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Drug Interchangeability and Dispensing Fee Act

R.S.O. 1990, CHAPTER P.23

Consolidation Period: From June 3, 2016 to the e-Laws currency date.

Last amendment: 2016, c. 6, Sched. 1, s. 2.

CONTENTS

Definitions

1. (1) In this Act,

"designated" means designated by the executive officer in the Formulary; ("désigné")

"dispenser" means a person who dispenses a drug pursuant to a prescription; ("préposé à la préparation")

"drug" means a drug as defined in the *Drug and Pharmacies Regulation Act*, and includes any substance designated as an interchangeable product before section 16 of the *Traditional Chinese Medicine Act, 2006* came into force; ("médicament")

"executive officer" means the executive officer of the Ontario public drug programs appointed under the *Ontario Drug Benefit Act*; ("administrateur")

"Formulary" means the Formulary that the executive officer is required to keep, maintain and publish under the *Ontario Drug Benefit Act*; ("Formulaire des médicaments")

"inspector" means a person appointed under section 12 of this Act; ("inspecteur")

"interchangeable product" means a drug or combination of drugs in a particular dosage form and strength identified by a specific product name or manufacturer and designated as interchangeable with one or more other such products; ("produit interchangeable")

"Minister" means the Minister of Health and Long-Term Care; ("ministre")

"operator of a pharmacy" means the holder of a certificate of accreditation for the operation of a pharmacy under section 139 of the *Drug and Pharmacies Regulation Act*; ("exploitant d'une pharmacie")

"prescription" means a direction from a person authorized to prescribe drugs within the scope of his or her practice of a health discipline directing the dispensing of a drug or mixture of drugs for a specified person; ("ordonnance")

"Registrar" means the Registrar of the Ontario College of Pharmacists; ("registrateur")

"regulations" means the regulations made under this Act. ("règlements") R.S.O. 1990, c. P.23, s. 1; 1996, c. 1, Sched. G, s. 20; 2006, c. 19, Sched. L, s. 1; 2006, c. 14, s. 1 (1, 2); 2006, c. 27, s. 15.

No therapeutic substitution

(2) Nothing in this Act shall be construed to permit therapeutic substitution. 2006, c. 14, s. 1 (3).

Executive officer and interchangeability

1.1 (1) The executive officer may designate a product as being interchangeable with another product by designating it as such in the Formulary. 2006, c. 14, s. 2.

Formulary and interchangeability

(2) A product becomes interchangeable with another product on the effective date of its being designated as interchangeable with that product, and ceases to be interchangeable with that product on the effective date of the removal of its interchangeability designation by the executive officer. 2006, c. 14, s. 2.

Requirements for interchangeability

(3) The executive officer may designate a product as being interchangeable with another product if it is in the public interest to do so, but shall not do so if,

(a) it does not contain a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the other product; or

(b) the prescribed conditions under clause 14 (1) (a) have not been met. 2006, c. 14, s. 2.

Similar active ingredients

(4) In clause (3) (a),

"similar active ingredients" means different salts, esters, complexes or solvates of the same therapeutic moiety. 2006, c. 14, s. 2.

Ceasing to be interchangeable

(5) The executive officer may remove a product's interchangeability designation,

(a) where authorized to do so under subsection 12.1 (8);

(b) if one of the conditions prescribed under clause 14 (1) (b) has been breached; or

(c) in any case, if he or she considers it advisable in the public interest to do so. 2006, c. 14, s. 2.

Modification

(6) Any modification of a designation takes place on the effective date of its being designated in the Formulary as a modification. 2006, c. 14, s. 2.

Non-application of SPPA

(7) The *Statutory Powers Procedure Act* does not apply to anything done by the executive officer under this Act. 2006, c. 14, s. 2.

Transitional

(8) A product that was interchangeable with another product immediately before October 1, 2006 continues to be interchangeable with that product until its interchangeability designation is removed by the executive officer. 2006, c. 14, s. 2.

