Environmental Protection Act

ONTARIO REGULATION 298/12

COLLECTION OF PHARMACEUTICALS AND SHARPS — RESPONSIBILITIES OF PRODUCERS

Consolidation Period: From October 1, 2012 to the e-Laws currency date.

Last amendment: O. Reg. 298/12.

This is the English version of a bilingual regulation.

Definitions

1. (1) In this Regulation,

"brand" means any mark, word, name, symbol, design, device or graphical element, or a combination thereof, including a registered or unregistered trade-mark, which identifies a product and distinguishes it from other products; ("marque")

"collection location" means a location at which the collection of one or both of pharmaceuticals and sharps is provided for, for the purposes of one or both of sections 2 and 3; ("point de collecte")

"consumer" means an individual acting for personal, family or household purposes, including acting in respect of a companion animal; ("consommateur")

"designated material" means, in respect of a producer of a pharmaceutical or sharp, the items referred to in section 2 and subsection 3 (1) in respect of which the producer is required to provide for collection under one or both of sections 2 and 3; ("matériel désigné")

"importer" means a person who imports a pharmaceutical or sharp into Ontario for the purpose of sale; ("importateur")

"manufacturer" means a person who manufactures or processes a pharmaceutical or sharp for the purpose of sale; ("fabricant")

"pharmaceutical" means, subject to subsection (2), a drug within the meaning of section 2 of the Food and Drugs Act (Canada) that is sold to consumers in Ontario, whether it is sold by the producer of the pharmaceutical or by another person, and includes a natural health product within the meaning of the Natural Health Products Regulations made under that Act; ("produit pharmaceutique")

"producer" means, in respect of a pharmaceutical or sharp, the person who sells it in Ontario, as determined under subsection (3); ("producteur")

"sell" includes offer for sale, expose for sale, have in possession for sale and distribute; ("vendre")

"sharp" means a needle, safety engineered needle, lancet or other similar instrument that is designed to puncture the skin of individuals or companion animals for medical purposes and that is sold to consumers in Ontario, whether it is sold by the producer of the sharp or by another person, and includes anything affixed to the sharp, including a syringe; ("objet pointu")

"trade-mark" has the same meaning as in section 2 of the Trade-marks Act (Canada). ("marque de commerce") O. Reg. 298/12, s. 1 (1).

(2) For the purposes of this Regulation, a pharmaceutical does not include the following:

1. A substance or mixture of substances manufactured, sold or represented for use in disinfection in premises in which food within the meaning of section 2 of the Food and Drugs Act (Canada) is manufactured, prepared or kept.

2. A food within the meaning of section 2 of the Food and Drugs Act (Canada).

3. A cosmetic within the meaning of section 2 of the Food and Drugs Act (Canada).

4. Any of the following items, if the item does not contain a substance prescribed under the Drug and Pharmacies Regulation Act as being included in Schedule I established by the regulations made under that Act:

i. A contact lens disinfectant.

ii. An anti-dandruff product, including shampoo.

iii. An anti-perspirant.

iv. A sunburn protectant.

v. A mouthwash.

vi. A fluoridated toothpaste.

vii. A lozenge for cough, sore throat or halitosis.

viii. A topical substance that does not contain antibiotics or anti-fungal agents.

5. A radiopharmaceutical. O. Reg. 298/12, s. 1 (2).

(3) For the purposes of the definition of producer in subsection (1), the producer of a pharmaceutical or sharp is,

(a) the manufacturer of the pharmaceutical or sharp, if it is sold to consumers in Ontario under a brand that the manufacturer owns, licenses or otherwise has rights to;

(b) if there is no person described in clause (a), the owner or licensee of the brand or the person who otherwise has rights to the brand under which the pharmaceutical or sharp is sold to consumers in Ontario;

(c) if there is no person described in clause (a) or (b), the importer of the pharmaceutical or sharp into Ontario; or

(d) if there is no person described in clause (a), (b) or (c), the first person who sells the pharmaceutical or sharp to another person in Ontario. O. Reg. 298/12, s. 1 (3).

Note: On January 1, 2013, section 2 comes into force. (See: O. Reg. 298/12, s. 12 (2))

Pharmaceuticals

2. A producer of a pharmaceutical shall provide for the following in accordance with this Regulation:

1. The collection of the pharmaceutical at collection locations from consumers who bring the pharmaceutical to the collection locations.

