# NEWFOUNDLAND AND LABRADOR INTERCHANGEABLE DRUGS PRODUCTS FORMULARY (NIDPF)

## Addition of Medications to the NIDPF:

In order for a drug company to have a generic medication considered for listing on the NIDPF, a submission must be made electronically via email to the Secretary of the NIDPF.

All submissions must be made electronically by email to NIDPF_NLPDPdrugsubmission@gov.nl.ca. Attachments must be in Adobe Acrobat PDF OR MS Word format. A product sample for any drug contained in a device or apparatus for the purpose of drug delivery that cannot be sent electronically should be sent by mail or courier 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:**
45 Major's Path, St. John's, NL A1A 4Z9

## Submission Requirements:

The following information must be included in the submission in order for the submission to be considered by the Minister or NIDPF Advisory Committee:

- Confirmation that the price meets the pricing requirements as established by the PCPA Generics Tiered Pricing Framework where applicable. Pricing of products for which the PCPA Generics Tiered Pricing Agreement does not apply, should be in accordance with NIDPF regulations.
- The proposed price of the product in the smallest unit price irrespective of package size where applicable.
- Health Canada Notice of Compliance (NOC) if one has been issued. If there is no NOC, a copy of the Drug Notification Form is necessary.
- Confirmation that the applicant can supply the drug to supply the needs of the market throughout the entire province of Newfoundland and Labrador. An "Ability to Supply" form has been drafted to aid in this process and is attached (please see end of this document). If a drug has not been launched

at the time of application, the anticipated launch date is required however, the submission will be held until the product is available in the province of Newfoundland and Labrador. When the product is officially launched, updated pricing information and an updated "Ability to Supply" form or letter is required.

- A Letter of consent providing permission to contact Health Canada and other federal, provincial, or territorial departments or agencies for additional information where necessary regarding the product. This must be supplied from the applicant and from any other company who has a business arrangement in place with the applicant regarding the product.
- Health Canada's Comprehensive Summary: Bioequivalence (CSBE) document for the product.
- A product sample for any drug that is contained within a device or apparatus for the purpose of drug delivery.
- If the submission relates to an ultra-generic or cross licensed drug, a letter must be included to provide confirmation of the business arrangement from the company with whom the business arrangement is in place.

**Maximum Price for Interchangeable Products:**

Newfoundland and Labrador is an active participant in the Pan-Canadian Pharmaceutical Alliance (pCPA). Part of this initiative is a national coordinated approach to reduce the cost of generic drugs. Generic manufacturers provide a price submission to the PCPA office for confirmation. Pricing is verified by the PCPA office to ensure generic drugs are in compliance with the Tiered Pricing Framework. Pricing submitted to the NIDPF for a generic drug should not exceed the unit price confirmed through PCPA.

. The price, if accepted by the PCPA, is distributed to the provinces and territories as the agreed upon national price. Pricing submitted through the PCPA process does not prevent the province from accepting a lower price on a generic drug other than what was submitted to the PCPA. Price submissions from a manufacturer that are lower than the current PCPA price level will be assessed on a case by case basis.

Through the Council of Federation and PCPA process, several commonly used generic drugs are priced to not exceed 18% of the cost of the brand name referenced product. Six drugs were added April 1, 2013, four were added April 1, 2014 and four were added April 1, 2015. A final four products will be added effective April 1, 2016.

| **18% of Brand Effective April 1, 2013** | **18% of Brand Effective April 1, 2014** | **18% of Brand Effective April 1, 2015** | **18% of Brand Effective April 1, 2016** |
|---|---|---|---|
| Amlodipine 5mg, 10mg | Citalopram 10mg, 20mg, 40mg | Clopidogrel Bisulfate 75mg | Donepezil 5mg, 10mg |
| Atrovastatin | Pantoprazole | Gabapentin 100mg, | Ezetimibe 10mg |

| | | | |
|---|---|---|---|
| 10mg, 20mg, 40mg, 80mg | Sodium 20mg, 40mg | 300mg, 400mg | |
| Omeprazole 20mg DR | Rosuvastatin 5mg, 10mg, 20mg, 40mg | Metformin HCL 500mg, 850mg | Quetiapine 25mg, 100mg, 200mg, 300mg |
| Rabeprazole Sodium 10mg, 20mg | Simvastatin 5mg, 10mg, 20mg, 40mg, 80mg | Olanzapine 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 5mg disintegrating, 10mg disintegrating | Imovane 5mg, 10mg |
| Ramipril 1.25mg, 2.5mg, 5mg, 10mg | | | |
| Venlafaxine XR 37.5mg, 75mg, 150mg | | | |

In addition to this, Newfoundland and Labrador as an active participant in the Pan-Canadian Competitive Value Price Initiative for Generic Drugs, will require pricing of generic drugs to be compliant with the Generic Pricing Framework (see table).

| **Pan-Canadian Generic Value Price Initiative –Generic Pricing Framework** | | |
|---|---|---|
| **Category* Description** | **% of Brand** | **Progression** |
| **New single source (i.e., only one manufacturer of a generic drug)** | 75% of brand if product listing agreement (PLA) for brand exists in any jurisdiction. Other single source: 85%<br><br>Products at this level will be reassessed after 2 years ** | ⇩<br>As soon as another manufacturer begins selling its version of the drug in any jurisdiction, the price of the drug will drop to the next tier (i.e., 75% to 50% to 25%) |
| Two generics | 50% | |
| Three or more generics | 25% Oral Solid***<br><br>35% All dosage forms other than oral solids (e.g. liquids, patches, injectables, inhalers, etc.) | |
| Pan-Canadian 18% group – specific molecules negotiated with industry; may be new or existing drugs | | |
| Pan-Canadian 18% | 18% | |

***Price reduction to the next pricing tier is triggered by market entry of additional competitors.**

****After 2 years PTs will reassess continued listing of the single source product against international prices and the number of Notice of Compliance approvals that Health Canada has granted for the drug.**

*****Modified release products will be treated the same as regular tablets and capsules**

The movement of formulary prices as drugs move between pricing tiers will be coordinated with the national PCPA price confirmation process.

