Presubmission and Pipeline Meeting Briefing Paper

**Instructions for Sponsors**

Sponsors are required to complete this template for all presubmission and pipeline meetings for pending reimbursement review applications to Canada’s Drug Agency (CDA-AMC). This template must be filed **no later than 10 business days** prior to the scheduled date of the meeting. Failure to provide the form within this time frame may result in postponement of the meeting.

Before Completing the Template:

Please review the following documents to ensure an understanding of CDA-AMC 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://cadth.ca/sites/default/files/Drug_Review_Process/CADTH_TLR_Procedures.pdf)
* Pharmaceutical Review Updates for any applicable information.

Completing the Template:

The briefing paper is intended to provide a **concise summary** of key issues and questions.

* Section 1 must be completed for pre-submission meetings (please delete sections for time-limited recommendations if not applicable).
* Section 2 must be completed for pipeline meetings.

Please delete the section that is not applicable.

The completed document **must not exceed 12 pages for a 1-hour presubmission or pipeline meeting or 15 pages for 1.5-hour presubmission meeting that will include discussion regarding a time-limited recommendation.**

For pre-submission meetings, ensure that any questions for CDA-AMC are clearly stated and address specific items where the applicant is uncertain about the CDA-AMC procedures. For example, *“What does* CDA-AMC *think about the proposed approach for the economic evaluation”* is not an appropriate question for a presubmission meeting as this would require a detailed assessment.

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 a Microsoft Word format.

Filing the Completed Template:

Upload the completed template to the Pharmaceutical Submissions SharePoint site’s “Pre-submission Meeting” folder within the “Sponsor Submissions” subfolder. Please refer to the [Pharmaceutical Submissions SharePoint Site – Set-Up Guide](https://www.cda-amc.ca/sites/default/files/Drug_Review_Process/CADTH_SP_Application_Instructions.pdf) for full instructions on requesting access to the SharePoint site and uploading files.

Should there be any changes to this information, please upload a revised template to the same folder within the Pharmaceutical Submissions SharePoint site and advise CDA-AMC via email ([requests@cda-amc.ca](mailto:requests@cda-amc.ca)) as soon as possible.

Section 1: Briefing Paper for a Presubmission Meeting

| **Meeting Date and Time** |  |
| --- | --- |
| **Sponsor** |  |
| **Drug** | Brand (generic); dosage form; route of administration |
| **Indication to be reviewed** |  |
| **Requested reimbursement criteria** |  |
| **Sponsor contact** |  |

|  |
| --- |
| **Confidentiality Guidelines** |
| By filing this document with Canada’s Drug Agency (CDA-AMC), the sponsor accepts and agrees to the terms of the [*Procedures for Reimbursement Reviews*](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Reimbursement_Review_Procedures.pdf) 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 this document and all presubmission or pipeline meeting materials with the authorized recipients. |

1. **Meeting Attendees**

|  |  |
| --- | --- |
| **Organization** | **Attendees** |
| Sponsor | * Name; Job title; company or organization * Include all sponsor employees, clinical experts and/or consultants in this section |
| CDA-AMC | * Director, Pharmaceutical Reviews, or designate * Pharmaceutical Review Manager(s) * Health Economics Manager or Lead (as needed) * Other CDA-AMC staff may attend as needed |
| Drug Programs | * Invited by CDA-AMC, but attendance is optional |

1. **Meeting Agenda**

A sample agenda is provided below. Please modify the agenda as required and delete these instructions.

|  |  |  |
| --- | --- | --- |
| **Time** | **Topic** | **Lead** |
| **Sample Meeting Agenda for a 1-hour Presubmission** | | |
| 3 min | Welcome and opening remarks | CDA-AMC |
| 5 min | 1. Background information | *Add sponsor lead* |
| 5 min | 2. Target patient population | *Add sponsor lead* |
| 5 min | 3. Proposed place in therapy | *Add sponsor lead* |
| 5 min | 4. Appropriate comparators | *Add sponsor lead* |
| 15 min | 5. Clinical evidence | *Add sponsor lead* |
| 15 min | 6. Economic evidence | *Add sponsor lead* |
| 5 min | 7. Questions and Answers | All |
| 2 min | Wrap up | CDA-AMC |
| **Sample Meeting Agenda for a 1.5-hour Presubmission** | | |
| 3 min | Welcome and opening remarks | CDA-AMC |
| 5 min | 1. Background information | *Add sponsor lead* |
| 5 min | 2. Target patient population | *Add sponsor lead* |
| 5 min | 3. Proposed place in therapy | *Add sponsor lead* |
| 5 min | 4. Appropriate comparators | *Add sponsor lead* |
| 15 min | 5. Clinical evidence | *Add sponsor lead* |
| 15 min | 6. Economic evidence | *Add sponsor lead* |
| 30 min | 7. Consideration for a time-limited recommendation |  |
| 7.1. Key gaps in the evidence | *Add sponsor lead* |
| 7.2. Evidence generation plans | *Add sponsor lead* |
| 7.3. Timelines for evidence generation and reassessment | *Add sponsor lead* |
| 7.4. Initial perspectives on eligibility for time-limited recommendation | CDA-AMC |
| 5 min | 8. Questions and Answers | All |
| 2 min | Wrap up | CDA-AMC |