2. The disposal of the pharmaceutical.

3. The collection, and the recycling or disposal, of containers in which consumers bring the pharmaceutical to the collection locations and that have come into direct contact with the pharmaceutical. O. Reg. 298/12, s. 2.

Note: On January 1, 2013, section 3 comes into force. (See: O. Reg. 298/12, s. 12 (2))

Sharps

3. (1) A producer of a sharp shall provide for the following in accordance with this Regulation:

1. The collection of the sharp at collection locations from consumers who bring the sharp to the collection locations.

2. The disposal of the sharp.

3. The collection and disposal of containers designed for the safe handling of sharps in which consumers bring the sharp to the collection locations. O. Reg. 298/12, s. 3 (1).

(2) Despite paragraph 1 of subsection (1), a sharp may be refused for collection if it is not contained in a container designed for the safe handling of sharps. O. Reg. 298/12, s. 3 (2).

Note: On January 1, 2013, section 4 comes into force. (See: O. Reg. 298/12, s. 12 (2))

Collection locations

4. (1) Subject to subsection (2), a producer of a pharmaceutical or sharp shall ensure that the number of collection locations at which collection of the designated material of the producer is provided for in a calendar year is, at a minimum, the lesser of the following:

1. The number equal to 80 per cent of retail locations in Ontario, as of October 1 in the preceding calendar year, at which the pharmaceutical or sharp was sold.

Note: On January 1, 2014, paragraph 1 is amended by striking out “80 per cent” and substituting “90 per cent”. (See: O. Reg. 298/12, ss. 11 (1), 12 (3))

2. The number equal to 80 per cent of pharmacies in Ontario, as of October 1 in the preceding calendar year, in respect of which a certificate of accreditation is in effect under section 139 of the Drug and Pharmacies Regulation Act, as set out by the Director on the internet through the Ministry’s website. O. Reg. 298/12, s. 4 (1).

Note: On January 1, 2014, paragraph 2 is amended by striking out “80 per cent” and substituting “90 per cent”. (See: O. Reg. 298/12, ss. 11 (2), 12 (3))

(2) A producer of a pharmaceutical or sharp shall ensure that there is at least one collection location at which collection of the designated material of the producer is provided for in each local municipality in Ontario in which there is a retail location at which the pharmaceutical or sharp is sold. O. Reg. 298/12, s. 4 (2).

(3) A producer of a pharmaceutical or sharp shall ensure that at each collection location at which the producer provides for collection of the designated material of the producer, the collection is,

(a) available free of charge to consumers;

(b) not subject to any limitations with respect to the quantity of the designated material of the producer that a consumer may bring for collection; and

(c) if the collection location is in a pharmacy in respect of which a certificate of accreditation is in effect under section 139 of the Drug and Pharmacies Regulation Act, available during the business hours of the pharmacy. O. Reg. 298/12, s. 4 (3).

Note: On January 1, 2013, section 5 comes into force. (See: O. Reg. 298/12, s. 12 (2))

Exemption, provisions of the Act

5. (1) Section 27 of the Act does not apply with respect to the collection, handling, storage and transfer of pharmaceuticals, sharps and containers at a collection location that are collected for the purposes of one or both of sections 2 and 3 if,

(a) an agreement that meets the requirements set out in section 6 is in effect with respect to the collection location; and

(b) a person registered as a pharmacist under the Pharmacy Act, 1991 or a person registered as a pharmacy technician under that Act is present when the collection is offered. O. Reg. 298/12, s. 5 (1).

(2) Section 40 of the Act does not apply with respect to the deposit, or the causing, permitting or arranging for the deposit of, pharmaceuticals, sharps and containers at a collection location for the purposes of one or both of sections 2 and 3 if the conditions set out in clauses (1) (a) and (b) are met. O. Reg. 298/12, s. 5 (2).

(3) Section 41 of the Act does not apply with respect to facilities or equipment used, or caused, permitted or arranged to be used, for the storage, handling and collection of pharmaceuticals, sharps and containers at a collection location for the purposes of one or both of sections 2 and 3 if the conditions set out in clauses (1) (a) and (b) are met. O. Reg. 298/12, s. 5 (3).

(4) The requirements in section 18, subsection 19 (1), sections 21 to 25 and subsections 27 (3), (4), (5), (5.1) and (6) of Regulation 347 of the Revised Regulations of Ontario, 1990 (General — Waste Management) made under the Act do not apply with respect to pharmaceuticals, sharps and containers collected at a collection location for the purposes of one or both of sections 2 and 3 if the conditions set out in clauses (1) (a) and (b) are met. O. Reg. 298/12, s. 5 (4).

