



## **PLEASE NOTE**

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This document is *not* the official version of these regulations. The regulations and the amendments printed in the [Royal Gazette](#) should be consulted to determine the authoritative text of these regulations.

For more information concerning the history of these regulations, please see the [Table of Regulations](#).

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## CHAPTER P-6

### PHARMACY ACT

#### INTERCHANGEABLE DRUG LIST REGULATIONS

Pursuant to section 28.2 of the *Pharmacy Act* R.S.P.E.I. 1988, Cap. P-6, Council made the following regulations:

1. In these regulations
- |  | Definitions                  |
|--|------------------------------|
| (a) “interchangeable drug product” means a drug product listed on the interchangeable drug list established under subsection 28.1(1) of the Act; | interchangeable drug product |
| (b) “patient” means a person for whom a drug product is prescribed;  | patient                      |
| (c) “prescriber” means   | prescriber                   |
| (i) a physician licensed under the <i>Medical Act</i> R.S.P.E.I. 1988, Cap. M-5,   |                              |
| (ii) a dentist licensed under the <i>Dental Profession Act</i> R.S.P.E.I. 1988, Cap. D-6, or   |                              |
| (iii) any other person authorized by the Minister to prescribe a drug;   |                              |
| (d) “representative” means an adult who attends a pharmacy on behalf of a patient to obtain a drug product for the patient. (EC288/05)           | representative               |

#### INTERCHANGEABLE DRUG LIST COMMITTEE

2. (1) The term of appointment of members to the Committee shall be up to three years.
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|--|----------------------------|
|  | Terms of Committee members |
|--|----------------------------|
- (2) Committee members may be re-appointed. (EC288/05)
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|--|----------------|
|  | Re-appointment |
|--|----------------|
3. Three members of the Committee shall constitute a quorum. (EC288/05)
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|--|--------|
|  | Quorum |
|--|--------|
4. (1) A Committee member may resign at any time by giving written notice to the Minister.
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|--|--------------|
|  | Registration |
|--|--------------|
- (2) The Minister may terminate the appointment of a Committee member by providing written notice to the Committee member where the Committee member
- |  |                         |
|--|-------------------------|
|  | Termination by Minister |
|--|-------------------------|
- (a) has ceased to be a resident of the province;
- (b) has failed to declare the Committee member’s conflict of interest in the matter pursuant to section 5; or

(c) has had the Committee member's license suspended or revoked by an appropriate regulatory body pursuant to clauses 28(2)(a) or (b) of the Act. (EC288/05)

- Conflict of interest **5.** Where a Committee member knows or ought reasonably to know that he or she may be in a conflict of interest with respect to a matter before the Committee, that Committee member shall
- (a) declare his or her interest at the outset of that meeting; and
  - (b) refrain from voting on that matter. (EC288/05)

#### INTERCHANGEABLE DRUG LIST

- Interchangeable drug list **6.** Before making any recommendations to the Minister with respect to the establishment of the interchangeable drug list, the Committee shall review the interchangeable drug lists of other jurisdictions and the drug products currently listed as being interchangeable by Prince Edward Island drug benefit plans in the province. (EC288/05)
- Ministerial review **7.** The Minister shall review the recommendations of the Committee and may
- (a) approve the Committee's recommendations;
  - (b) add further drug products to the list recommended by the Committee; or
  - (c) remove drug products from the interchangeable drug list recommended by the Committee where the Minister considers it is in the public interest to do so. (EC288/05)
- Caution **8.** Where the Minister considers it is in the public interest to do so, the Minister shall place a caution on a drug product on the list, including a caution that the drug product is interchangeable only in the treatment of a specific illness or condition. (EC288/05)
- Prescription drugs **9.** Only Schedule I drugs shall be included in the interchangeable drug list. (EC288/05)
- Required documentation **10.** (1) For each strength and dosage form of a drug product that a manufacturer wishes to be considered for inclusion on the interchangeable drug list, the manufacturer shall submit to the Committee the following documentation:
- (a) a copy of the Notice of Compliance issued by Health Canada;
  - (b) a copy of the product monograph approved by Health Canada;
  - (c) a letter authorizing the Committee to exchange information concerning the drug product with representatives of
    - (i) the government of Prince Edward Island,
    - (ii) Health Canada,
    - (iii) the Patented Medicine Prices Review Board,

- (iv) the Canadian Coordinating Office for Health Technology Assessment,
  - (v) the government of any Canadian province or territory or body in any province or territory with responsibility for the interchangeability of drug products,
  - (vi) Canadian federal government drug programs,
  - (vii) health authorities in the province;
- (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 the drug product is currently listed in the *Compendium of Pharmaceuticals and Specialties*, or a letter of intent to have the drug product so listed;
- (f) evidence showing 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 both, or other *in vivo* studies, show the interchangeability of the submitted drug product with the original drug product to which it is compared.
- (2) Where the requirement in clause 10(1)(b) cannot be met because Health Canada has not approved a product monograph for the drug product being submitted to the Committee by the manufacturer, the manufacturer shall submit the following to the Committee: Exception
- (a) pharmaceutical information;
  - (b) information with respect to the clinical pharmacology of the drug product;
  - (c) information with respect to the indications and clinical use of the drug product;
  - (d) a list of any contraindications, warnings, or precautions in the use of the drug product and possible adverse reactions to its use;
  - (e) a list of symptoms of an overdose of the drug product and information with respect to the treatment of an overdose;
  - (f) information with respect to the dosage and administration of the drug product;
  - (g) information with respect to the availability of dosage forms for each strength of the drug product marketed in Canada. (EC288/05)

