drug must

- (a) provide a written report to a member of a police force within 24 hours after becoming aware of the theft or loss; and
- (b) provide a written report to the Minister within 72 hours after becoming aware of the theft or loss and include a confirmation that the report required under paragraph (a) has been provided.

## **Explainable loss — licensed dealer**

**(2)** Subsection (1) does not apply to a licensed dealer that becomes aware of a loss of a restricted drug that can be explained on the basis of normally accepted business activities.

SOR/2019-171, s. 22.

## Suspicious transaction

**J.01.069 (1)** A licensed dealer must provide a written report containing the following information to the Minister within 72 hours after becoming aware of a transaction occurring in the course of their activities that they have reasonable grounds to suspect may be related to the diversion of a restricted drug to an illicit market or use:

- (a) their name, municipal address, telephone number and, if the licensed dealer is a corporation, 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, its type, the name and quantity of the restricted drug and, in the case of a product or compound, the quantity of every restricted drug that it contains;
- (d) in the case of a product that contains the restricted drug, other than a test kit, the drug identification number that is assigned to the product under section C.01.014.2, if any; and
- (e) a detailed description of the reasons for those suspicions.

## Good faith

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

## Non-disclosure

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

SOR/2019-171, s. 22.

## Partial protection against self-incrimination

**J.01.070** A report made under any of sections J.01.067 to J.01.069, or any evidence derived from it, is not to be used or received to incriminate the licensed dealer in any criminal proceeding against them other than a prosecution under [section 132](#), [136](#) or [137](#) of the *Criminal Code*.

SOR/2019-171, s. 22.

# Destruction of Restricted Drugs

## Destruction at site

**J.01.071** A licensed dealer that intends to destroy a restricted drug at the site specified in their licence must ensure that the following conditions are met:

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

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

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

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

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

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

SOR/2019-171, s. 22.

### **Destruction elsewhere than at site**

**J.01.072** A licensed dealer that intends to destroy a restricted drug elsewhere than at the site specified in their licence must ensure that the following conditions are met:

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

**(b)** the licensed dealer takes any measures that are necessary to ensure the security of the restricted drug while it is being transported in order to prevent its diversion to an illicit market or use;

**(c)** the destruction is carried out by a person working for a business that specializes in the destruction of dangerous goods and in the presence of another person working for that business;

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

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

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

**(ii)** the name and quantity of the restricted drug and, if applicable, the brand name and quantity of the product containing it or the name and quantity of the compound containing it,

**(iii)** the method of destruction,

**(iv)** the date of destruction, and

(v) the names in printed letters and signatures of that person and the other person who was present at the destruction.

SOR/2019-171, s. 22.

## **Application for prior approval**

**J.01.073 (1)** A licensed dealer must submit to the Minister an application that contains the following information in order to obtain the Minister's prior approval to destroy a restricted drug:

- (a) their name, municipal address and dealer's licence number;
- (b) the proposed date of destruction;
- (c) the municipal address of the place of destruction;
- (d) a brief description of the method of destruction;
- (e) if the destruction is to be carried out at the site specified in the dealer's licence, the names of the persons proposed for the purpose of paragraph J.01.071(b) and information establishing that they meet the conditions of that paragraph;
- (f) the name of the restricted drug and, if applicable, the brand name of the product containing it or the name of the compound containing it; and
- (g) the form and quantity of the restricted drug or the product or compound containing it and if applicable, the strength per unit of the restricted drug in the product or compound, the number of units per package and the number of packages.

## **Signature and attestation**

**(2)** The application must

- (a) be signed and dated by the qualified person in charge or an alternate qualified person in charge; and
- (b) include an attestation by that person that
  - (i) the proposed method of destruction complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction, and
  - (ii) all of the information submitted in support of the application is correct and complete to the best of the signatory's knowledge.

## **Additional information and documents**

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

SOR/2019-171, s. 22.

## **Approval**

**J.01.074** On completion of the review of the application for approval, the Minister must approve the destruction of the restricted drug unless

(a) in the case of a destruction that is to be carried out at the site specified in the dealer's licence, the persons proposed for the purpose of paragraph J.01.071(b) do not meet the conditions of that paragraph;

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

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

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

(e) the Minister has reasonable grounds to believe that the approval would likely create a risk to public health or safety, including the risk of the restricted drug being diverted to an illicit market or use.

SOR/2019-171, s. 22.

## Documents

### Licensed Dealers

#### Method of recording information

**J.01.075** A licensed dealer must record any information that they are required to record under this Part using a method that permits an audit of it to be made at any time.