Application of this Act

2. This Act does not apply to the dispensing of a drug in or by a hospital approved as a public hospital under the *Public Hospitals Act* if the drug is dispensed for a patient or an out-patient of the hospital. R.S.O. 1990, c. P.23, s. 2.

Over the counter drugs excepted

3. Subsections 4 (2) and (3) and sections 5, 6, 7, 9 and 10 do not apply in respect of an interchangeable product that does not require a prescription for sale. R.S.O. 1990, c. P.23, s. 3; 1996, c. 1, Sched. G, s. 26 (1).

Substitution where named product

4. (1) If a prescription directs the dispensing of a specific interchangeable product, the dispenser may dispense in its place another product that is designated as interchangeable with it. R.S.O. 1990, c. P.23, s. 4 (1); 1996, c. 1, Sched. G, s. 26 (1, 2).

Request for interchangeable product

(2) If a prescription directs the dispensing of a specific interchangeable product, the dispenser, on the request of the person for whom the product was prescribed or the person presenting the prescription, shall dispense in its place another product that is designated as interchangeable with it. R.S.O. 1990, c. P.23, s. 4 (2); 1996, c. 1, Sched. G, s. 26 (1, 2).

Inform customer

(3) If a prescription directs the dispensing of a specific interchangeable product, the dispenser shall not supply that product without informing the person for whom the product was prescribed or the person presenting the prescription, in the manner prescribed by the regulations, of the right to request an interchangeable product. R.S.O. 1990, c. P.23, s. 4 (3); 1996, c. 1, Sched. G, s. 26 (1).

Exceptions

(4) Subsection (3) does not apply if,

(a) the amount to be charged for supplying the product specified in the prescription is not more than the least amount that would have been charged for supplying a product that is interchangeable with it and available in the dispenser's inventory; or

(b) REPEALED: 1996, c. 1, Sched. G, s. 21.

(c) the product is being supplied pursuant to a repeat of the prescription. R.S.O. 1990, c. P.23, s. 4 (4); 1996, c. 1, Sched. G, ss. 21, 26 (3).

Selection of interchangeable product

(5) If a prescription directs the dispensing of a product that is not designated as an interchangeable product and there is an interchangeable product that contains a drug or drugs in the same amounts of the same active ingredients in the same dosage form as the product prescribed, the dispenser may dispense the interchangeable product. R.S.O. 1990, c. P.23, s. 4 (5); 1996, c. 1, Sched. G, s. 26 (1).

Exception

(6) Subsections (1), (2), (3) and (5) do not apply to a prescription that includes,

(a) in the case of a written prescription, the written words "no sub", "pas de rempl.", "no substitution" or "pas de remplacement"; or

(b) in any other case, a direction recorded by the dispenser that there be no substitution. R.S.O. 1990, c. P.23, s. 4 (6); 2016, c. 6, Sched. 1, s. 2.

Dispensing generic drug

5. If a prescription directs the dispensing of a drug for which there are interchangeable products without identifying a specific product name or manufacturer, the dispenser shall dispense an interchangeable product of that drug. R.S.O. 1990, c. P.23, s. 5; 1996, c. 1, Sched. G, s. 26 (1).

Maximum dispensing fee

6. (1) Every operator of a pharmacy shall set a single specific amount as a usual and customary dispensing fee and shall file a statement with the Registrar setting out that fee. R.S.O. 1990, c. P.23, s. 6 (1); 1996, c. 1, Sched. G, s. 22 (1).

Change of fee

(2) An operator of a pharmacy may change the usual and customary dispensing fee by filing a statement with the Registrar setting out the new fee. R.S.O. 1990, c. P.23, s. 6 (2); 1996, c. 1, Sched. G, s. 22 (2).

Effective date of fee

(3) The usual and customary dispensing fee becomes effective on the day the statement is received by the Registrar. R.S.O. 1990, c. P.23, s. 6 (3); 1996, c. 1, Sched. G, s. 22 (3).

