**CADTH Reimbursement Review**

**Application Overview**

**Instructions for Sponsors**

This form provides CADTH 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 CADTH submission filing process or requirements, please email requests@cadth.ca with the complete details of your question(s).

Before Completing the Template:

Please review the following documents to ensure an understanding of CADTH’s procedures and submission guidelines:

* [Procedures for CADTH Reimbursement Reviews](https://cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Reimbursement_Review_Procedures.pdf)
* [CADTH Procedures for Time-limited Reimbursement Recommendations](https://cadth.ca/sites/default/files/Drug_Review_Process/CADTH_TLR_Procedures.pdf)
* CADTH 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 CADTH 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 with CADTH.

**CADTH Reimbursement Review**

**Application Overview**

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| **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 CADTH**  | 1.
2.
 |
| **Sponsor requested reimbursement criteria** | [ ]  As per indication(s) to be reviewed by CADTH[ ]  Other: *please specify* *Note: Please do not include confidential brand names in this section* |
| **Does the indication under review include usage in pediatric patients (i.e., <18 years of age)?** | [ ]  No[ ]  Yes |
| **CADTH Application Information** |
| **Product eligibility criteria** | [ ]  New drug[ ]  New indication |
| [ ]  New combination product |
| [ ]  New formulation that is eligible for review by CADTH |
| [ ]  Subsequent entry non-biologic complex drug |
| **Drug category** | ☐ Non-oncology drug |
| ☐ Oncology drug |
| ☐ Plasma protein product  |
| **Type of CADTH review:** | [ ]  Standard review [ ]  Complex review[ ]  Tailored review[ ]  Resubmission (Eligibility decision date: DAY, MONTH, YEAR)[ ]  Reassessment (Eligibility decision date: DAY, MONTH, YEAR) |
| **Cell or gene therapy** | [ ]  No [ ]  Cell therapy[ ]  Gene therapy |
| **Has this drug previously been filed with CADTH 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 new information to CADTH. 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 CADTH Reimbursement Reviews](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_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** by CADTH.[ ]  Yes, request was **partially accepted** by CADTH.[ ]  Yes, request was **not accepted** by CADTH.***Note:*** *The letter from CADTH 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)[ ]  Project Orbis[ ]  To be confirmed (requested, Health Canada decision pending)[ ]  Other expedited pathway (please specify) |
| **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): |

[ ]

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 CADTH. | [ ]  | 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 CADTH  | [ ]  | 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 CADTH 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 CADTH in accordance with the time frames specified in the procedures for time-limited recommendations. The sponsor acknowledges that the CADTH 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 CADTH submission.

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

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 CADTH 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.CADTH 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 (CADTH appreciates this information may not be known. Please provide an estimate based on prior experience).