NOVA SCOTIA CRITERIA FOR INTERCHANGEABILITY

The Nova Scotia Department of Health and Wellness, through its Pharmaceutical Services and Extended Health Benefits branch, approves a schedule of commonly prescribed, interchangeable pharmaceutical products in accordance with Section 9(1) of Chapter 7 of the Acts of 2011, the Fair Drug Pricing Act, and Section 8 of the Drug Plan Regulations.

INCLUSION CRITERIA

Pharmaceutical products are considered for interchangeability only when they are the subject of a formal submission which complies with the Nova Scotia Criteria for Interchangeability as outlined in this document.

EXCLUSIONS

The following categories are excluded:

- products not assigned a Drug Identification Number (DIN)
- new products that have not received a Notice of Compliance (NOC)
- products not currently available on the Canadian market
- submissions with Health Canada Assigned Canadian Reference Product (CRP) where the reference product is not marketed in the submitted strength
- regulated natural health products
- non-prescription products
- artificial sweetening agents, dietary supplements
- soaps, cleaners, and shampoos
- Subsequent Entry Biologics/Biosimilars
- injectable medications, such as antineoplastics that are typically used in a hospital setting

GUIDELINES FOR INTERCHANGEABILITY

The determination of "interchangeability" among pharmaceutical products which are sold in Nova Scotia by more than one manufacturer is solely the responsibility of the Department of Health and Wellness.

1. To be considered for interchangeability, the drug product must be the pharmaceutical equivalent of the comparator brand and must:

    - contain the same amount(s) of the same active ingredient(s)

    - have the same route(s) of administration

2. Submitted product(s) must have a declaration of bioequivalence from Heath Canada (i.e., the product has been issued a Notice of Compliance with a Canadian Reference Product (CRP)). The following will be considered: Canadian innovator CRP, non-Canadian innovator CRP and non-innovator CRP.

3. Old Drugs as defined by the Pharmaceutical Drugs Directorate, Health Canada, may be considered for review provided the submitted product has already been deemed interchangeable in at least one other Canadian jurisdiction.

4. Drugs without a CRP may be considered for review provided the submitted product has already been deemed interchangeable in at least one other Canadian jurisdiction.

5. Cross-referenced products

   Products which are subject to a cross-licensing agreement and also have a declaration of bioequivalence with a Canadian Reference Product should be submitted according to the guidelines for cross-referenced products.

   - products which are subject to a cross-licensing agreement (i.e. cross-referenced submission) must be declared
   - cross-referenced products falling under the list of exclusions are ineligible for review
   - cross-referenced products defined as “Old Drugs” by the Pharmaceutical Drugs Directorate, Health Canada, may be eligible for review provided the cross-referenced product(s) are already deemed as interchangeable products in the Nova Scotia Formulary
   - cross-referenced products without a reference product may be eligible for review provided the cross-referenced product(s) are already deemed as interchangeable products in the Nova Scotia Formulary
   - cross-referenced submissions apply only in cases where the submitted product is identical to the cross-referenced/cross-licensed product in all aspects including:
     - strength and dosage form
     - formulation including both active and inactive ingredients and their quantities
     - raw materials and finished product specifications
     - manufacturing processes
     - manufacturing site
   - drug sponsors must provide written notification of any changes in the cross-licensing agreement

NOTICE OF SIGNIFICANT CHANGES

Upon declaration of interchangeability in the Nova Scotia Formulary, the drug sponsor must provide written notification of any change made in the future to the Notice of Compliance, DIN, product name, ownership, manufacturer or distributor, cross-license and/ or distribution agreement, product formulation, site of manufacture, or any other significant product change which could be considered to affect bioequivalence, or interchangeability due to patient safety, acceptance, or compliance. Additional information may be requested to support continued declaration of interchangeability in the Nova Scotia Formulary.

Notice of change submissions:

Please include the following documentation:

- Health Canada approval for change (i.e., No Objection Letter, Notice of Compliance)
- updated product monograph
- if applicable, a letter confirming that there have not been any changes to formulation or bioavailability that could affect bioequivalence.
- if applicable, updated letters of cross-license and updated authorization letter(s) of unrestricted communication (Appendix B)

Please note: Notifiable changes filed with Health Canada to update the product monograph to the brands' product monograph are not required to be submitted unless they fall in any of the above listed categories.

SUBMISSION REQUIREMENTS

The following are requirements for submissions. Please note that for any submission, additional information may be requested at any time on a case-by-case basis.

