Sponsor Comments Template

**Instructions for Sponsors**

This template is to be used by sponsors when providing comments on the draft reports and by Canada’s Drug Agency (CDA-AMC) when providing responses to the commentary. Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions, please [contact us](https://www.cda-amc.ca/contact-us).

Before Completing the Template:

Please review the following to ensure an understanding of the reimbursement review procedures:

* [Procedures for Reimbursement Reviews](https://cadth.ca/sites/default/files/Drug_Review_Process/Drug_Reimbursement_Review_Procedures.pdf)
* Pharmaceutical Review Updates for any applicable information.

Completing the Template:

Complete the appropriate section of the template delete the section that is not applicable.

**Section 1: Reports for a standard or a complex review**

* + A maximum of 10 pages for comments on the clinical and economic reports (i.e., 10 pages for both reports combined, not 10 pages for each individual report).
  + 1 additional page for comments on the ethics report (if applicable)
  + 1 additional page for comments on the testing procedure assessment report (if applicable).

**Section 2: Report for a tailored review or request for advice**

* + A maximum of 10 pages is permitted for comments.

Do not change any of the following:

* + Table layout (including margin adjustment, cell padding, cell format, and table orientation)
  + Page layout (including margin size and page orientation)
  + Font color, font size, letter spacing, or line/paragraph spacing

The identification of errors and the reference list are not included in the total number of pages.

Please include specific references (page numbers, table numbers, etc.) to text within the reports, quoting text directly where appropriate/necessary. Use lower case letters for citations.

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 cover page, disclaimer, header, footer, etc. as required.

Filing the Completed Template:

Send the completed template as a Word document using the Pharmaceutical Submissions SharePoint Site.

**Reimbursement Review**

Sponsor Comments Template

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

**SECTION 1: STANDARD OR COMPLEX REVIEWS**

|  |  |  |
| --- | --- | --- |
| Sponsor’s Comments | | CDA-AMC Response |
| Clinical Review Report | | |
| **1** | Your text here | Leave blank – for CDA-AMC use |
| **2** | Your text here | Leave blank – for CDA-AMC use |
| **3** | Your text here | Leave blank – for CDA-AMC use |
| **4** | Your text here | Leave blank – for CDA-AMC use |
| **5** | Insert/delete table rows as appropriate | Leave blank – for CDA-AMC use |
| Pharmacoeconomic Review Report | | |
| **6** | Your text here | Leave blank – for CDA-AMC use |
| **7** | Your text here | Leave blank – for CDA-AMC use |
| **8** | Your text here | Leave blank – for CDA-AMC use |
| **9** | Your text here | Leave blank – for CDA-AMC use |
| **10** | Insert/delete table rows as appropriate | Leave blank – for CDA-AMC use |
| **Ethics Review Report (Delete section if not applicable)** | | |
| **11** | Your text here | Leave blank – for CDA-AMC use |
| **12** | Your text here | Leave blank – for CDA-AMC use |
| **13** | Insert/delete table rows as appropriate | Leave blank – for CDA-AMC use |
| **Testing Procedure Assessment Report (Delete section if not applicable)** | | |
| **14** | Your text here | Leave blank – for CDA-AMC use |
| **15** | Your text here | Leave blank – for CDA-AMC use |
| **16** | Insert/delete table rows as appropriate | Leave blank – for CDA-AMC use |

|  |  |  |
| --- | --- | --- |
| **ERRORS IDENTIFIEDa** | | |
| **Specify report, exact wording, and page number** | **Please provide details regarding why this is an error** | **CDA-AMC Response** |
|  |  |  |
|  |  |  |
|  |  |  |

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**

|  |  |  |
| --- | --- | --- |
| Sponsor’s Comments | | CDA-AMC Response |
| Review Report | | |
| **1** | Your text here | Leave blank – for CDA-AMC use |
| **2** | Your text here | Leave blank – for CDA-AMC use |
| **3** | Your text here | Leave blank – for CDA-AMC use |
| **4** | Your text here | Leave blank – for CDA-AMC use |
| **5** | Your text here | Leave blank – for CDA-AMC use |
| **6** | Your text here | Leave blank – for CDA-AMC use |
| **7** | Your text here | Leave blank – for CDA-AMC use |
| **8** | Your text here | Leave blank – for CDA-AMC use |
| **9** | Your text here | Leave blank – for CDA-AMC use |
| **10** | Insert/delete table rows as appropriate | Leave blank – for CDA-AMC use |

|  |  |  |
| --- | --- | --- |
| **ERRORS IDENTIFIEDa** | | |
| **Specify report, exact wording, and page number** | **Please provide details regarding why this is an error** | **CDA-AMC Response** |
|  |  |  |
|  |  |  |
|  |  |  |

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.

**Sponsor’s References**

1. First citation here
2. Second citation here

**CDA-AMC References**

1. For CDA-AMC Response use