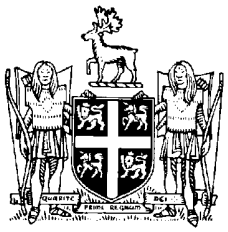

THE NEWFOUNDLAND AND LABRADOR GAZETTE

EXTRAORDINARY

Part II

PUBLISHED BY AUTHORITY

ST. JOHN'S, MONDAY, FEBRUARY 10, 2014

NEWFOUNDLAND AND LABRADOR REGULATION

NLR 10/14

NEWFOUNDLAND AND LABRADOR
REGULATION 10/14

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

(Filed February 10, 2014)

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

Dated at St. John's, February 10, 2014.

Susan Sullivan
Minister of Health and Community Services

REGULATIONS

Analysis

NLR 23/12 as amended

1. Section 2 of the *Interchangeable Drug Products Formulary Regulations, 2012* is amended by adding immediately after paragraph (c) the following:

(c.1) "cross licensed drug" means a drug that is the subject of an agreement between 2 companies where one company supplies a drug product to another company for sale under the second company's name;

2. (1) Paragraph 4(a) of the regulations is repealed.

(2) Paragraph 4(e) of the regulations is repealed and the following substituted:

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

3. Section 9 of the regulations is repealed and the following substituted:

Review processes

9. (1) Where a drug meets the submission requirements of section 4 it shall be reviewed for inclusion in the formulary in accordance with subsection (2), (3) or (4) by

(a) the minister, in an administrative review; or

(b) the advisory committee, in a standard review process or an expert review process.

(2) The following drugs shall be subject to an administrative review process:

(a) an ultra-generic drug;

(b) a cross licensed drug where the other drug is currently listed in the formulary;

(c) a drug with a Canadian reference product to a generic drug currently listed in the formulary;

(d) a drug with a Canadian reference product to a generic drug that had not previously been submitted or reviewed for inclusion in the formulary; and

(e) a drug with a Canadian reference product to a brand name product.

(3) The following drugs shall be subject to a standard review process:

(a) a drug with a Canadian reference product to a generic drug that has either been rejected from inclusion in the formulary or removed from the formulary for any reason;

(b) a drug with a Canadian reference product to a non-Canadian reference product; and

(c) notwithstanding subsection (2), a drug which the minister determines should be reviewed in accordance with a standard review process.

(4) The following drugs shall be subject to an expert review process:

(a) a drug without a Canadian reference product which is not

(i) an ultra-generic drug, or

(ii) a cross licensed drug

with another drug currently listed on the formulary;

(b) a drug referred for an expert review process as a result of concerns identified in the standard review process; and

(c) notwithstanding subsection (2) or subsection (3), a drug which the minister determines should be reviewed in accordance with an 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 advisory committee may require to assess the drug.

(6) In addition to the submission requirements in section 4, when assessing a drug for inclusion in the formulary the minister or the advisory committee, shall consider the following:

(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 minister or advisory committee considers necessary in the review process.

Extraordinary Gazette Index

Title of Act and Subordinate Legislation made thereunder	CNLR or NL Reg.	Amendment	XNL Gazette Date & Page No.
Pharmaceutical Services Act			
Interchangeable Drug Products Formulary Regulations, 2012 (Amdt.)	NLR 10/14	Amends NLR 23/12 S.2 Amdt. S.4 Amdt. S.9 R&S	Feb 10/14 p. 3