SOR/2019-171, s. 22.

#### Information — general

**J.01.076** A licensed dealer must record the following information:

(a) the name, form and quantity of any restricted drug that the dealer orders, the name of the person who placed the order on the dealer's behalf and the date of the order;

(b) the name, form and quantity of any restricted drug that the dealer receives, the name and municipal address of the person who sold or provided it and the date on which it was received;

(c) in the case of a restricted drug that the dealer sells or provides,

(i) the brand name of the product or the name of the compound containing the restricted drug and the name of the restricted drug,

(ii) the drug identification number that has been assigned to the product under section C.01.014.2, if any,

**(iii)** the form and quantity of the restricted drug and, if applicable, the strength per unit of the restricted drug in the product or compound, the number of units per package and the number of packages,

**(iv)** the name and municipal address of the person to whom it was sold or provided, and

**(v)** the date on which it was sold or provided;

**(d)** the name, form and quantity of any restricted drug that the dealer manufactures or assembles and the date on which it was placed in stock and, if applicable, the strength per unit of the restricted drug in the product or compound, the number of units per package and the number of packages;

**(e)** the name and quantity of any restricted drug that the dealer uses in the manufacturing or assembling of a product or compound, as well as the brand name and quantity of the product or the name and quantity of the compound, and the date on which the product or compound was placed in stock;

**(f)** the name, form and quantity of any restricted drug in stock at the end of each month;

**(g)** the name, form and quantity of any restricted drug that the dealer delivers, transports or sends, the name and municipal address of the consignee and the date on which it was delivered, transported or sent;

**(h)** the name, form and quantity of any restricted drug imported, the date on which it was that the dealer imports, the name and municipal address of the exporter, the country of exportation and any country of transit or transshipment; and

**(i)** the name, form and quantity of any restricted drug that the dealer exports, the date on which it was exported, the name and municipal address of the importer, the country of final destination and any country of transit or transshipment.

SOR/2019-171, s. 22.

### **Explainable loss of restricted drug**

**J.01.077** A licensed dealer that becomes aware of a loss of a restricted drug that can be explained on the basis of normally accepted business activities must record the following information:

**(a)** the name of the lost restricted drug and, if applicable, the brand name of the product or the name of the compound containing it;

**(b)** the form and quantity of the restricted drug and, if applicable, the form of the product or compound containing it, the strength per unit of the restricted drug in the product or compound, the number of units per package and the number of packages;

**(c)** the date on which the dealer became aware of the loss; and

**(d)** the explanation for the loss.

SOR/2019-171, s. 22.

## **Destruction**

**J.01.078** A licensed dealer must record the following information concerning any restricted drug that they destroy at the site specified in their licence:

- (a) the municipal address of the place of destruction;
- (b) the name, form and quantity of the restricted drug and, if applicable, the brand name and quantity of the product containing the drug or the name and quantity of the compound containing the drug;
- (c) the method of destruction; and
- (d) the date of destruction.

SOR/2019-171, s. 22.

## **Annual report**

**J.01.079 (1)** Subject to subsections (2) and (3), a licensed dealer must provide to the Minister, within three months after the end of each calendar year, an annual report that contains

- (a) the name, form and total quantity of each restricted drug that they receive, produce, sell, provide, import, export or destroy during the calendar year, as well as the name and total quantity of each restricted drug that they use to manufacture or assemble a product or compound;
- (b) the name, form and quantity of each restricted drug in physical inventory taken at the site specified in their licence at the end of the calendar year; and
- (c) the name, form and quantity of any restricted drug that has been lost in the course of conducting activities during the calendar year.

## **Non-renewal or revocation within first three months**

**(2)** If a licensed dealer's licence expires without being renewed or is revoked during the first three months of a calendar year, the dealer must provide to the Minister

- (a) within three months after the end of the preceding calendar year, the annual report in respect of that year; and
- (b) within three months after the expiry or revocation, a report in respect of the portion of the current calendar year during which the licence was valid that contains the information referred to in subsection (1), in which the quantity in physical inventory is to be calculated as of the date of expiry or revocation.

## **Non-renewal or revocation after third month**

**(3)** If a licensed dealer's licence expires without being renewed or is revoked after the first three months of a calendar year, the dealer must provide to the Minister, within three months after the expiry or revocation, a report in respect of the portion of the calendar year during which the licence was valid that contains the information referred to in

subsection (1) for that period, in which the quantity in physical inventory is to be calculated as of the date of expiry or revocation.

