**Application Overview**

**Instructions for Sponsors**

This form provides Canada’s Drug Agency (CDA-AMC) with a reference document to improve the efficiency of the application intake process.

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the CDA-AMC submission filing process or requirements, please [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 documents to ensure an understanding of the CDA-AMC procedures and submission guidelines:

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

Completing the Template:

Please complete all sections of the template. 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, disclaimer, header, footer, etc. as required. Save the completed template in PDF or Microsoft Word format.

Filing the Completed Template:

Incorporate the completed template into the package of required documents. Please consult the relevant procedural documentation for details on how to file the application.

**Application Overview**

Drug and Indication

|  |  |
| --- | --- |
| **Name of product** | Non-proprietary name:  Brand name: |
| Is the brand name confidential until NOC or NOC/c issued?  Yes  No  N/A |
| **Sponsor(s)** | Sponsor name(s): |
| Submitting consultant (if applicable): |
| **Indication(s) to be reviewed by CDA-AMC** | *Note: Please do not include confidential brand names in this section*  *Please do not use symbols (e.g., state greater than or equal to instead of using ≥)* |
| **Sponsor requested reimbursement criteria** | As per indication(s) to be reviewed by CDA-AMC  Other: *please specify*  *Note: Please do not include confidential brand names in this section*  *Please do not use symbols (e.g., state greater than or equal to instead of using ≥)* |
| **Does the indication under review include usage in pediatric patients (i.e., <18 years of age)?** | No  Yes |

Application Information

|  |  |
| --- | --- |
| **Product eligibility criteria** | New drug  New indication |
| New combination product |
| New formulation that is eligible for review by CDA-AMC |
| Subsequent entry non-biologic complex drug |
| **Drug category** | ☐ Non-oncology drug |
| ☐ Oncology drug |
| ☐ Plasma protein or related product |
| **Type of review:** | Standard review  Complex review (Eligibility decision date: DAY, MONTH, YEAR)  PACES tailored review (Eligibility decision date: DAY, MONTH, YEAR)  Product variation tailored review (Eligibility decision date: DAY, MONTH, YEAR)  Resubmission (Eligibility decision date: DAY, MONTH, YEAR)  Reassessment (Eligibility decision date: DAY, MONTH, YEAR) |
| **Time-limited recommendation** | Not eligible  Eligible (Eligibility decision date: DAY, MONTH, YEAR) |
| **Cell or gene therapy** | No  Cell therapy  Gene therapy |
| **Has this drug previously been filed with CDA-AMC and withdrawn?** | Yes  No |
| **Is the sponsor planning to submit additional data after the application has been accepted for review?** | No  Yes  *If yes, please specify the study and the target date for submitting the additional information to CDA-AMC. The sponsor must ensure that the information regarding the new information is reported in the table of studies template. Please refer to the* [Procedures for Reimbursement Reviews](https://www.cadth.ca/sites/default/files/Drug_Review_Process/Drug_Reimbursement_Review_Procedures.pdf) *for details on the implications and deadlines with respect to the inclusion of new information.* |
| **Does the application include one or more indirect comparisons?** | No  Yes |
| **Did you file a request for deviation from the pharmacoeconomic requirements?** | No  Yes, request **accepted**.  Yes, request was **partially accepted**.  Yes, request was **not accepted**.  ***Note:*** *The letter from CDA-AMC will describe if the request was accepted, partially accepted (in the case of multiple deviations requested), or not accepted.* |

Health Canada Review Information

|  |  |
| --- | --- |
| **Health Canada**  **review type** | The drug is undergoing or underwent review by Health Canada through an expedited pathway:  No (standard review pathway)  Priority review  Advance consideration under Notice of Compliance with Conditions (NOC/c)  To be confirmed (requested, Health Canada decision pending)  Other expedited pathway (please specify) |
| **Project Orbis** | Not applicable (non-oncology drug)  Not reviewed through Project Orbis  Project Orbis (Type A)  Project Orbis (Type B)  Project Orbis (Type C) |
| **NOC status** | Pre-NOC  Post-NOC  Unlabeled indication |
| **Date of NOC or NOC/c**  **(issued or anticipated)** | DD-MM-YYYY |
| **Health Canada Information Sharing** | Yes, Health Canada will be or has been provided with a completed consent form.  No, Health Canada will not be provided with a completed consent form.  Not applicable (post-NOC submission, resubmission, or reassessment). |
| **Has this drug previously received an NOD or NON?** | Yes  No |

Contact Information

|  |  |
| --- | --- |
| **Primary contact** | Name:  Title:  Email:  Phone:  Mailing Address: |
| **Secondary contact** | Name:  Title:  Email:  Phone:  Mailing Address: |
| **Application fee contact**  **(if not primary contact)** | Name: |
| Title: |
| Email: |
| Phone:  Mailing Address (if different than primary contact): |