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pharmacist [Repealed, SOR/2021-271, s. 1]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

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