1. **Background Information**

|  |  |
| --- | --- |
| **Anticipated filing date with CDA-AMC** | DD-MM-YYYY |
| **Date of NOC** | DD-MM-YYYY (issued or anticipated) |
| **Health Canada**  **review type** | Standard review  Priority review  Advance consideration under NOC/c  Project Orbis  To be confirmed (Health Canada decision pending)  Other expedited pathway (please specify) |
| **NOC status at filing** | Pre-NOC  Post-NOC  Unlabeled indication |
| **Health Canada Information Sharing** | 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). |

NOC = Notice of Compliance; NOC/c = Notice of Compliance with Conditions

1. **Target Patient Population**

Present a very brief outline of the disease, how patients are diagnosed (i.e., what testing resources are used), and noting the incidence/prevalence in Canada.

Specify the proposed or approved indication of interest. Specify the reimbursement criteria that will be requested by the sponsor and provide a rationale.

Highlight key areas where there is unmet medical need for those who may be eligible for treatment with the drug to be reviewed.

| **Questions Regarding the Target Population** |
| --- |
| 1. Question 1 (please state ‘none’ if there are no questions) |
| 1. Question 2 |
| 1. Add additional rows if required |

1. **Proposed Place in Therapy**

Summarise the current treatment paradigm for the clinical management of the condition, including any diagnostic or other testing procedure(s) performed as part of routine care. Clearly state the sponsor’s interpretation for how the drug to be reviewed will impact the existing treatment paradigm, including impacts to testing resources.

For oncology drugs, sponsor must present diagrams showing the current and proposed funding algorithms for the drug to be reviewed (i.e., as described in the [*Proposed place in therapy template*](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Place_In_Therapy_Template.docx)).

| **Questions Regarding the Potential Place in Therapy** |
| --- |
| 1. Question 1 (please state ‘none’ if there are no questions) |
| 1. Question 2 |
| 1. Add additional rows if required |

1. **Comparators**

Prior to completing this section, please review the application requirements with respect to appropriate comparators in the *Procedures for Reimbursement Reviews*.

Clearly identify the appropriate comparators for the drug under review. If the sponsor is proposing that a relevant comparator, as described in the *Procedures for Reimbursement Reviews*, should not be included in the proposed application, clearly state which comparator(s) and provide a clear rationale.

Irrespective of the discussion at the presubmission meeting, all sponsors who wish to omit a relevant comparator must file a [request for deviation form](https://cadthcanada.sharepoint.com/sites/pwa/PWAReports/CDR_Stats.xlsm?web=1) and obtain written approval from CDA-AMC prior to filing the application.

| **Questions Regarding Appropriate Comparators** |
| --- |
| 1. Question 1 (please state ‘none’ if there are no questions) |
| 1. Question 2 |
| 1. Add additional rows if required |

1. **Clinical Evidence**
   1. **Randomized Controlled Trials and Pivotal Studies**

Present a brief outline of the clinical development program for drug and indication of interest.

Summarize the key results from the pivotal trials.

Clearly state if you anticipate updated data for any of the studies to become available during the CDA-AMC review.

* 1. **Indirect Comparisons**

Provide a summary of all indirect treatment comparisons that will be included in the application.

* 1. **Other Evidence**

Provide a summary of other relevant evidence, including long-term extension phase 4 studies or other studies that may address important gaps in the evidence derived from the clinical development program.

| **Questions Regarding the Clinical Evidence** |
| --- |
| 1. Question 1 (please state ‘none’ if there are no questions) |
| 1. Question 2 |
| 1. Add additional rows if required |

1. **Economic evaluation**

Present an outline of the economic evaluation.

