**Identification of Confidential Information Template**

**Instructions for Sponsors**

This template is used by sponsors when formally identifying confidential information contained within documents produced by Canada’s Drug Agency (CDA-AMC). Please read the instructions below and consult the recommended documentation prior to completing the template. If you have any questions, please [contact us](https://www.cda-amc.ca/contact-us) with the complete details of your question(s).

Prior to Completing the Template:

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

* + [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:

Ensure that the appropriate section of the template is completed and delete all sections that are not applicable:

* + **Section 1:** Reports for a standard or complex review
	+ **Section 2:** Report for a tailored review or request for advice
	+ **Section 3:** Expert committee recommendation
	+ **Section 4:** Feedback from drug programs on a draft recommendation

Information in the public domain will not be redacted from CDA-AMC documents. Please ensure that information requested for removal is not available in the public domain, including websites for regulatory authorities (e.g., United States Food and Drug Administration, Health Canada, European Medicines Agency) or heath technology assessment agencies (e.g., National Institute for Health and Care Excellence [NICE], Pharmaceutical Benefits Advisory Committee [PBAC], Scottish Medicines Consortium [SMC], Institute for Quality and Efficiency in Health Care [IQWiG]). Outputs of economic models (e.g., incremental cost-utility ratios) are not generally considered confidential*.*

Add or remove rows to the tables as required and do not add text to the column for CDA-AMC Responses. Please use 10-point Arial font when completing the table.

When the template is complete, delete this cover page with the instructions (including the CDA-AMC document header).

Filing the Completed Template:

The completed template should be sent as a Word document using the Pharmaceutical Submissions SharePoint Site.

**Identification of Confidential Information Form**

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| **Drug Name**  |  |
| **Sponsor**  |  |
| **Date**  |  |

**SECTION 1: STANDARD OR COMPLEX REVIEWS**

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| **Confidential information to be redacted from clinical report** |
| **Specify exact wording and page number** | **Sponsor’s rationale for removing information** | **CDA-AMC response** |
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| **Confidential information to be redacted from pharmacoeconomic report** |
| **Specify exact wording and page number** | **Sponsor’s rationale for removing information** | **CDA-AMC response** |
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| **Confidential information to be redacted from ethics report****Please delete if not applicable** |
| **Specify exact wording and page number** | **Sponsor’s rationale for removing information** | **CDA-AMC response** |
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| **Confidential information to be redacted from test procedure assessment report****Please delete if not applicable** |
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a Please limit this section to any errors that are identified in the document (e.g., transcription or typographical errors). Note that this does not include any issues with the presentation or interpretation of evidence.

**SECTION 2: TAILORED REVIEWS AND REQUESTS FOR ADVICE**

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| **CONFIDENTIAL INFORMATION TO BE REMOVED FROM CDA-AMC REPORT** |
| **Specify exact wording and page number** | **Sponsor’s rationale for removing information** | **CDA-AMC response** |
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a Please limit this section to any errors that are identified in the document (e.g., transcription or typographical errors). Note that this does not include any issues with the presentation or interpretation of evidence.

**SECTION 3: EXPERT COMMITTEE RECOMMENDATION**

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| **CONFIDENTIAL INFORMATION TO BE REMOVED FROM RECOMMENDATION** |
| **Specify exact wording and page number** | **Sponsor’s rationale for removing information** | **CDA-AMC response** |
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a Please limit this section to any errors that are identified in the document (e.g., transcription or typographical errors). Note that this does not include any issues with the presentation or interpretation of evidence.

**SECTION 4: DRUG PROGRAM FEEDBACK ON A DRAFT RECOMMENDATION**

CDA-AMC provides an opportunity for the sponsor to review the feedback from the drug programs to ensure that it does not contain any confidential information. This is offered as the drug programs may consider the unredacted draft recommendation when providing their input to CDA-AMC.

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| **CONFIDENTIAL INFORMATION TO BE REDACTED FROM DRUG PROGRAM FEEDBACK** |
| **Specify exact wording and page number** | **Sponsor’s rationale for removing information** | **CDA-AMC response** |
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