Note: On January 1, 2013, section 6 comes into force. (See: O. Reg. 298/12, s. 12 (2))

Agreement

6. (1) For the purposes of this section, “owner” and “operator” have the same meanings as in Part V of the Act. O. Reg. 298/12, s. 6 (1).

(2) For the purposes of section 5, the agreement shall meet the following requirements:

1. The agreement shall be between,

i. the owner or operator of each collection location in respect of which the agreement applies, which person shall not be the same person as the person mentioned in subparagraph ii, and

ii. the operator of a waste management system who holds an environmental compliance approval in respect of the collection, handling and transportation of the pharmaceuticals, sharps and containers to be collected, handled and transported.

2. The agreement shall address the following, at a minimum, in respect of each collection location to which it applies:

i. The types of containers that are to be used for collecting, handling and storing the pharmaceuticals, sharps and containers and the manner in which the containers used for collecting, handling and storing are to be labelled.

ii. Procedures in respect of how the pharmaceuticals, sharps and containers collected are to be collected, handled and stored, including the manner in which they are to be segregated from each other.

3. The agreement shall include a requirement that persons collecting, handling and storing pharmaceuticals, sharps or containers collected for the purposes of one or both of sections 2 and 3 receive annual training with respect to the safe collection, handling and storage and the requirements of the agreement. O. Reg. 298/12, s. 6 (2).

(3) The operator of the collection location shall ensure that a copy of the agreement and any related records are retained at the collection location during the time period when the agreement applies and the following five-year period. O. Reg. 298/12, s. 6 (3).

Note: On January 1, 2013, section 7 comes into force. (See: O. Reg. 298/12, s. 12 (2))

Promotion and education

7. (1) A producer of a pharmaceutical or sharp shall ensure that the following information is made available publicly and free of charge in accordance with subsection (2):

1. The location of the collection locations at which collection of the designated material of the producer is provided for.

2. A description of how consumers should safely store and handle the designated material of the producer before bringing it to a collection location. O. Reg. 298/12, s. 7 (1).

(2) The information described in subsection (1) shall, at a minimum, be made available,

(a) on the internet through the producer's website; and

(b) in print at each collection location at which collection of the designated material of the producer is provided for. O. Reg. 298/12, s. 7 (2).

Note: On January 1, 2013, section 8 comes into force. (See: O. Reg. 298/12, s. 12 (2))

Interim report

8. (1) On or before June 30, 2013, a producer of a pharmaceutical or sharp shall ensure that a report is prepared that sets out, at a minimum, the following information with respect to the period commencing on October 1, 2012 and ending on March 31, 2013:

1. A description of actions taken and outcomes achieved by the producer in respect of the requirements of this Regulation.

2. The number of collection locations and the location of each of the collection locations at which collection of the designated material of the producer is provided for. O. Reg. 298/12, s. 8 (1).

(2) A report required under subsection (1) may be prepared on behalf of more than one producer of pharmaceuticals or sharps and, if this is done, the report shall set out, at a minimum, the following information:

1. The name of each producer on whose behalf the report is prepared.

2. A description of actions taken and outcomes achieved by the producers in respect of the requirements of this Regulation.

3. The number of collection locations and the location of each of the collection locations at which collection of the designated material of the producers is provided for. O. Reg. 298/12, s. 8 (2).

(3) The report shall be made available publicly and free of charge on the internet through the producer's website for a minimum of one year. O. Reg. 298/12, s. 8 (3).

Note: On January 1, 2013, section 9 comes into force. (See: O. Reg. 298/12, s. 12 (2))

Annual report

9. (1) On or before April 1, 2014 and on or before April 1 in each subsequent year, a producer of a pharmaceutical or sharp shall ensure that a report is prepared that sets out, at a minimum, the following information with respect to the producer:

1. The number of collection locations and the location of each of the collection locations at which collection of the designated material of the producer was provided for during the previous calendar year and a description of any changes that occurred with respect to the number and location of collection locations from the previous calendar year.

2. The total weight of all of the following that was collected at the collection locations during the previous calendar year:

i. Pharmaceuticals.

ii. Containers described in paragraph 3 of section 2, excluding any containers that were recycled.

