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Introduction to the Newfoundland and Labrador Interchangeable Drug Products Formulary (NIDPF)

Introduction

The Newfoundland and Labrador Interchangeable Drug Products Formulary (NIDPF) is a list of commonly used drugs which have therapeutic equivalence to a reference product, and are listed alphabetically by generic name.

The drugs listed in the NIDPF have been produced in accordance with sound manufacturing principles and found, on adequate testing, to conform to official Canadian standards and are under continuous review. Changes will be made, where necessary, on the basis of new information. All drugs listed in the NIDPF have conformed to the standards of manufacturing and qualitative assessment of the Drugs and Health Products Branch of Health Canada, and have met the Provincial requirements for inclusion in the NIDPF.

The NIDPF was initially established by regulations on the advice of the Advisory Committee to the Minister of Health and Community Services, Province of Newfoundland and Labrador. This Advisory Committee was originally appointed in accordance with the provisions of *The Pharmaceutical Association Act 1994*, Chapter P-12.1. The NIDPF and the Advisory Committee now fall under *The Pharmaceutical Services Act, 2012, and The Interchangeable Drug Products Formulary Regulations, 2012.*

The *Act* provides for the establishment of a Professional Committee which is appointed by the Minister of Health and Community Services in consultation with the Newfoundland and Labrador Medical Association and the Pharmacist's Association of Newfoundland and Labrador. The Professional Committee has the responsibility to advise the Minister on matters relating to the NIDPF

The objective of the legislation is to assist the people of Newfoundland and Labrador to obtain prescription drugs of acceptable quality at reasonable prices. For some provinces, prices published in the Interchangeable Formulary apply only to residents who are covered under Government programs; however, **all residents of Newfoundland and Labrador benefit from prices published in the NIDPF**. Products listed as interchangeable in the NIDPF have no relation to the Newfoundland and Labrador Prescription Drug Program (NLPDP) benefit listing.

Definition of Interchangeable Drug Products

The definition of Interchangeable Drug Products, as outlined in the Act, is as follows:

Interchangeable drug products means pharmaceutical equivalents or pharmaceutical alternatives that are the therapeutic equivalents of and that have the same route of administration as a reference product.

Pharmaceutical alternativesmeans drug products that contain the same or similar amount of the same or similar medicinal ingredients, in comparable dosage forms but do not necessarily contain the same non-medicinal ingredients;

Pharmaceutical equivalents

means drug products that contain the identical amounts of the identical medicinal ingredients, but do not necessarily contain the same non-medicinal ingredients;

Therapeutic equivalents mean pharmaceutical equivalents or pharmaceutical alternatives that have been shown to be bioequivalent to a reference product as demonstrated by bioavailability, pharmacodynamic or clinical studies

^ Top of Page

Mandatory Substitution/Charge of Lowest Price

A person legally authorized to dispense drugs, when presented with a prescription for a drug listed in the NIDPF, must dispense either the lowest price brand of the drug within a category listed in the NIDPF or another approved substitute brand of that drug at the lowest price listed in the NIDPF, in accordance with the 30 day provision discussed in the Maximum Price section.

A client is free to choose a specific brand within a category if they wish; however, the pharmacist must notify the patient of the difference in price between the brand chosen and that of the lowest price listed in the NIDPF for that category. The client or their insuring agency is responsible for the difference in the price of the drug chosen and the lowest price listed in the NIDPF.

^ Top of Page

Where the Lowest Price Is Not Available

Where due to exceptional circumstances the lowest priced drug is not available to pharmacies, a dispenser may supply and/or charge for the next lowest price listed in the NIDPF. The Secretary of the NIDPF Advisory Committee must first be advised of product unavailability so that payment for the next lowest price can be arranged. **Please call our claims office at (709) 753-3615 or 1 (888) 724-7760 to report product shortages.**

If a discontinued DIN is the lowest priced product in a category and has been listed as DOD (Discontinued On Depletion of Inventory) in a previous volume, the next lowest price in that category will be the Mandatory Lowest Price (MLP).

If a discontinued DIN is the lowest priced product in a category and has not been listed as DOD in a previous volume of the NIDPF, the discontinued DIN's price will continue to be the MLP, until the next volume of the NIDPF or until confirmation of inventory depletion (whichever occurs first).

^ Top of Page

Inventory Adjustment

The Department of Health and Community Services recognizes there is a need for pharmacies to adjust their inventory when additions or deletions or other changes are made to the NIDPF.

30 Day Inventory Adjustment Period

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New Drug Categories:

Pharmacies are given a 30 day period from the date of interchangeability before the mandatory lowest price (MLP) becomes effective. This 30 day period is to allow time to adjust inventory and advise their clients of any change in status of current therapies.

New Products Added to Existing Categories:

When a new product is added to an existing category, its price will be based on the current MLP for that category. Should the new product be lower in price than the category's current MLP, the new product's price will become the MLP. **The new MLP will become effective 30 days from the date of interchangeability.**

Both of the above policies are enacted by government such that all payers (patients, government, and third party insurances) are held to the policy. Where indicated to comply with the 30 day post interchangeability policy, the date on which MLP is effective is listed at the end of each category.

