THE NEWFOUNDLAND AND LABRADOR

INTERCHANGEABLE DRUG PRODUCTS FORMULARY

INTRODUCTION

The Newfoundland and Labrador Interchangeable Drug Products Formulary is a list of commonly used drugs which have chemical and therapeutic equivalence and are listed alphabetically by generic name.

The Drugs listed in this Formulary 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 Formulary have conformed to the standards of manufacturing and qualitative assessment of the Health Protection Branch of Health and Welfare Canada. The assistance of that Agency has been invaluable in the preparation of this Formulary.

This Formulary was 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 appointed in accordance with the provisions of The Pharmaceutical Association Act 1994, Chapter P-12.1. 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 Formularies apply only to residents who are covered under Government programs; however, **all residents of Newfoundland and Labrador benefit from prices published in this Formulary.**

SUBMISSION REQUIREMENTS FOR THE NEWFOUNDLAND INTERCHANGEABLE DRUG PRODUCTS FORMULARY (NIDPF)

Prior to any drug manufacturer having its drug products included in the Formulary, it must meet guidelines that have been established by the Expert Advisory Committee. Submission requirements for the NIDPF should include a notice of compliance, bioavailability studies, a product monograph and pricing policies.

Criteria to be met for inclusion into the NIDPF:

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

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

3. Drug products must conform to the drug quality which are in accordance with standards of manufacturing and qualitative assessment of the Health Protection Branch of Health and Welfare Canada.

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

5. Drug products listed must be of a proven therapeutic value.

6. A drug company wishing to have its drug products included in the Formulary must satisfy the Formulary Committee that it is capable of meeting the needs of retail pharmacies throughout Newfoundland and Labrador.

7. Failure to comply with any reasonable request from the Formulary Committee or the Newfoundland Government may result in the deletion of a company's drug products.

8. Requests for inclusion of products should be directed to -

Secretary, The Formulary Committee
c/o Department of Health and Community Services
Government of Newfoundland and Labrador
Confederation Building, West Block
St. John's, NF. A1B 4J6

FORMULARY PUBLISHING

The Formulary is officially published in January and July. Additional supplements are added as requests for new products are received and approved to allow consumers to realize savings as soon as feasible.

In addition to the official publication of the Formulary and its supplements, the Formulary will also be available on the Internet at *http://www.gov.nf.ca/health/nlpdp*.

MAXIMUM PRICES

The Department of Health and Community Services recognizes there is a need for pharmacies to have time to adjust their inventory for new drugs being added to the Formulary.

New Drug Categories: Whenever a new drug category is added to the Formulary, pharmacies are given a 60 day period to adjust their inventory and advise their clients of any change in status of current therapies. For new drug categories added to the Formulary, mandatory charging of the lowest price is effective 60 days from the date of notification by government to pharmacies that a drugs(s) is interchangeable.

New Drugs Added to Existing Categories: When a new drug is added to an existing category, its price will be based on the current lowest price for that category. Should the new product be lower priced than the category's current lowest price, the new category price will be set at the new product's price. This price will become effective 60 days following notification of the new product addition.

Both of the above policies are enacted by government such that all payers (patients, government, third party insurance's) are held to the policy. Where indicated to comply with the 60 day policy, the mandatory charge date is listed at the end of each category.

Prices published in the Formulary are the best available prices submitted by a drug manufacturer for the purpose of inclusion in the Formulary regardless of package size and are also inclusive of a 9% inventory adjustment charge. This inventory adjustment charge is to compensate pharmacies for circumstances when inventory must be purchased from a source where the best available price is not available. The prices published are the maximum prices a pharmacy may charge a client.

MANDATORY SUBSTITUTION/CHARGE OF LOWEST PRICE

A person legally authorized to dispense drugs, when presented with a prescription for a drug listed in the Formulary, must dispense either the lowest price brand of the drug within a category listed in the Formulary or another approved substitute brand of that drug at the lowest price listed in the Formulary, in accordance with the 60 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 of the brand chosen from that of the lowest price that is listed in the Formulary. The client or their insuring agency is responsible for the difference in the price of the drug chosen and the price listed in the Formulary.

WHERE THE LOWEST PRICE IS NOT AVAILABLE

Where due to exceptional circumstances (such as production and distribution problems) the lowest priced drug may not be generally available to pharmacies within the Province, a dispenser may supply or charge for the next lowest price listed in the Formulary. **This clause is not intended to cover the charging of a price higher than the lowest price where the lowest priced drug is generally available to pharmacies within the Province but is intended to cover costs when some pharmacies may not have the drug in stock.**

PROFESSIONAL COMMITTEE

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 Medical Association and the Newfoundland Pharmaceutical Association. The Professional Committee has the responsibility to advise the Minister on matters relating to the Formulary.

DEPARTMENT OF HEALTH AND COMMUNITY SERVICES

DRUG PROGRAMS AND SERVICES DIVISION

P O Box 8700
Confederation Building - West Block
St. John's, NF
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NEWFOUNDLAND INTERCHANGEABLE DRUG PRODUCTS FORMULARY COMMITTEE

PRODUCT DEFECT FORM

Product:_____ Lot #: _____ Manufacturer: _____

Details:

Was Manufacturer _____H.P.B. _____Notified?

Sample Enclosed: Yes _____No _____

Reported By

Name:

Address: