PRINCE EDWARD ISLAND
ÎLE-DU-PRINCE-ÉDOUARD

DRUG PRODUCT INTERCHANGEABILITY AND PRICING ACT

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For more information concerning the history of this Act, please see the ***Table of Public Acts*** on the Prince Edward Island Government web site (www.princeedwardisland.ca).

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DRUG PRODUCT INTERCHANGEABILITY AND PRICING ACT

Table of Contents

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CHAPTER D-15

1. Definitions

In this Act,

(a) "**drug**" means a drug as defined in the *Pharmacy Act* R.S.P.E.I. 1988, Cap. P-6.1;

(b) "**drug product**" means a drug or combination of drugs in a particular dosage form and strength identified by a specific product name or manufacturer;

(c) "**formulary**" means the formulary established under section 12;

(d) "**interchangeable drug product**" means a drug product designated as interchangeable by the Minister under section 6;

(e) "**interchangeable drug product list**" means the interchangeable drug product list referred to in section 2;

(f) "**manufacturer**" means a manufacturer of a drug product and for the purposes of section 13 includes a supplier, distributor, broker or agent of a manufacturer;

(g) "**Minister**" means the Minister of Health and Wellness;

(h) "**regulations**" means regulations made under this Act. *2012,c.12,s.1; 2014,c.39,s.61(2).*

PART I

Interchangeable Drug Product List

2. Interchangeable drug product list

(1) The Minister shall establish an interchangeable drug product list for the purpose of designating certain drug products as interchangeable with other drug products where each interchangeable drug product contains the same active ingredients in the same dosage form and strength as the drug product for which it may be interchanged.

Duties and powers of Minister

(2) The Minister, in accordance with this Act,

(a) shall maintain and publish the interchangeable drug product list;

(b) may, with respect to the interchangeable drug product list,

(i) designate a drug product as being interchangeable with another drug product in accordance with section 6,

(ii) refuse to designate a drug product as interchangeable in accordance with section 7,

(iii) remove a drug product's interchangeable designation in accordance with section 8, or

(iv) place a caution on a drug product's interchangeable designation in accordance with subsection 3(2).

Delegation

(3) The Minister may delegate the Minister's powers and duties under subsection (2) and sections 3 to 8 to an employee of the Department of Health and Wellness.

Exception

(4) Notwithstanding subsection (1), the Minister may determine that drug products having the same route of administration but different dosage forms are interchangeable. *2012,c.12,s.2.*

3. Interchangeability

(1) A drug product becomes interchangeable with another drug product on the effective date of its designation by the Minister, and ceases to be interchangeable with that drug product on the effective date of the removal of its designation by the Minister.

Caution

(2) Where the Minister considers it in the public interest to do so, the Minister may place a caution on an interchangeable drug product, including a caution that the drug product is interchangeable only in the treatment of a specific illness or condition. *2012,c.12,s.3.*

4. Notice to manufacturer

Where the Minister designates a drug product as interchangeable, removes an interchangeable designation from a drug product or places a caution on an interchangeable drug product, the Minister shall in writing notify the manufacturer of the drug product of the action taken and its effective date. *2012,c.12,s.4.*

5. Required documentation

For each strength and dosage form of a drug product that a manufacturer wishes to be considered for designation as interchangeable, the manufacturer shall submit to the Minister the following information:

(a) a copy of the Notice of Compliance issued by Health Canada or, for drug products without a Notice of Compliance, the Drug Notification Form;

(b) a copy of the product monograph approved by Health Canada;

(c) a letter authorizing the Minister to exchange information concerning the drug product with representatives of

(i) Health Canada,

(ii) the Patented Medicine Prices Review Board,

(iii) the Canadian Agency for Drugs and Technologies in Health,

(iv) the government of any Canadian province or territory or a body in any province or territory with responsibility for interchangeability of drug products,

(v) Canadian federal government drug programs, and

(vi) Health PEI;

(d) evidence that the manufacturer is able to supply the drug product in quantities sufficient to meet the anticipated demand in the province;

(e) evidence that

(i) the dosage form, strength, formula, manufacturing process and testing standards of the submitted drug product are identical to those of the original drug product to which it is compared,

(ii) Health Canada has designated the submitted drug product as being equivalent to the original drug product to which it is compared through designation of the original drug product as the Canadian Reference Product under the *Food and Drug Regulations* (Canada), or

(iii) comparative bioavailability studies on humans, comparative clinical studies on humans or other in vivo studies demonstrate the bioequivalence of the submitted drug product with the original drug product to which it is compared;

(f) a cover letter or executive summary of the information respecting the submission;

(g) the name and contact information of a person who may be contacted regarding the submission;

(h) the manufacturer's current list prices for all drug dosage forms and strengths of the drug product. *2012,c.12,s.5.*

6. Criteria for designation

The Minister may designate a drug product as interchangeable

(a) where the Minister is satisfied that

(i) the dosage form, strength, formula, manufacturing process and testing standards of the drug product are identical to those of the original drug product to which it is compared,