Submissions must not be made until there is product ready for sale and shipment to pharmacies in Nova Scotia. **Incomplete submissions will not be reviewed or retained and must be resubmitted in full.**

Submission Requirements

1. Cover letter outlining the submission with table of contents.
2. Completed Manufacturer Checklist (Appendix A).
3. Notice of Compliance (NOC) or Drug Notification Form for old drugs without NOCs. If the DIN is not included on a supplemental NOC, a copy of the original NOC confirming the product Drug Identification Numbers must be included.
4. A letter authorizing unrestricted communication regarding the drug product between Nova Scotia and (Appendix B):
    - other federal, provincial, and territorial (F/P/T) drug programs
    - F/P/T health authorities and related facilities
    - Health Canada
    - Patented Medicine Prices Review Board (PMPRB)
    - Canadian Agency for Drugs and Technologies in Health (CADTH)
    - other provincial interchangeability committees and their administrators
5. Health Canada approved product monograph. Revisions must be supported by an NOC or No Objection letter issued by Health Canada. Rationale for differences in the date of the NOC or No Objection Letter that supports the control number on the product monograph must be included.
6. Letter indicating the product is available in sufficient quantity to meet demand and is available to all pharmacies in Nova Scotia (Appendix B).
7. Pricing information including a completed pCPA assessment.

Additional Documentation Required for Cross-Referenced Submissions

The following should be provided from both the Manufacturer/Sponsor of the cross-referenced product and of the product being submitted:

- letter authorizing unrestricted communication as noted above
- letter(s) of cross-license (Appendix B):
  - identifying the manufacturer for both the cross-referenced product and the product being reviewed
  - confirming a cross-licensing agreement exists between the manufacturers
  - confirming that the product being reviewed is identical to the cross-referenced product in all aspects including strength and dosage form, formulation including both active and inactive ingredients and their quantities, raw materials and finished product specifications, manufacturing processes and manufacturing site

SUBMISSION PROCESS

Information related to the submission process may be found at:

https://novascotia.ca/dhw/pharmacare/formulary-review-pathways.asp

Submissions for interchangeability consideration must be sent through a secure file transfer site. To gain access to the secure site, the manufacturer should email ns.interchangeability@medavie.bluecross.ca to inform the staff.

The manufacturer will be sent a link to the secure site to submit the documents. After a manufacturer has submitted through this process once, all subsequent submissions can be made the same way, using the same portal link.

Notification:

Manufacturers will receive written notification via email of the outcome of the submission review.

Interchangeable products will be listed in the Nova Scotia Formulary. The Nova Scotia Formulary may be accessed in .pdf on the following website: www.nspharmacare.ca.

APPENDIX A

MANUFACTURER SUBMISSION CHECKLIST

Nova Scotia Criteria for Interchangeability

Manufacturer Submission Check List

Summary of Product Information

Generic Name:	
Dosage Form:	
Manufacturer:	
ATC Code:	

Submitted Product:	**Strength(s):**	**DIN Number(s):**

☐ **Submitted product has a declaration of bioequivalence from Health Canada (i.e., has been issued a Notice of Compliance with a Canadian Reference Product (CRP)). Please indicate the applicable CRP:**

- ☐ Declaration of bioequivalence with a Canadian innovator reference product
- ☐ Declaration of bioequivalence with a non-Canadian innovator reference product
- ☐ Declaration of bioequivalence with a Canadian non-innovator reference product

☐ **Submitted product is an "Old Drug" as defined by the Pharmaceutical Drugs Directorate, Heath Canada**

The drug product is listed as an interchangeable product in at least one other Canadian jurisdiction that deems interchangeability: ☐ **Yes** ☐ **No**

If applicable, please provide the name of the jurisdiction and listing date:

Jurisdiction: _____**Date:** _____

☐ **Submitted product has no reference product**

The drug product is listed as an interchangeable product in at least one other Canadian jurisdiction that deems interchangeability: ☐ **Yes** ☐ **No**

If applicable, please provide the name of the jurisdiction and listing date:

Jurisdiction: _____ **Date:** _____

Comparator Innovator Reference Product (for all submitted strengths) is in the Nova Scotia Formulary: ☐ **Yes** ☐ **No**

Comparator Innovator Reference Product:	**Strength(s):**	**DIN Number(s):**

Submitted Product is subject to a Cross-Licensing Agreement: ☐ **Yes** ☐ **No**

Submitted Product is an Ultrageneric: ☐ **Yes** ☐ **No**

Cross-Licensed Comparator Product (for all submitted strengths) is in the Nova Scotia Formulary: ☐ **Yes** ☐ **No**

Cross-Licensed Comparator Product:	Strength(s):	DIN Number(s):

Product Monograph Information

Date of Health Canada Approval for the submitted product monograph: **Date:** _____

NOC or No Objection Letter supporting the control number on the submitted product monograph is included ☐ **Yes** ☐ **No**

If applicable, please provide rationale for any difference in the date of the product monograph from that of the date on the NOC or No Objection Letter.

_____

_____

Submission Requirements

☐ Cover Letter (description of the submission, Table of Contents)

☐ Notice of Compliance (NOC) or Drug Notification Form (DNF) for old Drugs without NOCs (a copy of the original NOC confirming product DIN(s) must be included if DIN(s) not included on a supplemental NOC)

☐ For an NOC with Conditions (NOC/c), please include the *Request for Letter of Undertaking* and the *Letter of Undertaking*.