Pricing for generic drugs where the PCPA Tiered Pricing Framework does not apply (e.g. non-benefit generics) should not exceed the percentage established under the Newfoundland and Labrador Interchangeable Drug Products Formulary Regulations.

**Price exemption:**

An applicant may apply to the Minister to have a drug included in the NIDPF which falls outside the Tiered Pricing agreement and does not meet the pricing requirements , and the Minister may allow that exemption where:

- The product is a sole source generic;
- The brand name product has been discontinued; or
- In the opinion of the minister, the applicant has demonstrated that they have incurred extraordinary production, manufacturing or development costs for the drug.

The Minister may require the drug company to provide information necessary for the purpose of evaluating an application for an exemption. Conditions may be imposed on the exemption and the time period granted may be limited.

Price exemptions will be granted for up to a one year period ending March 31$^{st}$ of each year. Price increases on generic drugs will only be accepted as part of the annual exemption confirmation process.

**<u>30 Day Inventory Adjustment Period:</u>**

**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 pharmacies time to adjust inventory and advise their clients of any change in status of current therapies.

**New Products Added to Existing Categories:**

I. If a price drop has been triggered by a new market entrant and has been confirmed by the PCPA Generics office, the product will be listed at the appropriate tier and price as determined by the price confirmation process. A 30 day washout does not apply to products under this initiative.

II. If the Tiered Pricing Framework does not apply to a new product 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 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 as per the PANL Agreement, expiry date March 31, 2016. The price listed is the manufacturer price, as per pricing requirements, plus a percentage based inventory adjustment allowance. The inventory adjustment allowance for April 1, 2015 to March 31, 2016 is 9%. Future adjustment rate will depend on negotiations with PANL.

**Manufacturer Price Increase Requested for an Existing Benefit (Generic Medication):**

The NLPDP will only accept price increases from Manufacturers for generic medications listed in the NIDPF annually. Price increase requests must be received by January 15th of each year with implementation of any accepted new price on April 1st of that year.

All price increases will be subject to a **Review** and could result in change of benefit status.

The **Review** is completed to ensure that reimbursement of a product is supported by NIDPF Regulations and the PCPA Generics Price Confirmation Process. As well, the reason for pricing exemption (if applicable) is acceptable by the Department and the price has been accepted in other jurisdictions of Canada. A generic product may be removed from the NIDPF and/or NLPDP Benefit List if price increase is not approved.

**Requirements for Price Increases and/or other changes:**

A manufacturer must:

- Inform the Secretary of the NIDPF of price increases, other changes, and the discontinuation of products in **only electronic format no later than January 15th annually;**
- Make a submission to the PCPA Generics Office for price confirmation where applicable;
- Address notification nlpdp_bpo@bell.ca **only**;
- Email must note 'Manufacturer Price Change', 'Manufacturer Change Excluding Price', or 'Generic Medications Being Discontinued' in the subject line;
- **Price Changes**
  Provide the following information in an Excel spreadsheet:
  - Medication name, strength, and DIN,
  - Package size,
  - Current list price,
  - Requested increased price,
  - Current price as % of brand,
  - What price should be under regulations,
  - Supporting reason why exemption is required,
  - Current list price in all other jurisdictions.
- **Changes Excluding Price Changes**
  Provide the following information in an Excel spreadsheet:
  - Current medication name, strength, dosage form, and DIN,
  - Current manufacturer,
  - New medication name and DIN, if applicable,
  - New package size, if applicable,
  - New manufacturer name, if applicable,
  - Price confirmation,
  - Indicate if there has been a change in formulation, and if so, details of the change,
  - Updated Confirmation of Ability to Supply form,
  - Indicate requested effective date of the change.
- **Generic Medications Being Discontinued**
  Provide the following information in an Excel spreadsheet:
  - Medication name, strength, and DIN,
  - Manufacturer name,
  - Discontinued date,
  - Package size affected,
  - Alternate package sizes that are not discontinued, and
  - Expiry date of the last lot manufactured.

# Confirmation of Ability to Supply

Secretary of the NIDPF,

This letter confirms the current availability of the following product(s) and the ability to supply these product(s) to meet the anticipated demands of Newfoundland and Labrador.

| **Drug Name** | **Strength** | **DIN** | **Date Available in Newfoundland and Labrador** |
|---|---|---|---|
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| | | | |

I made/will make arrangements with the following wholesaler(s) to distribute these product(s) throughout Newfoundland and Labrador.

1. _____

2. _____

3. _____

If in the future problems arise with regard to availability of these product(s), we will notify the Secretary of the NIDPF immediately and provide details of the shortage.

I understand that the inability to supply these product(s) may result in the delisting of these product(s) from the NIDPF and the Benefit Listing for the Newfoundland and Labrador Prescription Drug Program (NLPDP) (if applicable).

Signature: _____

Date: _____