(ii) Health Canada has designated the drug product as being equivalent to the original drug product to which it is compared through designation of the original drug product as the Canadian Reference Product under the *Food and Drug Regulations* (Canada),

(iii) the drug product is designated as an interchangeable drug product in another Canadian jurisdiction and is available for purchase by pharmacies in the province, or

(iv) the drug product is shown to be the equivalent of the original drug product by means of comparative bioavailability studies on humans, comparative clinical studies on humans or other in vivo studies that demonstrate the bioequivalence of the submitted drug product with the original drug product to which it is compared; or

(b) as set out in the regulations. *2012,c.12,s.6.*

7. Refusal, grounds

The Minister may, notwithstanding that a manufacturer has complied with section 5, refuse to designate a drug product as interchangeable or remove the drug product's interchangeable designation if

(a) the Minister is satisfied that the manufacturer has provided false or incomplete information; or

(b) the Minister considers it advisable in the public interest to do so. *2012,c.12,s.7.*

8. Immediate removal of designation

(1) The Minister shall immediately remove the interchangeable designation from a drug product where the Minister considers it advisable in the public interest to do so.

Removal of designation

(2) The Minister may remove the interchangeable designation from a drug product on receipt of:

(a) a notification from the manufacturer that the sale of the drug product in Canada has been discontinued;

(b) a notification from Health Canada or the manufacturer that all other products that the drug product is designated as being interchangeable with have been discontinued by the manufacturer or are no longer approved for sale in Canada; or

(c) a notification from Health Canada that it has withdrawn its approval for the sale of the drug product in Canada. *2012,c.12,s.8.*

9. Circulation and posting of interchangeable drug product list

The Minister shall ensure that the interchangeable drug product list is posted on the government website and any changes or amendments made to it are circulated to all pharmacies, the Prince Edward Island Pharmacists Association, the College of Pharmacists and the College of Physicians and Surgeons in the province. *2012,c.12,s.9; 2014,c.39,s.61(3).*

10. Agreements

(1) Notwithstanding section 2, the Minister may enter into an agreement with any agency or person for the provision and maintenance of an interchangeable drug product list by that agency or person.

Compliance with Part I, etc.

(2) An agency or person who provides and maintains an interchangeable drug product list under an agreement with the Minister pursuant to subsection (1) shall ensure that the agency or person does so in accordance with the requirements of Part I of this Act and the regulations. *2012,c.12,s.10.*

PART II

Formulary and Pricing

11. Definitions

In this Part,

(a) "**maximum reimbursable price**" means the maximum price that will be reimbursed for a drug product or supplies listed in the formulary;

(b) repealed by *2014,c.39,s.61(4). 2012,c.12,s.11; 2014,c.39,s.61(4).*

12. Formulary

(1) The Minister shall establish and maintain a formulary which shall contain

(a) a list of drug products, including interchangeable drug products and supplies that are benefits for the purposes of the *Drug Cost Assistance Act* R.S.P.E.I. 1988, Cap. D-14, or any other drug benefit program of the province; and

(b) policies to govern selection where those drug products or supplies are dispensed for the purposes of the *Drug Cost Assistance Act* or another drug benefit program of the province.

Drug benefit price

(2) The Minister shall determine the maximum reimbursable price for each listed drug product and supplies in the formulary.

Agreements

(3) Notwithstanding subsection (1), the Minister may enter into an agreement with any agency or person for the provision and maintenance of a formulary by that agency or person.

Compliance with standards, etc.

(4) An agency or a person who provides and maintains a formulary under an agreement with the Minister pursuant to subsection (3) shall ensure that the formulary meets

(a) any standards or requirements respecting content or format established by the Minister; and

(b) the requirements of this Act.

Circulation of formulary

(5) The Minister shall ensure that the formulary is posted on the government website and any changes or amendments made to it are circulated to all pharmacies, the Prince Edward Island Pharmacists Association, the College of Pharmacists and the College of Physicians and Surgeons in the province.

Exemption from liability

(6) No action lies against a prescriber as defined in the *Pharmacy Act* R.S.P.E.I. 1988, Cap. P-6.1 or a person who dispenses a drug product or supplies on the grounds that a drug product or supplies other than that prescribed was dispensed for the purposes of the *Drug Cost Assistance Act*, or another provincial drug benefit program, in accordance with the formulary. *2012,c.12,s.12; 2014,c.39,s.61(3),(5).*

13. Maximum price to operator of pharmacy

(1) Subject to subsections (2) and (3), in order for an interchangeable drug product or a category of interchangeable drug products to be listed and to remain listed in the formulary, the cost from a manufacturer to the operator of a pharmacy for an interchangeable drug product or a category of interchangeable drug products shall not exceed the percentage of the manufacturer's list price for the original drug product, as of the date prescribed in the regulations, as set by the Minister by order.

Exception

(2) An interchangeable drug product that does not meet the criteria set out in subsection (1) may be listed in the formulary, and the Minister may by order, in the circumstances set out in the regulations, set a maximum cost from the manufacturer to the operator of a pharmacy for the interchangeable drug product or category of interchangeable drug products that exceeds the percentage of the manufacturer's list price referred to in subsection (1).

