Pipeline Meeting Briefing Paper

**Instructions for Sponsors**

Sponsors are required to complete this template for 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)
* 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 for pipeline meetings.The completed document **must not exceed 12 pages.**

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. 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.

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/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 |