Notify customers

(4) Every operator of a pharmacy shall post in the pharmacy, in the manner prescribed by the regulations, a notice containing the usual and customary dispensing fee filed with the Registrar and any other information prescribed by the regulations respecting the charge for interchangeable products. R.S.O. 1990, c. P.23, s. 6 (4); 1996, c. 1, Sched. G, ss. 22 (4), 26 (1).

Limit re dispensing fee

7. (1) A dispenser shall not charge, as a dispensing fee for supplying a drug product, more than the dispenser's usual and customary dispensing fee, unless a greater amount is provided for by the regulations. 1996, c. 1, Sched. G, s. 23.

Additional limit

(2) If a dispenser supplies a drug product that is an interchangeable product under this Act, the dispenser shall not charge, in addition to the dispensing fee, more than the lowest amount the dispenser would charge for the product dispensed or the products that are interchangeable with it in the dispenser's inventory. 1996, c. 1, Sched. G, s. 23.

Exception

(3) Subsection (2) does not apply if the person presenting the prescription has requested the dispensing of a particular interchangeable product or if the prescription includes a direction that there be no substitutions. 1996, c. 1, Sched. G, s. 23.

Same

(4) This section does not apply with respect to the supplying of a drug to which the *Ontario Drug Benefit Act* applies. 1996, c. 1, Sched. G, s. 23.

No liability for dispensing interchangeable products

8. If an interchangeable product is dispensed in accordance with this Act, no action or other proceeding lies or shall be instituted against the person who issued the prescription, the dispenser or any person who is responsible in law for the acts of either of them on the grounds that an interchangeable product other than the one prescribed was dispensed. R.S.O. 1990, c. P.23, s. 8; 1996, c. 1, Sched. G, s. 26 (1).

Dispense entire quantity

9. (1) Every person who dispenses a drug pursuant to a prescription shall dispense the entire quantity of the drug prescribed at one time unless before the drug is dispensed the person presenting the prescription in writing authorizes the dispensing of the drug in smaller quantities. R.S.O. 1990, c. P.23, s. 9 (1).

Exception

(2) Despite subsection (1), the regulations may authorize dispensing a drug in less than the entire quantity prescribed under specified conditions. R.S.O. 1990, c. P.23, s. 9 (2).

Idem

(3) The regulations may designate specific drugs that are to be exempt from the application of subsection (1). R.S.O. 1990, c. P.23, s. 9 (3).

Inform customer of cost of drugs

10. Every person who dispenses a drug pursuant to a prescription shall provide with the drug, in the manner prescribed by the regulations, particulars of the amount charged. R.S.O. 1990, c. P.23, s. 10.

Enforcement

11. The Ontario College of Pharmacists is responsible for the enforcement of this Act in respect of operators of pharmacies and dispensers in pharmacies. R.S.O. 1990, c. P.23, s. 11.

Inspectors

12. (1) The Ontario College of Pharmacists may appoint inspectors for the purpose of enforcing this Act. R.S.O. 1990, c. P.23, s. 12 (1).

Examine books

(2) An inspector may examine any records, in whatever form, in the possession or under the control of an operator of a pharmacy if the inspector believes on reasonable grounds that the records will assist the inspector in determining whether this Act and the regulations have been complied with. R.S.O. 1990, c. P.23, s. 12 (2).

Copies

(3) An inspector may, upon giving a receipt for it, take away a record for the purpose of making a copy, but the copy shall be made and the record shall be returned as promptly as reasonably possible. R.S.O. 1990, c. P.23, s. 12 (3).

Entry

(4) An inspector may at any reasonable time on producing proper identification enter any business premises where the inspector believes a record referred to in subsection (2) may be located for the purpose of an inspection. R.S.O. 1990, c. P.23, s. 12 (4).

Rebate, etc.

12.1 (1) A manufacturer shall not provide a rebate to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents,

(a) for any interchangeable product; or

(b) for any product in respect of which the manufacturer has made an application to the executive officer for designation as an interchangeable product, while that application is being considered. 2006, c. 14, s. 3.

