**Advance Notification Form**

**Instructions for Sponsors**

Receipt of this form notifies Canada’s Drug Agency (CDA-AMC) of an upcoming reimbursement review application. The information included below will be used in posting information about the pending application on the CDA-AMC website and issuing the call for patient and clinician group input.

CDA-AMC may share this form with the federal, provincial, territorial governments, including their agencies and departments and the pan-Canadian Pharmaceutical Alliance (pCPA).

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the application 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 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](https://www.cadth.ca/node/68411?keywords=&result_type%5B%5D=report&product_type%5B%5D=107782&sort=field_date%3Avalue-desc&amount_per_page=10&page=1) for any applicable information.

Completing the Template:

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

Submitting the Template:

Before submitting this template, sponsors must register for the Pharmaceutical Submissions SharePoint site. Sponsors must request access to the site a minimum of 10 business days before the intended date of submitting the Advance Notification Form (if not requesting a pre-submission meeting). Please refer to the [Pharmaceutical Submissions SharePoint Site – Set-Up Guide](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_SP_Application_Instructions.pdf) for full instructions on requesting access and uploading files. In the event the sponsor has not requested or received access prior to their target date for providing advance notification of the pending application, please contact CDA-AMC immediately (support@cda-amc.ca). CDA-AMC will work with the sponsor to ensure that the application is not delayed due to the timeframe for setting up the platform to securely receive the required documents.

Once sponsors have received access to the Pharmaceutical Submissions SharePoint site, the completed Advance Notification Form should be uploaded to the “Advance Notification” folder within the “Sponsor Submissions” subfolder for their assigned project.

If the economic information is incomplete when initially submitting the advanced notification form, this information should be updated as soon as possible and submitted to CDA-AMC no later than two weeks prior to filing the application.

Should there be any changes to this information, please upload a revised template to the Pharmaceutical Submissions SharePoint site and [advise CDA-AMC](https://www.cda-amc.ca/contact-us) as soon as possible.

**Reimbursement Review**

**Advance Notification Form**

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| **CONFIDENTIALITY GUIDELINES** |
| By filing this advance notification form with Canada’s Drug Agency (CDA-AMC), the sponsor accepts and agrees to the terms of the *Procedures for Reimbursement Reviews* and its Confidentiality Guidelines and consents to comply with the requirements of the Confidentiality Guidelines, which form an agreement between CDA-AMC and the sponsor. For clarity, the sponsor acknowledges that CDA-AMC may share certain information, including advance notification materials with authorized recipients. |

1. **Sponsor Information**

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| --- | --- |
| **Required Information** | **Response** |
| Name of sponsor | Add sponsor name |
| Name of submitting consultant | Add name of submitting consultant |
| Primary contact for submission | Name:Title:Email:Phone number: |
| Secondary contact for submission | Name:Title:Email:Phone number: |

1. **Product Information**

|  |  |
| --- | --- |
| **Required Information** | **Response** |
| Product Name | non-proprietary (brand) |
| Is the brand name confidential until NOC or NOC/c is issued?  | Yes [ ]  No [ ]  Not applicable (i.e., post-NOC submission) [ ]  |
| Date of Health Canada approval (issued or anticipated) | Month Day, Year |
| Anticipated date of filing the application with CDA-AMC | Month Day, Year |
| Indication to be reviewed by CDA-AMC | *Please do not use confidential brand names in this section* |
| Sponsor requested reimbursement criteria | *Please do not use confidential brand names in this section.**Please do not use symbols (e.g., state greater than or equal to instead of using ≥)* |
| Dosage Form / Strength / Route of Administration | Please add: Dosage Form / Strength / Route of Administration |
| Product category | ☐ Non-oncology drug☐ Oncology drug☐ Plasma protein or related product  |
| 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 |
| 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) |
| Diagnostic or other testing procedure(s) | If there is a novel diagnostic or other testing procedure(s)a associated with the proposed drug submission, please specify:[ ]  Medical imaging test [ ]  Companion diagnostic test[ ]  Other test (please specify): |

a Testing is defined as: "An intervention(s) and/or procedure(s) that can detect a condition, establish a diagnosis, inform a prognosis, plan treatment, or monitor treatment and its effect on a condition across time." (Reference: Medline Plus: Medical Tests. (n.d.) Published by the National Library of Medicine. Available from: https://medlineplus.gov/lab-tests/ Accessed 14 December 2023).