* Include information on the form of analysis (i.e., cost-minimization analysis or cost-utility analysis), and proposed modelling approach (e.g., Markov, PSM, microsim)
  + Please 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 indicate in the table below if you believe this may apply to your submission. Additional details are available in the *Procedures for Reimbursement Reviews*.
* Include the proposed comparators and rationale
* Include information on the clinical claim:
  + Better efficacy and/or safety
  + Similar efficacy and safety
* How is the clinical information from the trial(s) and/or indirect comparison being incorporated in the economic model (e.g., transformed / non-transformed)?
* Is a survival analysis being used to extrapolate time-to-event data?
  + If so, have the following parametric functions been fit: Weibull, Gompertz, gamma, exponential, generalised gamma, lognormal, and loglogistic?
* Include information on the cost claim:
  + Is there a difference in drug acquisition costs with the comparators?
  + Is there a difference in resource use and/or non-drug costs?

| **Questions Regarding the Economic Evaluation** |
| --- |
| 1. Question 1 (please state ‘none’ if there are no questions) |
| 1. Question 2 |
| 1. Add additional rows if required |
| ***If this submission could potentially be considered as a CMA, please indicate here.*** |

1. **Budget Impact Analysis**

Present a brief outline of the approach (epidemiological/market share/both) to estimating utilization forecasts, primarily of the submitted drug, but also of relevant changes in other in-scope health resources which warrant discussion.

| **Questions Regarding the Budget Impact Analysis** |
| --- |
| 1. Question 1 (please state ‘none’ if there are no questions) |
| 1. Question 2 |
| 1. Add additional rows if required |

1. **Diagnostic and Other Testing Resource Considerations (please delete if not applicable)**

Please note that test(s) and testing are defined as: "Interventions and/or procedures 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. **Is one or more diagnostic or other test(s) necessary to identify patient eligibility for this treatment (including medical imaging, companion diagnostic or other test[s])?**

​​​ Yes, required or recommended identify patients most likely to benefit from the drug

​​​ No

If required or recommended, please list the diagnostic or other test(s) that are necessary to identify patient eligibility for this treatment.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Diagnostic or other test** | **Required or Recommended** | **Purpose of the test** | **Timing of testing relative to treatment initiation** | **Test setting** |
| State the test | State if required or recommended | State the purpose of the test (e.g., what parameters are being evaluated) | State when the test is to performed relative to treatment initiation | Please indicate where the test is typically performed (e.g., imaging clinic, blood lab, specialist clinic) |
| Add rows as required |  |  |  |  |

* 1. **Is one or more test(s) necessary to monitor response to or safety of the treatment (check all that apply)?**

Yes, required or recommended to evaluate clinical response / disease progression

Yes, required or recommended to monitor for adverse events

​​ No

If applicable, please list the test(s) that are required or recommended.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Diagnostic or other test** | **Required or Recommended** | **Purpose of the test** | **Timing/Frequency of testing** | **Test setting** |
| State the test | State if required or recommended | State the purpose of the test (e.g., evaluate clinical response; monitor for adverse events [state the specific events]) | State the number of tests required, the interval of when testing should be performed, and if testing is required to reinitiate treatment after treatment discontinuation | Please indicate where the test is typically performed (e.g., imaging clinic, blood lab, specialist clinic) |
| Add rows as required |  |  |  |  |

1. **Considerations for a Time-Limited Recommendation (Please delete if not applicable)**
   1. **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. **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).

* 1. **Comparison of Studies**

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **Study Included in Initial Submission** | **Pending Phase III Study** |
| **Study Design** | Briefly describe (e.g., phase 2, open-label) | Briefly describe (e.g., phase 3, double-blind, placebo-controlled RCT) |
| **Sample size** | State the total N and include the sample size in each treatment group. | State the total N and include the sample size in each treatment group. |
| **Inclusion Criteria** | Please list key criteria only | Please list key criteria only |
| **Exclusion Criteria** | Please list key criteria only | Please list key criteria only |
| **Intervention** | State the drug, dosage, frequency of administration, route of administration, duration | State the drug, dosage, frequency of administration, route of administration, duration |
| **Comparator(s)** | For each comparator: state the drug, dosage, frequency of administration, route of administration, duration of treatment | For each comparator: state the drug, dosage, frequency of administration, route of administration, duration of treatment |
| **Primary End Point** | State the primary endpoint including the timeframe (e.g., through 24 weeks) | State the primary endpoint including the timeframe (e.g., through 24 weeks) |
| **Secondary and Exploratory End Points** | **Secondary:**  List the pre-specified secondary endpoints including the timeframe  **Exploratory:**  List the exploratory endpoints including the timeframe | **Secondary:**  List the pre-specified secondary endpoints including the timeframe  **Exploratory:**  List the exploratory endpoints including the timeframe |