Extended definition of "manufacturer"

(2) For the purposes of this section and in section 12.2, unless the context requires otherwise,

"manufacturer" includes a supplier, distributor, broker or agent of a manufacturer, except in,

(a) clause (1) (b) of this section,

(b) paragraph 2 of subsection (8) of this section,

(c) subsection (10) of this section, and

(d) clauses (b) and (c) of the definition of "drug benefit price" in subsection (14) of this section. 2006, c. 14, s. 3.

May not accept rebate

(3) No wholesaler, operator, company, director, officer, employee or agent mentioned in subsection (1) shall accept a rebate that is mentioned in subsection (1), either directly or indirectly. 2006, c. 14, s. 3.

Executive officer may make order

(4) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (5). 2006, c. 14, s. 3.

Calculation

(5) For the purposes of this section, the following rules apply to calculating the amount that is to be paid under subsection (4):

1. The amount shall be calculated by determining the difference between the expected value of all units of the drug products purchased and the actual cost of acquiring those units by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.

2. The expected value mentioned in paragraph 1 shall be determined by multiplying the drug benefit price by the volume of units provided by the manufacturer or wholesaler for all the products.

3. The actual cost of acquiring those products mentioned in paragraph 1 shall be determined by subtracting the monetary value of the rebate from the amount paid for all the products by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies. 2006, c. 14, s. 3.

Reconsideration

(6) Within 14 days of being served with the order, the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (5) is not correct, and the executive officer shall reconsider the order based on that evidence. 2006, c. 14, s. 3.

Actions of executive officer after reconsideration

(7) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision:

1. Affirm the order.

2. Rescind the order.

3. Vary the order. 2006, c. 14, s. 3.

Executive officer may act

(8) Where a manufacturer has not complied with an order under subsection (4) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (6) and the order has been affirmed or varied under subsection (7) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive

officer may either issue a further order under subsection (4) requiring the manufacturer to pay a revised amount calculated under subsection (5), or do either or both of the following:

1. If the drug that is the subject of the order is an interchangeable product, remove its designation.
2. Not make further designations of any of the manufacturer's products as interchangeable under this Act, or as listed drug products under section 1.3 of the *Ontario Drug Benefit Act*, nor consider any of its products for approval under section 16 of that Act, until such time as the executive officer is of the opinion that the manufacturer is no longer offering the rebate. 2006, c. 14, s. 3.

Limit on reconsideration

(9) Subsections (6) and (7) do not apply to a further order mentioned in subsection (8). 2006, c. 14, s. 3.

Required notice

(10) Where the executive officer proposes to act under paragraph 2 of subsection (8), the executive officer shall serve the manufacturer with at least 30 days notice. 2006, c. 14, s. 3.

Executive officer order where rebate accepted

(11) Where the executive officer believes, on reasonable grounds, that a person has accepted a rebate contrary to subsection (3), the executive officer may make an order requiring the person to pay to the Minister of Finance the amount calculated under subsection (5). 2006, c. 14, s. 3.

Reconsideration

(12) Subsections (6) and (7), subsection (8), other than paragraphs 1 and 2, and subsection (9) apply with any necessary modifications where an order has been made under subsection (11). 2006, c. 14, s. 3.

Lesser amount

(13) Despite any other provision of this section, the executive officer may, in an order under subsection (4) or (11), require the manufacturer or other person to pay an amount less than the amount calculated under subsection (5) and, where the executive officer does so, the following apply:

1. The executive officer shall set out in the order both the lesser amount and how it was calculated.
2. Any right of reconsideration that applies with respect to a calculation under subsection (5) applies with respect to the calculation under paragraph 1. 2006, c. 14, s. 3.

Definitions

(14) In this section,

"drug benefit price" means, with respect to a product,

(a) its drug benefit price under the *Ontario Drug Benefit Act*,

(b) in the case of a product that is not a benefit under the *Ontario Drug Benefit Act*, a price submitted by the manufacturer under the regulations that has been posted by the executive officer in the Formulary, or

(c) in the case of a product mentioned in clause (1) (b), the price submitted by the manufacturer; ("prix au titre du régime de médicaments")

"rebate", subject to the regulations, includes, without being limited to, currency, a discount, refund, trip, free goods or any other prescribed benefit, but does not include something provided in accordance with ordinary commercial terms. ("rabais") 2006, c. 14, s. 3; 2010, c. 1, Sched. 5, s. 1 (1).

