**CADTH Reimbursement Review**

**Tailored Review Application Form**

**Instructions for Sponsors**

This form must be completed by sponsors and submitted to CADTH ([requests@cadth.ca](mailto:requests@cadth.ca)) prior to filing a submission for products with the following characteristics:

* + New combination products (complete sections 1 and 2)
  + New formulations of existing drugs that are eligible for review (complete sections 1 and 3).

CADTH will review the information and, with input from the drug plans (as needed), confirm whether a standard or tailored review should be filed. A response will typically be provided within 10 business days of receiving the form. CADTH may share this form with the federal, provincial, territorial governments, including their agencies and departments, and the pan-Canadian Pharmaceutical Alliance.

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions, 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 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 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 sections of the template. When the template is complete, delete this cover page with the instructions (including the CADTH document header). You are welcome to add company-specific elements such as a disclaimer, header, footer, etc. as required. Save the completed template in PDF or Microsoft Word format.

Filing the Completed Template:

Send the completed template to [requests@cadth.ca](mailto:requests@cadth.ca).

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**Section 1: Background Information**

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| **Drug Characteristics** | **Sponsor’s Responses** |
| **Sponsor name** | Please provide the complete company name of the submission sponsor. |
| **Brand name** | Please state the brand name (if known). |
| **Generic name** | Please list the non-proprietary name(s) of the active substance(s) included in the drug of interest. |
| **Route of administration** | Please state the route of administration for the drug of interest. |
| **Dosage form and strengths** | Please identify the dosage forms and strengths for the drug of interest. |
| **Indication(s)** | Please list the indications that are approved or undergoing review by Health Canada for the drug of interest. |
| **Location of administration** | Please identify the location of administration (e.g., community and/or hospital) |
| **Date of Health Canada Approval** | Please provide the date or anticipated date of Health Canada approval for the drug of interest. |
| **Clinical development program** | Please provide a brief description of the clinical development program for the drug and indication. |
| **Comparator(s)** | Please provide a brief list of the comparators for the drug of interest. |
| **Contact information** | Name:  Title:  Email:  Phone:  Mailing Address: |

**Section 2: New Combination Products**

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| **Questions** | **Sponsor’s Responses** |
| 1. **Have the individual components been reviewed by CADTH for the same indication?** | **Response:  Yes  No**  **If yes, please state which components have been reviewed:** |
| 1. **Does the combination product contain at least one new active substance?** | **Response:  Yes  No**  **If yes, please state which components are new active substances:** |
| 1. **Are all of the individual components reimbursed by the drug plans?** | **Response:  Yes  No**  **Please provide a brief summary of the reimbursement status of the individual components, indicating any differences between the drug plans:** |
| 1. **Are the individual components currently indicated for use in combination therapy with one another?** | **Response:  Yes  No**  **Please provide details regarding the approved indications for combination usage of the individual components:** |
| 1. **Are the components marketed in Canada in the same dosage strength?** | **Response:  Yes  No**  **Please provide details regarding the dosage strengths for the combination product and the individual components:** |
| 1. **Is the price of the combination product the same or less than the sum of the individual components based on publicly available prices?** | **Response:  Yes  No** |

**Section 3: New Formulations of Existing Drugs that are Eligible for Review by CADTH**

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| **Questions** | **Sponsor’s Responses** |
| 1. **Does the new formulation have the same the indication as other existing formulation(s) of the drug?** | **Response:  Yes  No**  **If no, please state the indications and comment on the rationale for the differences in the indications:** |
| 1. **Has the active substance been reviewed by CADTH for the indication of interest?** | **Response:  Yes  No**  **If yes, please state which formulations have been reviewed and for what indications:** |
| 1. **Is the active substance currently reimbursed by the participating drug plans for the indication of interest?** | **Response:  Yes  No**  **Please provide details regarding the reimbursement status of the active substance, indicating any differences between the drug plans:** |
| 1. **Please describe the comparative clinical evidence available for the new formulation:** | **Direct evidence versus other formulation(s):  Yes  No**  **Indirect evidence versus other formulation(s):  Yes  No**  **Please provide details regarding the comparative evidence:** |
| 1. **Are there specific challenges with meeting the requirements for a standard review as described in CADTH’s procedures?** | **Response:  Yes  No**  **Please describe the specific requirements with which there are challenges and provide an explanation for each:** |