SOR/2019-171, s. 22.

## **Institutions**

### **Method of recording information**

**J.01.080** An institution must record any information that it is required to record under this Part using a method that permits an audit of the information to be made at any time.

SOR/2019-171, s. 22.

### **Information**

**J.01.081** An institution must record the following information:

(a) the name and quantity of any restricted drug that the institution orders, the name of the person who placed the order on the institution's behalf and the date of the order;

(b) the name and quantity of any restricted drug that the institution receives as well as the name and municipal address of the licensed dealer that sold or provided it and the date on which it was received;

(c) details of the use of restricted drugs in the institution;

(d) the names and qualifications of every person who makes use of a restricted drug in the institution; and

(e) all clinical data with respect to the use of every restricted drug received by the institution.

SOR/2019-171, s. 22.

## **Drug Received for Identification and Analysis**

### **Method of recording information**

**J.01.082** A person who records information in accordance with section J.01.083 must do so using a method that permits an audit of the information to be made at any time.

SOR/2019-171, s. 22.

### **Information**

**J.01.083** A person who receives a restricted drug in accordance with section J.01.061 must record the following information:

(a) the name and quantity of the restricted drug, as well as the name and municipal address of the person who provided it to them and the date on which it was received;

(b) details regarding the identification or analysis of the restricted drug; and

(c) the names of the persons who handled the restricted drug during the process of identifying or analyzing it.

## Record Keeping

### Retention period

**J.01.084** A licensed dealer, a former licensed dealer, an institution and a person referred to in section J.01.083 must keep any document containing the information that they are required to record under this Part, including every declaration and a copy of every report, for a period of two years following the day on which the last record is recorded in the document and in a manner that permits an audit of the document to be made at any time.

SOR/2019-171, s. 22.

### Location

**J.01.085** The documents must be kept

- (a) in the case of a licensed dealer, at the site specified in their licence;
- (b) in the case of an institution, at the institution;
- (c) in the case of a person referred to in section J.01.083, at a location in Canada;  
and
- (d) in the case of a former licensed dealer, at a location in Canada.

SOR/2019-171, s. 22.

### Quality of documents

**J.01.086** The documents must be complete and readily retrievable and the information in them must be legible and indelible.

SOR/2019-171, s. 22.

## Notification of Application for Order of Restoration

### Written notification

**J.01.087 (1)** For the purpose of [subsection 24\(1\)](#) of the [Act](#), notification of an application for an order of restoration must be given in writing to the Attorney General by registered mail and be mailed at least 15 days before the date on which the application is to be made to a justice.

### Content of notification

**(2)** The notification must specify

- (a) the name of the justice to whom the application is to be made;
- (b) the time and place at which the application is to be heard;
- (c) details concerning the restricted drug or other thing in respect of which the application is to be made; and

(d) the evidence on which the applicant intends to rely to establish that they are entitled to possession of the restricted drug or other thing referred to in paragraph (c).  
SOR/2019-171, s. 22.

## **SCHEDULE**

### **(Sections J.01.001, J.01.002 and J.01.004)**

#### **PART I**

- 1 The following amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues:
  - (1) N-ethylamphetamine (N-ethyl- $\alpha$ -methylbenzeneethanamine)
  - (2) 4-methyl-2,5-dimethoxyamphetamine (STP) (2,5-dimethoxy-4, $\alpha$ -methylbenzeneethanamine)
  - (3) 3,4-methylenedioxyamphetamine (MDA) ( $\alpha$ -methyl-1,3-benzodioxole-5-ethanamine)
  - (4) 2,5-dimethoxyamphetamine(2,5-dimethoxy- $\alpha$ -methylbenzeneethanamine)
  - (5) 4-methoxyamphetamine (4-methoxy- $\alpha$ -methylbenzeneethanamine)
  - (6) 2,4,5-trimethoxyamphetamine (2,4,5-trimethoxy- $\alpha$ -methylbenzeneethanamine)
  - (7) N-methyl-3,4-methylenedioxyamphetamine (N, $\alpha$ -dimethyl-1,3-benzodioxole-5-ethanamine)
  - (8) 4-ethoxy-2,5-dimethoxyamphetamine (4-ethoxy-2,5-dimethoxy- $\alpha$ -methylbenzeneethanamine)
  - (9) 5-methoxy-3,4-methylenedioxyamphetamine (7-methoxy- $\alpha$ -methyl-1,3-benzodioxole-5-ethanamine)
  - (10) N,N-dimethyl-3,4-methylenedioxyamphetamine (N,N,  $\alpha$ -trimethyl-1,3-benzodioxole-5-ethanamine)
  - (11) N-ethyl-3,4-methylenedioxyamphetamine (N-ethyl- $\alpha$ -methyl-1,3-benzodioxole-5-ethanamine)
  - (12) 4-ethyl-2,5-dimethoxyamphetamine (DOET) (4-ethyl-2,5-dimethoxy- $\alpha$ -methylbenzeneethanamine)
  - (13) 4-bromo-2,5-dimethoxyamphetamine (4-bromo-2,5-dimethoxy- $\alpha$ -methylbenzeneethanamine)
  - (14) 4-chloro-2,5-dimethoxyamphetamine (4-chloro-2,5-dimethoxy- $\alpha$ -methylbenzeneethanamine)
  - (15) 4-ethoxyamphetamine (4-ethoxy- $\alpha$ -methyl-benzeneethanamine)
  - (16) N-Propyl-3,4-methylenedioxyamphetamine ( $\alpha$ -methyl-N-propyl-1,3-benzodioxole-5-ethanamine)