Regulations

(15) The Lieutenant Governor in Council may make regulations clarifying the definition of "rebate" in this section, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition, clarifying how the calculations are to be made in this section and defining "ordinary commercial terms" for the purposes of that definition, including setting limits on ordinary commercial terms. 2010, c. 1, Sched. 5, s. 1 (2).

Rules re s. 12.1

12.2 (1) The following rules apply with regard to an order made or a notice given by the executive officer under section 12.1:

1. The order or notice must be in writing, and set out in brief the reason for which it is made.

2. An order must set out how any amount required to be paid under the order was calculated, specify any right of reconsideration that is available, and the time within which reconsideration is available.

3. In the case of an order or notice under section 12.1 that applies to a manufacturer, the order or notice may be served by leaving a copy of the document with an officer, director or agent of the manufacturer, or with an individual at any place of business of the manufacturer who appears to be in control or management of the place of business.

4. In the case of an order or notice under section 12.1 that applies to a person mentioned in subsection 12.1 (3), the order or notice may be served by leaving a copy of the document with the person if the person is an individual, or with an officer, director or agent of the person, or with an individual at any place of business of the person mentioned in subsection 12.1 (3) who appears to be in control or management of the place of business.

5. An order must specify the time period with respect to which the order is made, which may include a time period with respect to which a previous order was made, if the previous order has not been complied with.

6. An order must set out the time period in which the manufacturer or person mentioned in subsection 12.1 (3) is required to comply with the order.

7. An order must specify the consequences for failing to comply with the order. 2006, c. 14, s. 3.

Same, publication of enforcement action

(2) The executive officer may publish on the Ministry's website the corporate names of manufacturers or any other persons against whom the executive officer has taken action under section 12.1 and may also publish any information he or she considers appropriate about the action that has been taken. 2006, c. 14, s. 3.

No appeal

(3) There is no appeal from a decision or action of the executive officer under section 12.1, except as provided for in that section. 2006, c. 14, s. 3.

Offence

13. (1) Any person who,

(a) contravenes subsection 4 (2) (dispense product requested);

(b) contravenes subsection 4 (3) (inform customer of interchangeable product);

(c) contravenes section 5 (dispense interchangeable when generic prescribed);

(d) contravenes section 6 (usual and customary dispensing fee set and posted);

(e) contravenes section 7 (maximum allowable charge);

(f) contravenes section 9 (dispense entire quantity);

(g) contravenes section 10 (inform person of cost); or

(h) obstructs any person carrying out an inspection under section 12,

and any director or officer of a corporation who authorizes or permits such a contravention by a corporation is guilty of an offence under this Act and liable to a penalty of not more than $25,000. R.S.O. 1990, c. P.23, s. 13 (1); 1996, c. 1, Sched. G, ss. 24, 26 (1).

Idem

(2) The maximum penalty that may be imposed upon a corporation is $100,000 and not as provided in subsection (1). R.S.O. 1990, c. P.23, s. 13 (2).

Regulations

14. (1) The Lieutenant Governor in Council may make regulations,

(a) prescribing conditions to be met by products or by manufacturers of products in order to be designated as interchangeable with other products;

(b) prescribing conditions to be met for a product to continue to be designated as interchangeable;

(c) prescribing circumstances in which persons may charge more than their usual and customary dispensing fees;

(d) defining any word or expression used in this Act but not defined in this Act. 2004, c. 7, s. 7; 2006, c. 14, s. 4 (1).

(2)-(5) REPEALED: 2006, c. 14, s. 4 (3).

