# Letter for Sending NOC or NOC/c

**Instructions for Sponsors**

The purpose of this letter is: (1) to indicate that the NOC or NOC/c is being provided, and (2) to confirm whether or not there are any changes to the Health Canada-approved final product monograph wording that may necessitate revisions to the clinical and/or pharmacoeconomic information filed with Canada’s Drug Agency (CDA-AMC). Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the submission filing process or requirements, please email [contact us](https://www.cda-amc.ca/contact-us) with the complete details of your question(s).

Before Completing the Template:

Please review the following to ensure an understanding of the reimbursement review procedures:

* [Procedures for Reimbursement Reviews](https://cadth.ca/sites/default/files/Drug_Review_Process/Drug_Reimbursement_Review_Procedures.pdf)
* Pharmaceutical Review Updates for any applicable information.

Completing the Template:

Complete all sections of the template and ensure that only the most appropriate option is selected in section 2. Please note that an appropriate pharmacoeconomic evaluation is required for the full population identified in the Health Canada indication to be reviewed by CDA-AMC.

When the template is complete, delete this cover page with the instructions (including the CDA-AMC document header). Please feel free to add company-specific elements such as a cover page, disclaimers, headers, footers, etc. as required.

Filing the Completed Template:

The letter should be sent to CDA-AMC using the Pharmaceutical Submissions SharePoint Site.

Review of letter and finalized information:

CDA-AMC will assess finalized information in accordance with the *Procedures for Reimbursement Reviews*.

[Sponsor’s letterhead]

[Date]

Canada’s Drug Agency (CDA-AMC)

600-865 Carling Avenue

Ottawa, ON K1S 5S8

**Reference: Brand name (non-proprietary name)**

1. **Confirmation that NOC or NOC/c has been received**

This letter confirms that the [Health Canada NOC or NOC/c – select appropriate] for the above-noted submission filed on a pre-NOC basis is being provided to Canada’s Drug Agency (CDA-AMC) along with this letter.

1. **Summary of Product Monograph Revisions**

The following table summarizes product monograph wording changes that may impact the clinical and/or pharmacoeconomic information that was filed with CDA-AMC.

|  |  |  |
| --- | --- | --- |
| **Section** | **Draft Product Monograph** | **FinalProduct Monograph** |
| Indication | Provide the exact wording used in the draft product monograph at the time of acceptance for review by CDA-AMC. | Provide the exact wording from the Health Canada-approved final product monograph. |
| Dosage and Administration | As above | As above |
| Other | Please specify all other changes that may impact the clinical and/or pharmacoeconomic information. Add additional rows as necessary. | Please specify all other changes that may impact the clinical and/or pharmacoeconomic information. Add additional rows as necessary. |

1. **Requested Reimbursement Criteria**

The following table must summarize and wording changes to the sponsor’s requested reimbursement criteria.

|  |  |
| --- | --- |
| **Initial Requested Reimbursement Criteria** | **Revised Requested Reimbursement Criteria**  |
| Provide the exact wording used in that was provided to CDA-AMC at the time of acceptance for review (or most recent revision if applicable). | Provide the exact wording that reflects any changes resulting from the final approved indication. If there are no changes, please state “no revisions”. |

1. **Impact of Product Monograph Revisions**

**Option 1**

[Insert sponsor’s name] confirms that there are no wording changes to the final Health Canada-approved indication or any other pertinent sections of the product monograph information, as compared to the draft product monograph provided at the time the file was accepted for review by CDA-AMC.

**Option 2**

There are wording changes to the final Health Canada-approved product monograph. In [insert sponsor’s name] opinion, the wording changes to the final Health Canada-approved indication [and/or; specify any other or additional pertinent sections of the product monograph with changes], as compared to the draft product monograph provided at the time the file was accepted for review by CDA-AMC (and summarized in the table above), has/have no impact on the clinical and/or pharmacoeconomic information that was filed with CDA-AMC. Our rationale is as follows: [please provide a clear rationale].

**Option 3**

There are wording changes to the final Health Canada-approved product monograph. In [insert sponsor’s name] opinion, the wording changes to the final Health Canada-approved indication [and/or; specify any other or additional pertinent sections of the product monograph with changes], as compared to the draft product monograph provided at the time the file was accepted for review by CDA-AMC (and summarized in the table above), have an impact on the [clinical, pharmacoeconomic – indicate as appropriate] information that was filed with CDA-AMC. We therefore confirm that additional documentation to address the impact will be provided to CDA-AMC by [insert date].

[Signature]

[Name and title of senior company official for the sponsor]