**Feedback on Draft Implementation Advice Report**

**Instructions for Stakeholders**

This template is for eligible stakeholders to provide feedback and comments to Canada’s Drug Agency (CDA-AMC) on a draft implementation advice report. The draft implementation advice report is posted for feedback for 10 business days.

CDA-AMC will only consider feedback received from eligible stakeholders including drug manufacturers, patient groups, clinician groups, and the participating drug programs. If you have any questions regarding the process for implementation advice panels, 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 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:

The maximum size is 3 pages (this total does not include the reference list). Feedback should be presented clearly and succinctly in point form, whenever possible. The issue(s) should be clearly stated, and specific reference must be made to the section of the implementation advice report under discussion (i.e., page number, section title, and paragraph).

Comments should be restricted to the content of the draft report and should not contain any language that could be considered disrespectful, inflammatory, or could be found to violate applicable defamation law.

Feedback or comments must concern implementation questions that were considered by the panel. No other aspects will be investigated in this part of the review process.

If comments exceed three pages, the feedback will not be accepted for review by CDA-AMC. References may be provided separately.

**Patient groups must complete Appendix 1 and Clinician groups must complete Appendix 2**.

Filing the Completed Template:

**Submit the** completed template by clicking *Submit Feedback* on the project webpage. To ensure fairness in CDA-AMC procedures, all stakeholder feedback must be received by the deadline posted on the CDA-AMC website.

**Feedback on Draft Implementation Advice Report**

|  |  |
| --- | --- |
| **Stakeholder information** |  |
| Project number |  |
| Condition under review |  |
| Organization  |  |
| Contact informationa | Name:  |

a CDA-AMC may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CDA-AMC.

|  |
| --- |
| **SECTION 1: IMPLEMENTATION ADVICE** |
| 1. **Please indicate if the stakeholder agrees with the implementation advice.**
 | Yes |[ ]
|  | No |[ ]
| Please explain why the stakeholder agrees or disagrees with the draft advice. Whenever possible, please identify the specific text from the advice and the rationale. |
| **Implementation advice panel consideration of the stakeholder input** |
| 1. **Does the draft advice demonstrate that the panel has considered the stakeholder input that your organization provided to CDA-AMC?**
 | Yes |[ ]
|  | No |[ ]
| If not, what aspects are missing from the draft advice? |
| **Clarity of the draft implementation advice**  |
| 1. **Are the reasons for the panel’s advice clearly stated in the draft report?**
 | Yes |[ ]
|  | No |[ ]
| If not, please provide details regarding the information that requires clarification. |
| 1. **Have the implementation issues been clearly articulated and adequately addressed in the draft report?**
 | Yes |[ ]
|  | No |[ ]
| If not, please provide details regarding the information that requires clarification. |

**Appendix 1. Conflict of Interest Declarations for Patient Groups**

* To maintain the objectivity and credibility of the CDA-AMC drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
* This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
* CDA-AMC may contact your group with further questions, as needed.

|  |
| --- |
| **A. Patient Group Information** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation. |
| **B. Assistance with Providing Feedback** |
| 1. **Did you receive help from outside your patient group to complete your feedback?**
 | No | [ ]  |
|  | Yes | [ ]  |
| If yes, please detail the help and who provided it. |
| 1. **Did you receive help from outside your patient group to collect or analyze any information used in your feedback?**
 | No | [ ]  |
|  | Yes | [ ]  |
| If yes, please detail the help and who provided it. |
| **C. Previously Disclosed Conflict of Interest** |
| 1. **Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CDA-AMC review and have those declarations remained unchanged? If no, please complete section D below.**
 | No | [ ]  |
|  | Yes | [ ]  |
| **D. New or Updated Conflict of Interest Declaration** |
| 1. **List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.**
 |
| **Company** | **Check Appropriate Dollar Range** |
|  | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

**Appendix 2. Conflict of Interest Declarations for Clinician Groups**

* To maintain the objectivity and credibility of the CDA-AMC drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
* This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
* CDA-AMC may contact your group with further questions, as needed.
* For conflict of interest declarations:
	+ Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
	+ Please note that declarations are required for each clinician that contributed to the input.
	+ If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
	+ Please add more tables as needed (copy and paste).
	+ All new and updated declarations must be included in a single document.

|  |
| --- |
| **A. Assistance with Providing the Feedback** |
| 1. **Did you receive help from outside your clinician group to complete this submission?**
 | No | [ ]  |
| Yes | [ ]  |
| If yes, please detail the help and who provided it. |
| 1. **Did you receive help from outside your clinician group to collect or analyze any information used in this submission?**
 | No | [ ]  |
| Yes | [ ]  |
| If yes, please detail the help and who provided it. |
| **B. Previously Disclosed Conflict of Interest** |
| 1. **Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CDA-AMC review and have those declarations remained unchanged? If no, please complete section C below.**
 | No | [ ]  |
| Yes | [ ]  |
| If yes, please list the clinicians who contributed input and whose declarations have not changed:* Clinician 1
* Clinician 2
* *Add additional (as required)*
 |

**C. New or Updated Conflict of Interest Declarations**

|  |
| --- |
| **New or Updated Declaration for Clinician 1** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.  |
| **Company** | **Check Appropriate Dollar Range** |
|  | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

|  |
| --- |
| **New or Updated Declaration for Clinician 2** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.  |
| **Company** | **Check Appropriate Dollar Range** |
|  | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

|  |
| --- |
| **New or Updated Declaration for Clinician 3** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[x]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.  |
| **Company** | **Check Appropriate Dollar Range** |
|  | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

|  |
| --- |
| **New or Updated Declaration for Clinician 4** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.  |
| **Company** | **Check Appropriate Dollar Range** |
|  | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

|  |
| --- |
| **New or Updated Declaration for Clinician 5** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.  |
| **Company** | **Check Appropriate Dollar Range** |
|  | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |