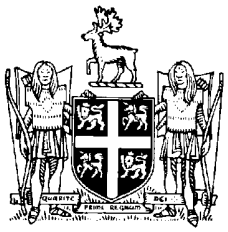

THE NEWFOUNDLAND AND LABRADOR GAZETTE

EXTRAORDINARY

Part II

PUBLISHED BY AUTHORITY

ST. JOHN'S, FRIDAY, MARCH 30, 2012

NEWFOUNDLAND AND LABRADOR REGULATION

NLR 23/12

NEWFOUNDLAND AND LABRADOR
REGULATION 23/12

Interchangeable Drug Products Formulary Regulations, 2012
under the
Pharmaceutical Services Act

(Filed March 30, 2012)

Under the authority of sections 19 and 52 of the *Pharmaceutical Services Act*, I make the following regulations.

Dated at St. John's, March 30, 2012.

Bruce Cooper
Deputy Minister of Health and Community Services

REGULATIONS

Analysis

Short title

1. These regulations may be cited as the *Interchangeable Drug Products Formulary Regulations, 2012.*

Definitions

2. In these regulations

(a) "Act" means the *Pharmaceutical Services Act*;

(b) "advisory committee" means the advisory committee appointed under the authority of section 20 of the Act to advise on the contents of the formulary and other matters relating to drugs;

(c) "brand price" means the price for a drug established by the brand manufacturer as recorded by the department at the time a submission for listing on the drug formulary is received;

(d) "formulary" means the drug formulary defined in paragraph 2(h) of the Act which is established by and is on file with the minister;

(e) "inventory adjustment fee" means a percentage set by the minister under the authority of section 50 of the Act which may be included in the price which may be charged for a drug accepted to be listed in the formulary; and

(f) "ultra-generic product" means a drug manufactured and packaged for a generic manufacturer which is identical to a brand manufacturer's product in every way, including its production, except for

(i) identifying markings,

(ii) product labelling,

(iii) the name of the manufacturer, and

(iv) the product trade name.

Drug formulary

3. (1) The Interchangeable Drug Products Formulary is continued and is on file with the minister.

(2) A copy of the formulary is available on the departmental website and may also be obtained from the office of the minister.

(3) The prices set out in the formulary for interchangeable drugs shall be effective for the period specified by the minister in the formulary.

Submission requirements

4. An applicant shall provide the following before the advisory committee will consider its submission for a drug to be included in the formulary:

(a) a list of the applicable Health Canada guidance documents on the assessment of bioavailability and bioequivalence of the drug;

(b) confirmation that the drug will be sold at the maximum price established under section 5, or where the percentage of savings is greater than required under that section, details of those savings and a guarantee of that price for the time period required by the minister;

(c) the quoted price for the drug, which shall be quoted in smallest unit pricing irrespective of package size;

(d) where a Notice of Compliance from Health Canada

(i) has been issued, a copy of that notice, or

(ii) has not been issued, a copy of the Drug Notification form;

(e) confirmation satisfactory to the committee that the applicant is able to supply the drug to meet the needs of the market for that drug throughout the entire province;

(f) consent permitting the province to contact Health Canada and other federal, provincial or territorial departments or agencies for additional information where necessary;

(g) a completed request for generic drug substitution in the form prescribed by the minister;

(h) a product sample for any drug contained in a device or apparatus for the purpose of drug delivery;

(i) where the submission relates to an ultra-generic or cross licensed drug, confirmation of the business arrangement from the company with whom the business arrangement is in place; and

(j) where a drug has not been launched at the time of the application, the anticipated launch date.

Maximum price for interchangeable products

5. (1) The price for a product listed in the formulary shall not exceed the maximum price as set out in the following table as of the applicable dates:

Date	Maximum Price
From April 16, 2012 to September 30, 2012	45% of the brand price
From October 1, 2012 to March 31, 2013	40% of the brand price
From April 1, 2013 onward	35% of the brand price

(2) Where, at the coming into force of this section, a drug is listed on the formulary which

(a) is a sole source product; or

(b) is a generic drug for which the equivalent brand product has been discontinued,

the manufacturer of that drug may, notwithstanding subsection (1), maintain the price listed in the formulary at the coming into force of this section until July 1, 2012, but after that date shall comply with the requirements of subsection (1) with respect to the maximum price of that drug unless an exemption is allowed under section 6.