3. The total weight of all of the following that was collected at the collection locations during the previous calendar year:

i. Sharps.

ii. Containers described in paragraph 3 of subsection 3 (1).

4. A description of how the designated material of the producer collected at collection locations was handled and how it was recycled or disposed of during the previous calendar year.

5. A description of actions taken by the producer during the previous calendar year, their effectiveness and outcomes achieved as part of complying with sections 2, 3, 4 and 7.

6. A description of any actions taken by the producer during the previous calendar year that exceeded the actions required for the purposes of section 4, in order to provide for the collection of the designated material of the producer.

7. A description of any actions taken by the producer during the previous calendar year that exceeded the actions required for the purposes of section 7, with respect to educational and public awareness activities in order to promote to consumers the collection locations and the availability of collection. O. Reg. 298/12, s. 9 (1).

(2) A report required under subsection (1) may be prepared on behalf of more than one producer of pharmaceuticals or sharps and, if this is done, the report shall set out, at a minimum, the following information with respect to those producers:

1. The name of each producer on whose behalf the report is prepared.

2. The number of collection locations and the location of each of the collection locations at which collection of the designated material of the producers was provided for by all of the producers and a description of any changes that occurred with respect to the number and location of collection locations from the previous calendar year.

3. The information mentioned in paragraphs 2 to 7 of subsection (1), reported with respect to all of the producers as a group. O. Reg. 298/12, s. 9 (2).

(3) The report shall include an opinion from a licensed public accountant confirming the accuracy of,

(a) if the report is prepared in respect of one producer, the information referred to in paragraphs 1, 2, 3, 4 and 7 of subsection (1); or

(b) in the case of a report prepared on behalf of more than one producer, the information referred to in paragraphs 2 and 3 of subsection (2), other than the information referred to in paragraphs 5 and 6 of subsection (1). O. Reg. 298/12, s. 9 (3).

(4) The report shall be made available publicly and free of charge on the internet through the producer's website for a minimum of three years. O. Reg. 298/12, s. 9 (4).

Transition

10. (1) Subject to subsection (5), section 27 of the Act does not apply with respect to the collection, handling, storage and transfer of pharmaceuticals, sharps and containers at a site to which consumers bring them if the pharmaceuticals, sharps and containers are collected on or after the day this section comes into force and before January 1, 2013 for the purposes of providing for collection, disposal or recycling that would comply with the requirements of sections 2 and 3, if those provisions were required to be complied with. O. Reg. 298/12, s. 10 (1).

(2) Subject to subsection (5), section 40 of the Act does not apply with respect to the deposit, or the causing, permitting or arranging for the deposit of, pharmaceuticals, sharps and containers that are collected on or after the day this section comes into force and before January 1, 2013 for the purposes of providing for collection, disposal or recycling that would comply with the requirements of sections 2 and 3, if those provisions were required to be complied with. O. Reg. 298/12, s. 10 (2).

(3) Subject to subsection (5), section 41 of the Act does not apply with respect to facilities or equipment used, or caused, permitted or arranged to be used, for the storage, handling and collection of pharmaceuticals, sharps and containers that are collected on or after the day this section comes into force and before January 1, 2013 for the purposes of providing for collection, disposal or recycling that would comply with the requirements of sections 2 and 3, if those provisions were required to be complied with. O. Reg. 298/12, s. 10 (3).

(4) Subject to subsection (5), the requirements in section 18, subsection 19 (1), sections 21 to 25 and subsections 27 (3), (4), (5), (5.1) and (6) of Regulation 347 of the Revised Regulations of Ontario, 1990 (General — Waste Management) made under the Act do not apply with respect to pharmaceuticals, sharps and containers collected on or after the day this section comes into force and before January 1, 2013 for the purposes of providing for collection, disposal or recycling that would comply with the requirements of sections 2 and 3, if those provisions were required to be complied with. O. Reg. 298/12, s. 10 (4).

(5) This section applies only if a person registered as a pharmacist under the Pharmacy Act, 1991 or a person registered as a pharmacy technician under that Act is present when the collection is offered. O. Reg. 298/12, s. 10 (5).

Note: On January 1, 2013, section 10 is revoked. (See: O. Reg. 298/12, ss. 11 (3), 12 (2))

11. Omitted (provides for amendments to this Regulation). O. Reg. 298/12, s. 11.

12. Omitted (provides for coming into force of provisions of this Regulation). O. Reg. 298/12, s. 12.