New Brunswick Drug Plans / Régimes de médicaments du Nouveau-Brunswick

Generic Drug Submission Requirements

Submissions filed by manufacturers to have a generic drug product listed on the NB Drug Plans Formulary must include the requirements outlined below. The NB Drug Plans may request additional information from the manufacturer, Health Canada, or any other source, or take other factors into consideration when reviewing the submission.

Submission Types:

A manufacturer may file a submission for a generic drug if:

1. The originator brand and strength of the drug is listed on the NB Drug Plans Formulary.
2. The originator brand of the drug is listed on the NB Drug Plans Formulary, but not the strength of the generic drug being submitted.
3. The originator brand is not listed but a generic brand of the drug is listed on the NB Drug Plans Formulary.
4. The generic drug was previously listed on the NB Drug Plans Formulary and was delisted or was withdrawn from the market and is being re-introduced.
5. There is a change in DIN/NPN for a generic drug that is listed on the NB Drug Plans Formulary.
6. The NB Drug Plans requests a submission for a generic drug that is being considered for listing.

Please contact the NB Drug Plans by email at submissions@nbdrugs-medicamentsnb.ca for guidance in the following cases:

- None of the submission types described above apply,
- There is doubt as to whether a submission should be made, or
- The submission is for a drug designated by Health Canada as a Tier 3 shortage.

Notification of Changes:

- Change in product name or ownership: By making a submission for a generic drug product, manufacturers acknowledge and agree that they are required to notify the NB Drug Plans of any change in product name or ownership. Once approved by Health Canada, notification of the change must be submitted by email to: submissions@nbdrugs-medicamentsnb.ca. No additional documentation is required to be submitted with the email.
- Notification of other changes (product monograph, formulation, etc.) is not required.

Requirements:

Submit the following requirements electronically in Portable Document Format (PDF):

1. Cover Letter
    - Indicate which of the submission types is being filed.
    - The names and contact information (email and phone number) for the primary and backup contact(s) who can be contacted regarding the submission. The manufacturer may designate the consultant(s) preparing the submission as primary and/or backup contact(s). Any changes in contacts should be communicated as soon as possible, by emailing submissions@nbdrugs-medicamentsnb.ca

- Additional information can be included in the Cover Letter. Please limit this to an explanation of unexpected situations or unusual features of a particular submission. For example, if any strengths of a product listed in the NOC will not be marketed, include this information as a comment in the Cover Letter.
- An electronic signature is acceptable.

2. Submission Summary Form
   - Include the completed form as part of the whole PDF file and also as a separate attachment in MS Word format.

3. Price
   - Indicate the submitted price in the Submission Summary Form.
   - Confirm that the price has been submitted to the pan-Canadian Pharmaceutical Alliance (pCPA) Centralized Price Confirmation Process.

4. Health Canada Approval
   - Notice of Compliance (NOC), or
   - Drug Notification Form (DNF) for drug products approved through an Application for a Drug Identification Number (DINA), or
   - Product License for each natural health product (NHP)

5. Product Monograph or Prescribing Information

6. Unrestricted Sharing of Information Letter
   - A letter, using the Unrestricted Sharing of Information Letter template, printed on company letterhead and signed by an appropriate senior official, permitting unrestricted sharing of information regarding the drug product submitted, between the NB Drug Plans and:
     1. Federal, provincial and territorial (FPT) drug plans
     2. FPT governments, including their agencies and departments
     3. FPT health authorities and related facilities
     4. Health Canada
     5. Patented Medicine Prices Review Board (PMPRB)
     6. Canadian Agency for Drugs and Technologies in Health (CADTH)

7. A processing charge of $300.00 plus HST (due at the time of submission)

Electronic Payments

For each payment made, an email must be sent specifying the submission(s) to which the payment applies and the amount of the payment. For example: Electronic payment has been sent to pay the processing charge for *Submission Product Name(s)* in the amount of $*XXX.XX*.

Contact the NB Drug Plans at submissions@nbdrugs-medicamentsnb.ca to set up electronic payments.

Format for Electronic Submissions:

- Send submissions by email to submissions@nbdrugs-medicamentsnb.ca. It is not necessary to copy any staff members.
- The subject line should be *Submission Product Name*.
- The email must contain the following attachments:
  - A single Portable Document Format (PDF) document that contains all the submission requirements with appropriate bookmarks for each component of the submission
  - Submission Summary form (in MS Word format)
- Individual e-mails must not exceed 20 MB. The file size must be reduced using an archiving or compression program such as WinZip or 7-zip.

Bookmark Names:

The following are suggested bookmark names:

- Cover Letter
- Submission Summary
- Health Canada Approval (Notice of Compliance, Drug Notification Form or Product License)
- Product Monograph (or Prescribing Information for NHPs)
- Unrestricted Sharing of Information Letter