1. **Health Canada Information**

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| --- | --- |
| **Required Information** | **Response** |
| 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) |
| Health Canada Information Sharing | As described in [*Notice to Industry: Aligned Reviews Between Health Canada and Health Technology Assessment Organizations*](https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices/notice-aligned-reviews-health-canada-health-technology-assessment-organizations.html), sponsors can consent to Health Canada sharing information and documents with CDA-AMC. Please indicate below if you are willing to participate in the information sharing process between Health Canada and CDA-AMC. **Note:** Sponsors are required to provide Health Canada with a completed [consent form](https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices/notice-aligned-reviews-health-canada-health-technology-assessment-organizations/unrestricted-sharing-information-template.html) to participate in this process. The acknowledgement provided below is only used by CDA-AMC to initiate the information sharing process once the submission has been received. [ ]  Yes, Health Canada will be or has been provided with a consent form. [ ]  No, Health Canada will not be provided with a consent form. [ ]  Not applicable (post-NOC) |
| **If yes, please complete this section**Submission control number (if known): Submission undergoing review with: [ ]  Biologic and Radiopharmaceutical Drugs Directorate (BRDD) [ ]  Pharmaceutical Drugs Directorate (PPD)  |

1. **Clinical Evidence to be Included in the Submission**

|  |  |
| --- | --- |
| **Required Information** | **Response** |
| Pivotal and RCT studies | Add number of studies |
| Extension phase studies | Add number of studies |
| Indirect comparisons  | Add number and type of indirect comparisons |
| Additional studies addressing gaps in the evidence |  |
| Clinical overview | *This section should not exceed ONE page and should include:* * *place in therapy (e.g., first-line, niche), current standard of care (including best supportive care), and description of jurisdictional differences*
* *a brief overview of key trials including outcomes, relevant data, trial design, limitations, mean number of treatment cycles per patient, doses used*
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1. **Economic Overview**

**Note:** If the economic information is incomplete when initially submitting the advanced notification form, this information should be updated as soon as possible and submitted to CDA-AMC no later than two weeks prior to filing the application.

**Note:** CDA-AMC economic guidelines have recently changed to include cost minimization analysis (CMA) in cases where the submitted drug represents an additional drug in a therapeutic class in which there is already a reimbursed drug for the same indication, and where the submitted drug demonstrates similar clinical effects to a reimbursed comparator. Please consult the *Procedures for Reimbursement Reviews* for further details.

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| **Required Information** | **Response** |
| Type of economic evaluation | Cost utility analysis, etc. |
| Could this submission be considered as a CMA? | Yes [ ]  No [ ]  Uncertain [ ]  |
| Model type | Markov, decision tree, etc. |
| Comparator treatments | State comparators |
| Will an indirect treatment comparison be included? | Yes [ ]  No [ ]  |
| Brief description of the model | Description should include item such as health states, event and outcomes considered (may include model diagram) |
| Comparators | Please provide a table with the cost(s) of the drug and the comparator treatments |

1. **Clinical Practice Guidelines**

*Please provide links to relevant clinical practice guidelines for the drug and indication under review. For oncology drugs, please provide the following guidelines (if available): American Society of Clinical Oncology (ASCO), European Society for Medical Oncology (ESMO), National Comprehensive Cancer Network (NCCN)*

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| --- | --- |
| **Guideline Group** | **URL to Guidelines** |
| Add name  | *Please provide a direct URL link to the guidelines* |
| Add name | *Please provide a direct URL link to the guidelines* |
| Add rows as required  | Add rows as required  |

1. **Evidence Presentation Meeting**

As part of the reimbursement review process, CDA-AMC offers the sponsor a 45-minute meeting with agency staff to provide an overview of the clinical and economic evidence. Please indicate below if you are interested in participating in a meeting:

[ ]  Yes, we would like to participate in a meeting with CDA-AMC staff.

[ ]  No, we do not require a meeting with CDA-AMC staff.

**Preferred dates for Evidence Presentation Meeting**

* Evidence presentation meetings are **only offered between 5 and 20 business days** after the application has been filed and in the timeslots noted in the [schedule](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Meeting_Dates.pdf) (no exceptions will be made).
* State the preferred dates in the table below.
* Ensure that each date aligns with one of the available timeslots and falls within 5 to 20 business days after the application will be filed.
* If you provide multiple options, please include a ranking for preference.

|  |  |
| --- | --- |
| **Date** | **Rank** |
| *Month-Day-Year* |  |
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1. **Sponsor Suggested Clinical Specialists**

The sponsor must notify each individual that their contact information is being provided to CDA-AMC.

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| --- | --- | --- | --- | --- | --- |
| **Clinical Specialist** | **Area of Clinical Specialization** | **Province or Territory**  | **Email address** | **Institution** | **Link to Bio** |
| Add name  |  |  |  |  |  |
| Add name |  |  |  |  |  |
| Add name  |  |  |  |  |  |
| Add name |  |  |  |  |  |
| Add name  |  |  |  |  |  |