Section 2: Pipeline Meeting Briefing Paper

| **Meeting Date and Time** |  |
| --- | --- |
| **Sponsor** |  |
| **Therapeutic Areas** |  |
| **Sponsor contact** |  |

|  |
| --- |
| **Confidentiality Guidelines** |
| By filing this *Pipeline Meeting Briefing Paper* with Canada’s Drug Agency (CDA-AMC), the sponsor accepts and agrees to the terms of the [*Procedures for Reimbursement Reviews*](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Reimbursement_Review_Procedures.pdf) 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 this document and all pipeline meeting materials with the authorized recipients. |

1. **Pipeline Meeting Attendees**

|  |  |
| --- | --- |
| **Organization** | **Attendees** |
| Sponsor | * Name; Job title; company or organization * Include all sponsor employees, clinical experts and/or consultants in this section |
| CDA-AMC | CDA-AMC attendees will be tailored based on available and subject matter. |

1. **Pipeline Meeting Agenda**

A sample agenda is provided below. Please modify the agenda as required and delete these instructions.

|  |  |  |
| --- | --- | --- |
| **Time** | **Topic** | **Lead** |
| 5 min | 1. **Welcome and opening remarks** | CDA-AMC |
| 30 min | 1. **Pipeline Overview**     1. **Volume of applications**   *Please summarize the number of CDA-AMC submissions anticipated by the sponsor within the scope of the pipeline (typically 2 to 3 years)*   * 1. **Anticipated timelines**   *Please highlight target timelines for both Health Canada and CDA-AMC submissions (graphical presentation is appreciated)*   * 1. **Therapeutic areas**   *Please highlight the different therapeutic areas and indications that are forthcoming in the sponsor’s pipeline.* | Sponsor |
| 10 min | 1. **Complex applications**   *Please highlight any applications that should be considered for review through the complex process and provide the rationale.* | Sponsor |
| 5 min | 1. **Diagnostic and other testing considerations**   *Please highlight any novel diagnostic, monitoring or other testing requirements, and/or any testing associated with the drug or drug regimen that* ***exceed*** *the current standards of care.* | Sponsor |
| 5 min | 1. **Questions and Answers** | All |
| 2 min | 1. **Wrap up** | CDA-AMC |

a Testing is defined as: "Interventions and/or procedures 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. **Summary of Pending Applications**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Drug name** | **Anticipated indication** | **Target date for Health Canada** | **Target date for CDA-AMC** | **Precision medicine** | **First drug for the indication** | **Impact on diagnostic or other testing resources** | **Impact on medical imaging resources** |
| Add generic name | Please state the anticipated indication | MM-YYYY or  QQ-YYYY | MM-YYYY or  QQ-YYYY | Yes / No | Yes / No | Yes / No | Yes / No |
| Add rows |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

1. **Volume of Applications**

Please identify the scope and timeframe of the pipeline meeting (typically 2 to 3 years).

Please briefly state the number of submissions anticipated by the sponsor within the scope of the pipeline.

If the meeting has been approved for a particular therapeutic area (e.g., new cancer drugs and indications), CDA-AMC encourages the sponsor to briefly summarize the number of applications that may be filed for other therapeutic areas (acknowledging that they will not be discussed in detailed during the pipeline meeting).

1. **Anticipated Timelines**

Please highlight target timelines for both Health Canada and CDA-AMC submissions using the table above. Whenever possible, more detail with respect to target timelines for filing is appreciated (e.g., target month or quarter).

1. **Therapeutic Areas**

Please briefly highlight the different therapeutic areas and indications that will be discussed in the pipeline meeting. This will help inform optimal attendance and discussion from CDA-AMC attendees.

1. **Complex Applications**

Please highlight any applications that should be considered for review through the complex process and provide a brief rationale.

1. **Diagnostic and Other Testing Resource Considerations**

Please highlight any novel diagnostic or other testing requirements (including but not limited to medical imaging) that **exceed** the current standards of care and will be required because of the drugs discussed during the pipeline meeting. Early identification of these potential issues could allow CDA-AMC to initiate work on implementation guidance earlier in the product lifecycle to help facilitate overall health system readiness (including through the [*Canadian Medical Imaging Inventory*](https://www.cadth.ca/canadian-medical-imaging-inventory)*)*.

1. **Questions for CDA-AMC**

| 1. Question 1 (please state ‘none’ if there are no questions) |
| --- |
| 1. Question 2 |
| 1. Add additional rows if required |