**Request for Reconsideration Template**

**Instructions**

This template should only be completed by sponsors in the following situations:

1. Sponsor is planning to file a request for reconsideration on the basis that the expert committee recommendation is not supported by the evidence that had been submitted or the evidence identified in the review report(s).
2. Sponsor is providing commentary on a request for reconsideration filed by the drug programs.

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) with the complete details of your question(s).

Prior to Completing the Template:

Please review the following documents 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:

**Requesting a reconsideration:** Complete section 1 of the template and do not change any of the margin sizes. The maximum size is 5 pages (this total does not include the reference list or the first page with the details regarding reconsideration meetings). The font size must be 10 point.

**Commenting on reconsideration filed by drug programs:** Complete section 2 of the template and do not change any of the margin sizes. The maximum size is 5 pages (this total does not include the reference list). The font size must be 10 point. Sponsors should file their commentary within 5 business days of receiving the request (as directed in the correspondence).

Please include specific references to text within the recommendation and/or review reports, quoting from them directly where appropriate or necessary. References must be provided in the following format: In-text citations must be numbered in order of appearance and a numbered reference list must be provided in the JAMA Oncology format. When the template is complete, delete this cover page and its instructions (including the Canada’s Drug Agency document header).

Submitting the Template:

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

Request for Reconsideration Template

SECTION 1: SPONSOR REQUEST FOR RECONSIDERATION

1. Product Information

|  |  |
| --- | --- |
| **Drug Name**  |  |
| **Indication(s)** |  |
| **Sponsor** |  |
| **Date**  |  |

2. Type of Reconsideration Request

|  |
| --- |
| Please check the type of reconsideration being filed by the sponsor |
| [ ]  | Request for major revisions  |
| [ ]  | Request for minor revisions  |

3. Reconsideration Meeting for Sponsors

As part of the reconsideration process, Canada’s Drug Agency (CDA-AMC) offers the sponsor a one-hour meeting with agency staff to ensure clarity around the key issues raised in request for reconsiderations that are filed by the sponsor. Please indicate below if you are interested in participating in a meeting:

[ ]  Yes, we would like to participate in a meeting with CDA-AMC staff.

[ ]  No, we do not require a meeting with CDA-AMC staff.

Please indicate below if you are interested in having INESSS observe the meeting:

[ ]  Yes, we would like CDA-AMC to extend the invitation to INESSS.

[ ]  No, CDA-AMC should not extend the invitation to INESSS.

Those interested in participating in a meeting will be contacted regarding next steps.

4. Preferred dates for Reconsideration Meeting

Reconsideration meetings are only offered in the timeslots noted in the [schedule](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Meeting_Dates.pdf) (no exceptions will be made). State the preferred dates in the table below. Ensure that each date aligns with one of the available timeslots. If you are providing multiple options, please include a ranking for preference.

|  |  |
| --- | --- |
| **Date** | **Rank** |
| *Month-Day-Year* |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

4. Request for Reconsideration

Provide the specific details of the request for reconsideration in this section of the template. Use a clear and descriptive subheading that highlights each issue being raised by the sponsor. Under each subheading, the sponsor must describe the issue in 1 to 2 sentences, clearly describe the requested action(s), and the sponsors must clearly articulate the evidence and key information that supports their perspective regarding the issue(s) of interest and requested action(s). **Please ensure each issue is distinct and avoid repetition in presenting supporting evidence across issues.**

This approach ensures that each of the issues identified by the sponsor are clearly delineated within the documentation that is considered by the expert committee. **There are word limits for each section and the total** **comments cannot exceed 5 pages (excluding references). Text exceeding the word and page limits will not be accepted by CDA-AMC.** The font must be Arial (font size 10 point).

1. **Descriptive heading for issue 1 (maximum 10 words)**

*Describe the issue in 1 to 2 sentences. Maximum 40 words.*

**Requested Action**

*Describe the specific action(s) the sponsor believes would address the issue (e.g., requested revisions to the draft recommendation). Please be specific regarding the applicable section(s) of the draft recommendation and/or review reports. Maximum 200 words.*

**Supporting Evidence**

*Add a concise summary of the evidence and key information that supports the sponsor’s perspective regarding the issue and requested action(s). Maximum 1000 words.*

Please repeat this approach for each of the issues being raised.

**References**

SECTION 2: COMMENTS ON RECONSIDERATION FILED BY THE DRUG PROGRAMS

Please provide comments on the request for reconsideration that has been filed by the drug programs.

Comments should not exceed 5 pages (excluding references).

**References**