Regulations by college

(6) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council of the Ontario College of Pharmacists may make regulations,

(a) prescribing the manner in which persons shall be informed of the right to request an interchangeable product;

(b) prescribing the information to be included in a notice and the manner of posting a notice;

(c) authorizing dispensing a drug in less than the entire quantity prescribed and specifying the conditions under which that authority is to apply;

(d) designating specific drugs that are to be exempt from the application of subsection 9 (1);

(e) prescribing the information concerning cost to be provided on sale and how it is to be provided;

(f) requiring operators of pharmacies to retain specified records respecting their purchase of drugs for the purposes of this Act and prescribing the period of time those records shall be retained. 2004, c. 7, s. 7.

Same

(7) Where the Minister requests in writing that the Council of the Ontario College of Pharmacists make, amend or revoke a regulation under subsection (6) and the Council has failed to do so within 60 days after the request, the Lieutenant Governor in Council may make the regulation, amendment or revocation specified in the request. 2004, c. 7, s. 7.

General or particular

(8) A regulation made under this section may be general or particular in its application. 2004, c. 7, s. 7.

Retroactive

(9) A regulation is, if it so provides, effective with reference to a period before it is filed. 2006, c. 14, s. 4 (4).

Public consultation before making regulations

(10) The Lieutenant Governor in Council shall not make any regulation under subsection 12.1 (15) or clauses 14 (1) (a), (b) or (d) unless,

(a) the Minister has published a notice of the proposed regulation on the website of the Ministry and in any other format the Minister considers advisable;

(b) the notice complies with the requirements of this section;

(c) the time periods specified in the notice, during which members of the public may exercise a right described in clause (11) (b) or (c), have expired; and

(d) the Minister has considered whatever comments and submissions that members of the public have made on the proposed regulation in accordance with clause (11) (b) or (c) and has reported to the Lieutenant Governor in Council on what, if any, changes to the proposed regulation the Minister considers appropriate. 2006, c. 14, s. 4 (5).

Contents of notice

(11) The notice mentioned in clause (10) (a) shall contain,

(a) a description of the proposed regulation and the text of it;

(b) a statement of the time period during which members of the public may submit written comments on the proposed regulation to the Minister and the manner in which and the address to which the comments must be submitted;

(c) a description of whatever other rights, in addition to the right described in clause (b), that members of the public have to make submissions on the proposed regulation and the manner in which and the time period during which those rights must be exercised;

(d) a statement of where and when members of the public may review written information about the proposed regulation; and

(e) all other information that the Minister considers appropriate. 2006, c. 14, s. 4 (5).

Time period for comments

(12) The time period mentioned in clauses (11) (b) and (c) shall be at least 30 days after the Minister gives the notice mentioned in clause (10) (a) unless the Minister shortens the time period in accordance with subsection (13). 2006, c. 14, s. 4 (5).

Shorter time period for comments

(13) The Minister may shorten the time period if, in the Minister's opinion,

(a) the urgency of the situation requires it;

(b) the proposed regulation clarifies the intent or operation of this Act or the regulations; or

(c) the proposed regulation is of a minor or technical nature. 2006, c. 14, s. 4 (5).

Discretion to make regulations

(14) Upon receiving the Minister's report mentioned in clause (10) (d), the Lieutenant Governor in Council, without further notice under subsection (10), may make the proposed regulation with the changes that the Lieutenant Governor in Council considers appropriate, whether or not those changes are mentioned in the Minister's report. 2006, c. 14, s. 4 (5).

No review

(15) Subject to subsection (16), a court shall not review any action, decision, failure to take action or failure to make a decision by the Lieutenant Governor in Council or the Minister under subsections (10) to (14). 2006, c. 14, s. 4 (5).

Exception

(16) Any person resident in Ontario may make an application for judicial review under the *Judicial Review Procedure Act* on the grounds that the Minister has not taken a step required by subsections (10) to (14). 2006, c. 14, s. 4 (5).

Time for application

(17) No person shall make an application under subsection (16) with respect to a regulation later than 21 days after the day on which the Minister publishes a notice with respect to the regulation under clause (10) (a). 2006, c. 14, s. 4 (5).

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