**Reimbursement Review**

**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 email [requests@cadth.ca](mailto:requests@cadth.ca) 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/CADTH_Drug_Reimbursement_Review_Procedures.pdf)
* [Procedures for Time-limited Reimbursement Recommendations](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_TLR_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@cadth.ca](mailto:support@cadth.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 via email ([requests@cadth.ca](mailto:requests@cadth.ca)) 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**

|  |  |
| --- | --- |
| **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 this submission 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* |
| 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  Tailored review  Resubmission (Eligibility decision date: DAY, MONTH, YEAR)  Reassessment (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**

|  |  |
| --- | --- |
| **Required Information** | **Response** |
| The drug is undergoing or underwent review by Health Canada through an expedited pathway | No (standard review pathway)  Yes  To be confirmed (Health Canada’s decision regarding expedited review is pending) |
| If yes, please provide further details | Priority review  Advance consideration under Notice of Compliance with Conditions (NOC/c)  Project ORBIS  Other expedited pathway (please specify) |
| 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 studies | Add number of studies |
| Non-pivotal phase 3 studies | Add number of studies |
| Studies with extension phases | Add number of studies |
| Indirect comparisons | Add number of indirect comparisons |
| 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* |

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.

|  |  |
| --- | --- |
| **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. **Regulatory Status**

|  |  |  |
| --- | --- | --- |
| **Agency (region)** | **Status** | **Link to decision** |
| Food and Drug Administation (United States) | *Under review*  *Approved*  *Not approved*  *Not filed for review* | *Please paste in URL* |
| European Medicines Agency  (European Union) | *Under review*  *Approved*  *Not approved*  *Not filed for review* | *Please paste in URL* |
| Therapeutic Goods Administration  (Australia) | *Under review*  *Approved*  *Not approved*  *Not filed for review* | *Please paste in URL* |
| Medicines and Healthcare products Regulatory Agency  (United Kingdom) | *Under review*  *Approved*  *Not approved*  *Not filed for review* | *Please paste in URL* |

1. **Health Technology Assessment Decisions**

|  |  |  |
| --- | --- | --- |
| **Agency** | **Status** | **Link to decision** |
| Institut national d'excellence en santé et services sociaux (INESSS)  (Quebec) | *Under review*  *Not recommended*  *Recommended*  *Not filed for review* | *Please paste in URL* |
| National Institute for Health and Care Excellence (NICE)  (NHS England) | *Under review*  *Not recommended*  *Recommended*  *Not filed for review* | *Please paste in URL* |
| Scottish Medicines Consortium  (NHS Scotland) | *Under review*  *Not recommended*  *Recommended*  *Not filed for review* | *Please paste in URL* |
| All Wales Medicines Strategy Group (AWMSG)  (NHS Wales) | *Under review*  *Not recommended*  *Recommended*  *Not filed for review* | *Please paste in URL* |
| Pharmaceutical Benefits Advisory Committee (PBAC)  (Australia) | *Under review*  *Not recommended*  *Recommended*  *Not filed for review* | *Please paste in URL* |
| PHARMAC  (New Zealand) | *Under review*  *Not recommended*  *Recommended*  *Not filed for review* | *Please paste in URL* |
| Haute Autorité de Santé  (France) | *Under review*  *Not recommended*  *Recommended*  *Not filed for review* | *Please paste in URL* |
| Institute for Clinical and Economic Review (ICER)  (USA) | *N/A* | *Please paste in URL* |

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)*

|  |  |
| --- | --- |
| **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. **Screening Eligibility for Time-Limited Recommendations based on Regulatory Status, Conduct of a Phase III Trial, and Reassessment Commitment**