- (17) N-hydroxy-3,4-methylenedioxyamphetamine (N-[ $\alpha$ -methyl-3,4-(methylenedioxy)phenethyl]hydroxylamine)
- (18) 3,4,5-trimethoxyamphetamine (3,4,5-trimethoxy- $\alpha$ -methylbenzeneethanamine)
- 2 Lysergic acid diethylamide (LSD) (N,N-diethyllysergamide) and any salt thereof
- 3 N,N-Diethyltryptamine (DET) (3-[(2-diethylamino)ethyl]indole) and any salt thereof
- 4 N,N-Dimethyltryptamine (DMT) (3-[(2-dimethylamino)ethyl]indole) and any salt thereof
- 5 N-Methyl-3-piperidyl benzilate (LBJ) (3-[(hydroxydiphenylacetyl)oxy]-1-methylpiperidine) and any salt thereof
- 6 Harmaline (4,9-dihydro-7-methoxy-1-methyl-3H-pyrido(3,4-b)indole) and any salt thereof
- 7 Harmalol (4,9-dihydro-1-methyl-3H-pyrido(3,4- $\beta$ )indol-7-ol) and any salt thereof
- 8 Psilocin (3-[2-(dimethylamino)ethyl]-4-hydroxyindole) and any salt thereof
- 9 Psilocybin (3-[2-(dimethylamino)ethyl]-4-phosphoryloxyindole) and any salt thereof
- 10 N-(1-phenylcyclohexyl)ethylamine (PCE) and any salt thereof
- 11 1-[1-(2-Thienyl)cyclohexyl]piperidine (TCP) and any salt thereof
- 12 1-Phenyl-N-propylcyclohexanamine and any salt thereof
- 13 Mescaline (3,4,5-trimethoxybenzeneethanamine) and any salt thereof, but not peyote (lophophora)
- 14 **[Repealed, SOR/2017-250, s. 2]**
- 15 2-Methylamino-1-phenyl-1-propanone and any salt thereof
- 16 1-[1-(Phenylmethyl)cyclohexyl]piperidine and any salt thereof
- 17 1-[1-(4-Methylphenyl)cyclohexyl]piperidine and any salt thereof
- 18 Etryptamine (3-(2-aminobutyl)indole) and any salt thereof
- 19 Rolicyclidine (1-(1-phenylcyclohexyl) pyrrolidine) and any salt thereof
- 20 Benzylpiperazine [BZP], namely 1-benzylpiperazine and its salts, isomers and salts of isomers
- 21 Trifluoromethylphenylpiperazine [TFMPP], namely 1-(3-trifluoromethylphenyl)piperazine and its salts, isomers and salts of isomers
- 22 Methylenedioxypropylamphetamine (MDPV), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues
- 23 Cathinone ((-)- $\alpha$ -aminopropiophenone) and its salts
- 24 2C-phenethylamines and their salts, derivatives, isomers and salts of derivatives and isomers that correspond to the following chemical description:

any substance that has a 1-amino-2-phenylethane structure substituted at the 2' and 5' or 2' and 6' positions of the benzene ring by an alkoxy or haloalkoxy group, or substituted at two adjacent carbon atoms of the benzene ring which

results in the formation of a furan, dihydrofuran, pyran, dihydropyran or methylenedioxy group — whether or not further substituted on the benzene ring to any extent, whether or not substituted at the amino group by one or two, or a combination of, methyl, ethyl, propyl, isopropyl, hydroxyl, benzyl (or benzyl substituted to any extent) or benzylene (or benzylene substituted to any extent) groups and whether or not substituted at the 2-ethyl (beta carbon) position by a hydroxyl, oxo or alkoxy group — and its salts and derivatives and salts of derivatives, including