Criteria respecting maximum cost

(3) The Minister, in setting the percentage of a manufacturer's list price for the purposes of subsection (1), shall consider the circumstances and the criteria, if any, set out in the regulations.

Prescribed date

(4) For the purposes of subsection (1), the date prescribed by the regulations may be a date prior to the coming into force of this section. *2012,c.12,s.13.*

14. Interchangeable drug product cost increases

If the cost to the operator of a pharmacy of an interchangeable drug product listed in the formulary increases, the Minister may require the manufacturer to provide documentation satisfactory to the Minister to support the cost increase in order to maintain the interchangeable drug product's status in the formulary. *2012,c.12,s.14.*

15. Regulations

The Lieutenant Governor in Council may make regulations

(a) prescribing criteria for designating a drug product as interchangeable for the purposes of clause 6(b);

(b) prescribing the date as of which the maximum cost to the operator of a pharmacy for an interchangeable drug product or a category of interchangeable drug products for the purposes of subsection 13(1) shall be set;

(c) respecting the circumstances in which the Minister may set a new maximum cost to the operator of a pharmacy for the purposes of subsection 13(2);

(d) defining any word or phrase used but not defined in this Act;

(e) respecting the criteria, including the maximum increase in percentage for a year or other period, and circumstances for the purposes of subsection 13(3);

(f) respecting such other matters as the Lieutenant Governor in Council considers necessary to give effect to the purposes of this Act. *2012,c.12,s.15.*

PART III

Interchangeable Drug Product Substitution

16. Definitions

(1) In this part,

(a) "**dispense**" means dispense as defined in the *Pharmacy Act*;

(b) "**patient**" means the person for whom a prescription has been given by a prescriber;

(c) "**pharmacist**" means a person who is registered as a pharmacist with the College of Pharmacists;

(d) "**prescriber**" means a prescriber as defined in the *Pharmacy Act*;

(e) "**prescription**" means a prescription as defined in the *Pharmacy Act.*

Application of part

(2) This part applies only with respect to prescriptions submitted to a pharmacy regulated under the *Pharmacy Act* or the Provincial Pharmacy. *2014,c.39,s.61(6).*

17. Interchangeable drug product

(1) Before a drug product specified in a prescription is dispensed, a pharmacist shall determine whether any interchangeable drug products may be substituted for that drug product, except where the prescriber has, in accordance with section 18, instructed that an interchangeable drug product should not be substituted for the drug product specified in the prescription.

Explanation

(2) Where a pharmacist determines under subsection (1) that an interchangeable drug product may be substituted for the drug product specified in a prescription, the pharmacist shall explain to the patient or a representative of the patient

(a) the nature of the interchangeable drug product list;

(b) the relative prices of the drug product specified in the prescription and any interchangeable drug products that may be substituted for that drug product; and

(c) that the patient or a representative of the patient may request the substitution of an interchangeable drug product for the drug product specified in the prescription.

Substitution requested

(3) Where, after receiving the explanation required under subsection (2) or on his or her own initiative, a patient or a representative of a patient requests the substitution of an interchangeable drug product for the drug product specified in a prescription, the pharmacist shall, subject to section 18, dispense the interchangeable drug product requested by the patient or a representative of the patient.

Substitution not requested

(4) Where, after receiving the explanation required under subsection (2), a patient or the representative of a patient does not request the substitution of an interchangeable drug product for the drug product specified in a prescription, the pharmacist shall dispense the drug product specified in the prescription. *2014,c.39,s.61(6).*

18. Written provision for no substitutions

(1) Where a prescriber is of the opinion that an interchangeable drug product should not be substituted for the drug product specified in a written prescription, the prescriber shall clearly write on the prescription the words "No Substitution".

Oral or electronic provision for no substitutions

(2) Where a prescriber is of the opinion that an interchangeable drug product should not be substituted for the drug product specified in a prescription given verbally or by electronic transmission, the prescriber shall give such an instruction each time a prescription is so given.

Duty of pharmacist

(3) A pharmacist shall comply with the instructions of a prescriber given in accordance with subsection (1) or (2) when dispensing the prescription initially and when dispensing any refills of the same prescription, unless the prescriber otherwise instructs. *2014,c.39,s.61(6).*

19. Conflict with formulary

Notwithstanding section 17 or 18, where

(a) a pharmacist is dispensing a drug product for a person who is eligible for benefits under the *Drug Cost Assistance Act* R.S.P.E.I. 1988, Cap. D-14 or another drug benefit program of the province; and

(b) there is a conflict between what is required under a provision of section 16 or 17 and the formulary,

the pharmacist shall comply with the requirements of the formulary to the extent of the conflict. *2014,c.39,s.61(6).*

20. Exemption from liability

No action lies against a prescriber or a pharmacist on the grounds that an interchangeable drug product that may be substituted for the drug product specified in a prescription was dispensed or not dispensed in accordance with this part. *2014,c.39,s.61(6).*