Exemption

6. (1) Notwithstanding subsection 5(1), an applicant may apply to the minister to have a drug included in the formulary which does not meet the pricing requirements of that subsection, and the minister may allow that exemption where

(a) the brand name product has been discontinued; or

(b) in the opinion of the minister, the applicant has incurred extraordinary production, manufacturing or development costs for the drug, as demonstrable to the satisfaction of the minister.

(2) The minister may request and the applicant shall provide the information the minister considers necessary for the purpose of evaluating an application for an exemption under subsection (2).

(3) The minister may impose conditions on an exemption granted under this section, and may limit the time period for which the exemption is granted.

(4) Where an application for an exemption has been approved under subsection (1), the advisory committee may consider that drug for inclusion in the formulary provided that all other requirements of section 4 are met.

Pricing of drugs within categories

7. (1) In accordance with section 21 of the Act, the minister may establish categories of drugs which are included in the formulary and may set the price which shall be charged for drugs within a category.

(2) The price of drugs in drug categories shall be the price charged on the date specified by the minister in the formulary, or where no date is specified, as of the effective date of the formulary.

(3) The price set under subsection (1) may include an inventory adjustment fee set by the minister.

Addition to existing categories

8. (1) Notwithstanding section 5**,** where a submission relates to an addition to an existing category and

(a) a brand manufacturer lowers its price after the drug becomes interchangeable; or

(b) the brand drug has been discontinued,

a submission received after that time shall include a price for the product which is less than or equal to the current lowest price in that category.

(2) Where a drug is approved for addition to an existing category under subsection (1), it shall not be included in a supplement to the formulary but shall be added to the formulary at its next publication.

Review process

9. (1) Where a submission for inclusion of a drug in the formulary meets the requirements in section 4, it shall be considered by the advisory committee according to either

(a) the standard review process; or

(b) the expert review process.

(2) The standard review process shall be employed for

(a) drugs with a Health Canada Declaration of Equivalence to a Canadian reference product;

(b) all ultra-generic drugs; and

(c) all cross-licensed drugs where the other drug is currently listed in the formulary.

(3) Drugs

(a) not falling within paragraphs (2)(a) to (c); or

(b) which have been reviewed under the standard review process and about which the committee has a clinical concern

shall be referred by the advisory committee for expert analysis of bioequivalence, bioavailability and other applicable data before the drugs may be considered by the advisory committee under the expert review process.

(4) The expert review process shall be employed for completed submissions for

(a) drugs without a Health Canada Declaration of Equivalence to a Canadian reference product; or

(b) any drug which has been reviewed under the standard review process about which the advisory committee has concerns and requires a further review under the expert review process.

(5) A submission to the expert review process shall include bioequivalence and bioavailability studies relating to the drug that is the subject of the submission, and any other information that the committee may require to assess the drug.

(6) In addition to the submission requirements noted in section 4, the advisory committee shall, in assessing a drug for inclusion in the formulary, consider

(a) the definition of interchangeable drug products as set out in the Act;

(b) whether the drug is of consistent satisfactory quality and safety;

(c) any clinical concerns raised to or by the advisory committee; and

(d) those other matters which the advisory committee considers necessary in the review process.

Advisory committee recommendation

10. (1) Where the advisory committee has approved a drug under the standard review process or the expert review process, as appropriate, the committee shall recommend to the minister that the drug be included in the formulary.

(2) Where the advisory committee does not approve a drug under the standard review process or the expert review process, as appropriate, the committee shall recommend to the minister that it not be included in the formulary.

Notification of change to a drug

11. Where a manufacturer makes a change to a drug listed in the formulary that requires the approval of Health Canada, the manufacturer, immediately after receipt of the approval of Health Canada, shall notify the advisory committee of the change.

Repeal

12. The *Interchangeable Drug Products Formulary Regulations, 2007,* Newfoundland and Labrador Regulation 125/07, are repealed.

Commencement

13. These regulations come into force on April 16, 2012.

Extraordinary Gazette Index

Title of Act and Subordinate Legislation made thereunder	CNLR or NL Reg.	Amendment	XNL Gazette Date & Page No.	
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