- (1) 4-bromo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25B-NBOMe)
  - (2) 4-chloro-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25C-NBOMe)
  - (3) 4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine (25I-NBOMe)
  - (4) 4-bromo-2,5-dimethoxybenzeneethanamine (2C-B)
- 25 AH-7921 (1-(3,4-dichlorobenzamidomethyl)cyclohexyldimethylamine), its salts, isomers and salts of isomers
- 26 MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, including
- (1) Diphenidine (DEP) (1-(1,2-diphenylethyl)piperidine)
  - (2) Methoxphenidine (2-MeO-Diphenidine, MXP) (1-[1-(2-methoxyphenyl)-2-phenylethyl]piperidine)
  - (3) Ephenedine (NEDPA, EPE) (N-ethyl-1,2-diphenylethylamine)
  - (4) Isophenedine (NPDPA) (N-isopropyl-1,2-diphenylethylamine)  
but not including
  - (5) Lefetamine ((-)-N,N-dimethyl- $\alpha$ -phenylbenzeneethanamine), its salts, derivatives and isomers and salts of derivatives and isomers
- 27 W-18 (4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-piperidinylidene]benzenesulfonamide), its salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues
- 28 U-47700 (3,4-dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide), its salts, derivatives, isomers and analogues, and salts of derivatives, isomers and analogues, including
- (1) Bromadoline (4-bromo-N-(2-(dimethylamino)cyclohexyl)benzamide)
  - (2) U-47109 (3,4-dichloro-N-(2-(dimethylamino)cyclohexyl)benzamide)
  - (3) U-48520 (4-chloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide)
  - (4) U-50211 (N-(2-(dimethylamino)cyclohexyl)-4-hydroxy-N-methylbenzamide)
  - (5) U-77891 (3,4-dibromo-N-methyl-N-(1-methyl-1-azaspiro[4.5]decan-6-yl)benzamide)

## **PART II**

- 1 *Salvia divinorum* (*S. divinorum*), its preparations and derivatives, including

- (1) Salvinorin A ((2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(3-furanyl)dodecahydro-6a,10b-dimethyl-4,10-dioxo-2H-naphtho[2,1-c]pyran-7-carboxylic acid methyl ester)
- 2 *Catha edulis* Forsk, its preparations, derivatives, alkaloids and salts, including
  - (1) Cathine (*d*-threo-2-amino-1-hydroxy-1-phenylpropane) but not including
  - (2) Cathinone ((-)- $\alpha$ -aminopropiophenone) and its salts

### PART III

Item	Column 1 Substance	Column 2 Period
1	Carisoprodol (2-((carbamoxyloxy)methyl)-2-methylpentyl isopropylcarbamate)	April 14, 2025 to April 13, 2026

SOR/97-228, s. 25; SOR/2003-34, ss. 4, 5; SOR/2012-65, s. 1; SOR/2012-177, s. 1; SOR/2013-172, s. 2; SOR/2015-210, ss. 4 to 6; SOR/2016-72, s. 1; SOR/2016-106, s. 2; SOR/2016-239, s. 1; SOR/2017-12, ss. 3, 4; SOR/2017-250, s. 2; SOR/2017-278, s. 1; SOR/2018-69, s. 66; SOR/2018-85, s. 4; SOR/2019-171, s. 23; SOR/2025-65, s. 1.

### SCHEDULE F

[Repealed, SOR/2013-122, s. 18]

### SCHEDULE K

## Reasonable Daily Intake for Various Foods

Item No.	Column I Name and Description	Column II R.D.I.
1	Alimentary Pastes, dry .....	3.0 oz. 85 g
2	Bacon (side) simulated meat product that resembles side bacon, (cooked) .....	1.0 oz. 28 g
3	Beverage Bases and Mixes, Flavoured, for Addition to Milk (ready to serve) .....	16.0 fl.oz. 454 ml
4	Bread, 5 slices .....	5.3 oz. 150 g
5	Butter .....	2.0 oz. 57 g
6	Buttermilk .....	30.0 fl.oz. 852 ml