Submission Requirements for the Addition of Generic Medications to the Newfoundland and Labrador Interchangeable Drug Products Formulary

To have a generic medication considered for listing on the Newfoundland and Labrador Interchangeable Drug Products Formulary (NIDPF), a submission must be made **electronically** to the Secretary of the NIDPF by emailing 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:
Department of Health and Community Services
Pharmaceutical Services Division
P.O. Box 8700
St. John's, NL
A1B 4J6

Courier Address:
Department of Health and Community Services
Pharmaceutical Services Division
Confederation Building, West Block
100 Prince Phillip Drive, St. John's, NL

NIDPF Submission Requirements:

The following information **must be included** in the manufacturer's submission, for the requested product to be considered by the NIDPF Advisory Committee and/or the Minister for inclusion in the NIDPF:

- Confirmation that the price submitted meets the pricing requirements established by the pan-Canadian Pharmaceutical Alliance (pCPA), where applicable. Pricing of generic products which fall outside of the pCPA price assessment process, must be in accordance with Newfoundland and Labrador 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 meet the needs of the entire province of Newfoundland and Labrador. An **Ability to Supply Form** has been drafted to aid in this process. If a drug has not been launched at the time of application, the anticipated launch date is helpful 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. This updated information must be sent electronically to the Secretary of the NIDPF.

- 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 if applicable, 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. Further to this, any biowaiver details to support proportionality of multiple strengths submitted, if applicable, should be included with this document.

- 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 pCPA. The pCPA aims to achieve greater value for drugs funded by public drug programs through the combined negotiating power of participating jurisdictions. Part of this initiative is a national coordinated approach to reduce the cost of generic drugs. Generic manufacturers seeking public drug plan benefit listing must provide a price submission to the PCPA office for price confirmation. Submitted pricing is verified by pCPA to ensure generic drugs are in compliance with the Tiered Pricing Framework (TPF) or the pan-Canadian Select Molecule Initiative**.** The pCPA confirmed price, is distributed to affected manufacturers and public drug plans, as the agreed upon national price. For more information regarding pCPA and generic pricing initiatives, please refer to the pCPA website.

Generic pricing submitted to for NIDPF consideration must not exceed the unit price confirmed through pCPA. Pricing confirmed by the pCPA does not prevent NLPDP from accepting a lower price on a generic drug. Submissions from a manufacturer offering a price that is lower than the current pCPA established price will be assessed on a case-by-case basis.

Changes in NIDPF generic pricing prompted by pCPA price confirmation and Tier change, will be coordinated with the PCPA office. Acceptance of revised pricing will be confirmed through communications with the individual manufacturer(s) when required, and updated in the next NIDPF supplement where possible.

Price exemption:

Pricing for a generic drug that does not qualify for a pCPA price assessment (e.g. select old drugs, non-benefits, etc.), must not exceed 25% of the brand price, in accordance with the Newfoundland and Labrador Interchangeable Drug Products Formulary Regulations. A manufacturer may apply to the Minister to have a drug included in the NIDPF where pricing exceeds the regulated requirements. The **Minister may allow that exemption** where:

- The product is a sole source generic
- The product offers value compared to the Brand name reference product
- In the opinion of the Minister, the applicant has demonstrated that they have incurred extraordinary production, manufacturing or development costs for the drug.

Under the exemption process, the manufacturer shall provide all information necessary to evaluate the application for a price exemption. Conditions may be imposed on the exemption, including limitations on the time period granted.

Price increases on generic drugs under the NIDPF that are **non-benefits of NLPDP**, may be accepted **any time of the year** under the exemption application process by submitting a request to the Secretary of the NIDPF.

Price increases for generic drugs listed as **benefits** of NLPDP, are accepted annually in accordance with the NLPDP Benefit Generic Price Increase policy.

30 Day Inventory Adjustment Period:

1. **New Drug Categories:**

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

2 New Products Added to Existing Categories:

I. If a price change has been triggered by the pCPA price confirmation process, the generic will be listed on the NIDPF at the new price in the upcoming supplement where possible. A 30-day washout period does not apply to products under this initiative.

II. If pCPA pricing initiatives do not apply to a new product added to an existing category, the 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.**

The above policy is enacted by the Pharmaceutical Services Division such that all payers (patients, government, and third-party insurances) are held to the policy. Where required 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 on the NIDPF. The published price is the manufacturer list price (MLP) plus a 9% inventory adjustment allowance.