|  |  |  |
| --- | --- | --- |
| **Eligibility for time-limited recommendations** | **Response** | |
| **Regulatory status** | | | |
| The drug has been issued an NOC/c by Health Canada or is undergoing review through Health Canada’s advance consideration process under the NOC/c policy. |  | Yes |
|  | No |
| **Evidence generation** | | | |
| A phase III clinical trial is being planned and/or conducted at the time of the submission to CDA-AMC. |  | Yes |
|  | No |
| The phase III trial is being or will be conducted in a patient population that is reflective of the indication being reviewed by CDA-AMC |  | Yes |
|  | No |
| The phase III trial will be completed within a time frame that will not exceed 3 years from the target expert committee meeting date. |  | Yes |
|  | No |
|  | N/Aa |
| Target expert committee meeting dateb | Month day, year | |
| **Commitment to file for reassessment (choose 1 of the following options)**  ***Note: only complete if answered ‘Yes’ to the regulatory status and evidence questions above*** | | | |
| Sponsor is **willing to commit** to file a reassessment application with CDA-AMC in accordance with the time frames specified in the procedures for time-limited recommendations. |  | Yes |
| Sponsor **will not commit** to filing a reassessment application with CDA-AMC in accordance with the time frames specified in the procedures for time-limited recommendations. The sponsor acknowledges that the expert committee will be informed of the sponsor’s decision and that a time-limited recommendation will not be an option for the drug under review. |  | Yes |

NA = not applicable; NOC/c = Notice of Compliance with Conditions

a Please check N/A if the sponsor does not have a relevant phase III trial planned or ongoing for the indication of interest to the CDA-AMC submission.

b Please refer to the [*Expert Committee Meeting Schedule*](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Expert_Committee_Schedule.pdf).

1. **Screening Eligibility for Time-Limited Recommendations Based on Details of the Evidence Generation Plans**

*Note: only complete if answered ‘Yes’ to the regulatory status and evidence questions above*

|  |  |
| --- | --- |
| **Evidence Generation Plans** | **Response** |
| Summary of key evidentiary gap(s) and how it will be addressed through evidence generation | Clearly identify the gaps and/or limitations with the preliminary evidence that will be submitted to CDA-AMC and briefly state how the forthcoming phase III trial will address the issues. |
| **Confirmed or Anticipated Post-Market Study Requirements** | |
| Population | Please state the patient populations where additional phase III evidence will be generated. |
| Intervention | Please state the intervention(s) that will be studied in the phase 3 trial, including all relevant background therapies, dosage strength(s), frequency of administration. |
| Comparator(s) | Please identify the comparator(s) that will be used in the phase 3 trial, including dosage strength and frequency of administration. |
| Outcome(s) | Please identify the outcomes that may be included to address the confirmed or anticipated regulatory conditions (e.g., as stated within the qualifying notice issued by Health Canada).  Please include additional primary, secondary, or exploratory endpoints that are or will be investigated in the pending phase 3 trial.  CDA-AMC acknowledges that sponsors may not have all this information at the time of completing this form, particularly for files that will be filed prior to regulatory approval by Health Canada. Please provide as much detail as possible to help inform initial discussions regarding eligibility for consideration to receive a time-limited recommendation. |
| **Timing (required follow-up)** | Please state the required follow-up to address the conditional market authorization issued by Health Canada (please focus on the relevant phase III trial). |
| **Study design** | Please briefly state the design of the phase III trial. |
| **Study protocol** | If available, please provide a link to the study protocol (or indicate that it is not currently published). If a protocol is currently unavailable, please note this within this section. |
| **Clinicaltrials.gov** | Please provide the clinicaltrials.gov identification number (or indicate that it is not currently available). |
| **Target dates for Phase III Study**  ***If dates are uncertain, please estimate to inform initial discussions regarding eligibility for consideration to receive a time-limited recommendation.*** | |
| **Start a** | Month day, year |
| **Primary completion b** | Month day, year |
| **Study completion c** | Month day, year |
| **Clinical Study Report completion d** | Month day, year |
| **Filing SNDS-c with Health Canada (if known)** | Day, Month, Year (or state if unknown) |

SNDS-c: Supplement to a New Drug Submission - Confirmatory

a Estimated date on which the clinical trial will be open for patient recruitment or the actual date on which the first patient was enrolled.

b Date that the final study participant was examined or received an intervention for the purpose of the final collection of data for the primary outcome.

c Date that the final study participant was examined or received an intervention for the purpose of the final collection of data for the primary and secondary outcome measures and adverse events.

d Estimate of the time required to finalize the Clinical Study Report after the study has been completed (CDA-AMC appreciates this information may not be known. Please provide an estimate based on prior experience).