- Committee recommendation
- 11.** The Committee may recommend to the Minister that a drug product be placed on the interchangeable drug list where
- (a) 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;
  - (b) the drug product is designated by Health Canada as being equivalent to the original product the drug product is being compared with, through designation of the original drug product as the Canadian Reference Product under the Food and Drug Regulations (Canada);
  - (c) 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
  - (d) the drug product is shown, to the satisfaction of the Committee, in comparative bioavailability studies on humans, comparative clinical studies on humans, or both, or other *in vivo* studies, to be the equivalent to the original product. (EC288/05)
- Refusal in public interest
- 12.** On receipt of a recommendation from the Committee for the placement of a drug product on the interchangeable list, the Minister may, notwithstanding the recommendation, refuse to place the drug product on the interchangeable drug list if the Minister considers it advisable, in the public interest, to do so. (EC288/05)
- Immediate removal of drug product
- 13.** (1) The Minister shall immediately remove a drug product from the interchangeable drug list where
- (a) Health Canada has withdrawn its approval for the sale of the drug product in Canada; or
  - (b) the Minister considers it advisable in the public interest to do so.
- Removal of drug product within 180 days
- (2) The Minister shall remove a drug product from the interchangeable drug list within 180 days of receipt of either:
- (a) a notification from the manufacturer that the sale of the drug product in Canada has been discontinued; or
  - (b) a notification from Health Canada or the manufacturer that all other products that the drug product is listed as being interchangeable with have been discontinued by the manufacturer or are no longer approved for sale in Canada. (EC288/05)
- Circulation and posting of interchangeable drug list
- 14.** The Minister shall cause the interchangeable drug list and any changes made to it to be
- (a) circulated to all pharmacies and all physicians in the province; and
  - (b) posted on the government website. (EC288/05)

**RULES FOR PRESCRIBING AND DISPENSING  
INTERCHANGEABLE DRUG PRODUCTS**

**15.** (1) Where a prescriber of a written prescription is of the opinion that a drug product other than the one specified in the written prescription should not be substituted, the prescriber shall clearly write on the prescription the words “No Substitution”.

Written provision  
for no substitutions

(2) Where a prescriber of a prescription by oral or electronic transmission is of the opinion that a drug product other than the one specified in the prescription should not be substituted, the prescriber shall instruct accordingly each time a prescription is transmitted.

Oral or electronic  
provision for no  
substitutions

(3) A pharmacist shall follow the prescriber’s instructions not to select a drug product other than the one specified in the prescription when filling the initial prescription and when filling any refills of the same prescription, unless the prescriber otherwise instructs. (EC288/05)

Pharmacists’ duties

**16.** Where a prescriber fails to indicate, in accordance with subsection 15(1) or (2), that there may be no substitution for the drug product specified in a prescription, the pharmacist filling the prescription shall

Substitutions

(a) dispense the lowest-priced drug product that is listed on the interchangeable drug list as a drug product that may be used interchangeably with the drug product specified in the prescription;  
or

(b) if the drug product referred to in clause (a) is not available due to the inability or failure of the manufacturer to supply the drug product, dispense

(i) the drug product specified in the prescription, or

(ii) any other drug product that is listed on the interchangeable drug list as a drug product that may be used interchangeably with the drug product specified in the prescription,

at the price of the second lowest-priced drug product on the list that may be used interchangeably with the drug product specified in the prescription. (EC288/05)

**17.** Where a drug product other than the drug product specified in the prescription is dispensed, the pharmacist shall inform the patient or the patient’s representative that an interchangeable drug product has been dispensed. (EC288/05)

Information  
regarding  
interchangeable  
drug products

**18.** (1) Notwithstanding anything to the contrary in section 16, a patient may, in person or through a representative,

Patient’s right to  
refuse

(a) refuse to accept a drug product listed on the interchangeable drug list in substitution for the drug product prescribed by a prescriber; or

(b) request the substitution, for the drug product prescribed by a prescriber, for a drug product on the list other than the lowest-priced interchangeable drug.

Pharmacist's duties

(2) Where the patient has refused a substitute or requested a substitute other than the lowest-priced, the pharmacist shall explain

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

(b) the relative prices of the drug product specified in the prescription and the interchangeable drug product listed on the interchangeable drug list.

Dispensing drug  
chosen by patient

(3) If, following the explanation by the pharmacist required under subsection (2), the patient maintains his or her refusal or request referred to in subsection (1), the pharmacist shall dispense the drug product chosen by the patient, at the cost of the drug product chosen by the patient. (EC288/05)

Offence

**19.** The Board shall consider, under section 17 of the Act, a contravention of these regulations by a pharmacist to be improper professional conduct. (EC288/05)