☐ Health Canada approved product monograph or patient information for Old Drugs

☐ Letter authorizing **unrestricted communication** regarding the drug product between Nova Scotia and:

- Other federal, provincial, and territorial (F/P/T) drug programs
- F/P/T health authorities and related facilities
- Health Canada
- Patented Medicine Prices Review Board (PMPRB)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- other provincial interchangeability committees and their administrators (Appendix B)

☐ Letter indicating the product is available in sufficient quantity to meet demand and is available to all pharmacies in Nova Scotia with effective date (Appendix B).

☐ Pricing information including a submitted pCPA assessment

Additional documentation required for cross-referenced Submissions (from both the Manufacturer/Sponsor of the cross-referenced product and of the product being submitted)

☐☐ Letters authorizing **unrestricted communication** regarding the drug product (as noted above)

☐☐ Letters of cross-license (appendix B):

- identifying the manufacturer for both the cross-referenced product and the product being reviewed
- confirming a cross licensing agreement exists between the manufacturers
- confirming that the product being reviewed is identical to the cross-referenced product in all aspects *including* strength and dosage form, formulation including both active and inactive ingredients and their quantities, raw materials and finished product specifications, manufacturing processes, and **manufacturing site**

By signing this form, you are affirming that the information provided is accurate as of the date entered. Changes to the above information must be submitted in writing.

Signature:	Date:
Name / Title:	

APPENDIX B

MANUFACTURER LETTER TEMPLATES

Template Letter of Unrestricted Communication

[Manufacturer's letterhead]

[Date]

Pharmacist Consultant
Nova Scotia Pharmacare Programs
230 Brownlow Ave
Dartmouth, N.S. B3B 0G5

Dear Pharmacist Consultant:

REFERENCE: [Product name, generic name, strength, and dosage form]

This letter authorizes unrestricted communication regarding the drug product between Nova Scotia and:

- other federal, provincial, and territorial (F/P/T) drug programs
- F/P/T health authorities and related facilities
- Health Canada
- Patented Medicine Prices Review Board (PMPRB)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- other provincial interchangeability committees and their administrators

[Signature]
[Name and Title of Company Official]

Template Letter Confirming Ability to Supply Product

[Manufacturer's letterhead]

[Date]

Pharmacist Consultant
Nova Scotia Pharmacare Programs
230 Brownlow Ave
Dartmouth, N.S. B3B 0G5

Dear Pharmacist Consultant:

REFERENCE: [Product name, generic name, strength, and dosage form]

This letter is to confirm that [name of manufacturer] is currently able to supply the above drug product in a quantity sufficient to meet the anticipated demands for this product and is available to all pharmacies in the Province of Nova Scotia effective [date].

Please provide specific details below for location/distributors of the product in Nova Scotia:

- [Wholesaler/Distributor Name], *and/or*
- Direct from manufacturer (clarify minimum order requirements and any additional charges that would be applied)

In the event pharmacies in Nova Scotia cannot obtain supply, please provide a contact for prompt supply confirmation [Contact Details].

If at any time the manufacturer foresees that it may not meet the supply demand in Nova Scotia for the above drug product, the manufacturer shall, as soon as practicable, notify the Nova Scotia Pharmacare Programs in writing. The manufacturer shall further take all reasonable steps necessary to rectify the aforementioned situation as quickly as possible. Notwithstanding the above, the manufacturer understands and acknowledges that the Nova Scotia Pharmacare Programs may, in its sole discretion and without notice, determine that the manufacturer is unable to meet the demand in Nova Scotia for the above drug product, thereby delist the drug product from the Nova Scotia Formulary, making the drug product no longer eligible for Pharmacare reimbursement.

The terms outline above are agreed to and accepted by [name of manufacturer], as evidenced by the signature below of the authorized representative of the manufacturer.

[Signature]
[Name and Title of Company Official]

Template Letter of Cross-License

[Manufacturer's letterhead]

[Date]

Pharmacist Consultant
Nova Scotia Pharmacare Programs
230 Brownlow Ave
Dartmouth, N.S. B3B 0G5

Dear Pharmacist Consultant:

REFERENCE: [Product A or B name, strength, and dosage form]

Company A has entered into a licensing agreement with Company B relating to the distribution and marketing of Product. Company A has licensed Product A to Company B.

Company B will market Product A under Company B's name, Product B.

Company A manufactures the above product according to the terms of the business agreement between Company A and Company B.

In addition, please note that Company A has information on file with Health Canada in the applicable Drug Submission.

Lastly, this letter is to confirm that, Product B is identical to Product A in all aspects including strength and dosage form, formulation including both active and inactive ingredients, and their quantities, raw materials and finished product specifications, manufacturing processes and manufacturing site.

[Signature]
[Name and Title of Company Official]