Inventory Adjustment Allowance:

An inventory adjustment allowance is included in the price of all products listed in the NIDPF. The price listed is the manufacturer price, as per pricing requirements, plus a percentage based inventory adjustment allowance. The schedule is as follows:

Schedule for Inventory Adjustment Allowance:

April 16, 2012 to March 31, 2013	12%
April 1, 2013 to March 31, 2014	15%
April 1, 2014 to March 31, 2015	12%
April 1, 2015 to March 31, 2016	9%

^ Top of Page

Publishing of the NIDPF

The NIDPF is officially published in April and October. Supplements are added between publications to allow consumers to realize savings as soon as feasible.

The NIDPF is available electronically on our website at:

www.health.gov.nl.ca/health/prescription/idf.html

Supplement notifications are posted under Bulletins at:

https://nlpdp.xwave.com/GeneralBulletins.aspx

^ Top of Page

Requirements for Consideration of Listing in the NIDPF

As outlined in *The Interchangeable Drug Products Formulary Regulations, 2012*, the following are the requirements for consideration of NIDPF listing, effective April 16, 2012:

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.

^ Top of Page

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.

^ Top of Page

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.

^ Top of Page

Guaranteed Prices

As outlined in *The Pharmaceutical Services Act, 2012*, the following is the requirement for Guaranteed Prices for the NIDPF, effective April 16, 2012:

Pricing requirements

23. (1) The price for a generic drug listed on the formulary shall be no more than the maximum price calculated in accordance with subsection (2).

(2) The maximum price shall be calculated as a percentage of brand price in the manner prescribed in the regulations

(3) Where a submission includes a price for a generic drug which is less than the maximum price of that drug calculated in accordance with this section, the price for that drug shall be guaranteed for the period of time determined by the minister.

(4) The price for a drug determined under this section, whether it is

(a) the maximum price calculated in accordance with this section; or

(b) less than the maximum price,shall be the price offered for that drug to all pharmacies and dispensing physicians in the province.

^ Top of Page

Additional Requirements

In addition to the specific submission requirements noted above, the criteria to be considered by the NIDPF Advisory Committee for inclusion into the NIDPF include, but are not limited to:

The definition of Interchangeable Drug Products as set out in the Act.

The drug product must be of consistent satisfactory quality and safety.

The manufacturer's methods, facilities and documentation must be acceptable to the NIDPF Advisory Committee.

Drug products must conform to the drug quality which is in accordance with standards of manufacturing and qualitative assessment of the Drugs and Health Products Branch of Health Canada.

The formulation of the drug product must be acceptable to the NIDPF Advisory Committee and all the active ingredients must be capable of identification and qualitative analysis in the finished dosage form.

Drug products listed must be of a proven therapeutic value.

Failure to comply with any reasonable request from the NIDPF Advisory Committee or the Government of Newfoundland and Labrador may result in product rejections or deletions.

^ Top of Page

Review Process

As outlined in *The Interchangeable Drug Products Formulary Regulations, 2012*, the following is the Review Process, effective April 16, 2012:

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;

(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.

^ Top of Page

2012 Schedule for Submissions

Cut Off Date for Submission Receipt	Meeting Date
Thursday, February 2, 2012	Thursday, March 29, 2012
Monday, March 26, 2012	Thursday, April 19, 2012
Tuesday, April 17, 2012	Thursday, May 17, 2012
Monday, May 14, 2012	Thursday, June 14, 2012
Tuesday, June 19, 2012	Thursday, July 19, 2012
Monday, July 16, 2012	Thursday, August 16, 2012
Monday, August 13, 2012	Thursday, September 13, 2012
Tuesday, September 18, 2012	Thursday, October 18, 2012
Monday, October 15, 2012	Thursday, November 15, 2012
Tuesday, November 13, 2012	Thursday, December 13, 2012

Submissions should be directed to the **Secretary of the NIDPF Committee**, as per the schedule listed above. Complete submissions, falling under the Standard Review Process, received by the cut-off date will be reviewed at the corresponding meeting date. Submissions falling under the Expert Review Process may require additional time to review due to the nature of the review process.

^ Top of Page

NIDPF Contact Information

Submissions should be directed to:

Secretary, the NIDPF Advisory Committee

c/o Pharmaceutical Services Division

Department of Health and Community Services

Government of Newfoundland and Labrador

Phone (709) 729-6507 or 1-888-222-0533

Fax (709) 729-2851

Mailing Address:

Confederation Building - West Block

P.O. Box 8700 St. John's, NL A1B 4J6

Courier address:

Belvedere Building

57 Margaret's Place St. John's, NL A1C 3Z3

To Report Product Shortages

:

Phone (709) 753-3615 or 1-888-724-7760

Website

Information regarding the NIDPF is available on our website at: **http://www.health.gov.nl.ca/health/prescription/idf.html**

Bulletins regarding the NIDPF including supplements can be found at: **https://nlpdp.xwave.com/GeneralBulletins.aspx**

^ Top of Page

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