**Declaration Letter Template**

**Instructions for Sponsors**

This form ensures that the sponsor acknowledges the terms and conditions of the reimbursement review procedures used by Canada’s Drug Agency (CDA-AMC), as well as the procedures related to submitted prices, disclosure of known clinical studies, and communications.

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the submission filing process or requirements, please [contact us](https://www.cda-amc.ca/contact-us) with the complete details of your question(s).

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:

Please complete all sections of the letter template. With the exception of the highlighted placeholders, do not alter the text of the letter template.

When the template is complete, delete this cover page with the instructions (including the document header). Please feel free 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:

Incorporate the completed template into the package of required documents. Please consult the relevant procedural documentation for details on how to file the application with CDA-AMC.

**[Sponsor’s letterhead]**

[Date]

Canada’s Drug Agency (CDA-AMC)

600-865 Carling Avenue

Ottawa, ON

K1S 5S8

Reference: [Brand name/generic name]

|  |
| --- |
| **Agreement to Supply at the Submitted Price** |
| This letter confirms that [name of sponsor] will supply the above-named drug at a price no greater than the submitted price, as provided in the application to Canada’s Drug Agency (CDA-AMC), to all the drug programs that participate in the CDA-AMC reimbursement review process.We understand that the submitted price is the price per smallest dispensable unit that is submitted to CDA-AMC and that must not be exceeded for any of the drug programs or cancer agencies following completion of the review processes. The submitted price will be disclosed in all applicable CDA-AMC reports. |
| **Disclosure of all Studies** |
| This letter confirms that [name of sponsor] has disclosed all unpublished studies known to [name of sponsor], including those undertaken by other companies that distribute, market, and license this drug in Canada or in other countries and those undertaken by other groups or individuals as of [insert date]. |
| **Authorizing Unrestricted Sharing of Information** |
| This letter acknowledges that CDA-AMC may communicate, without restriction with respect to the product under review, with the authorized recipients in accordance with the *Reimbursement Review Confidentiality Guidelines*. This includes, but is not limited to:* Federal, provincial, and territorial government representatives (including their agencies and departments)
* pan-Canadian Pharmaceutical Alliance office
* Canadian Association of Provincial Cancer Agencies
* Canadian Blood Services
 |
| **Consenting to Terms and Conditions**  |
| This letter acknowledges that by filing an application with CDA-AMC, the sponsor consents to be bound by the terms and conditions specified in the *Procedures for Reimbursement Reviews* and all provisions regarding withdrawal from the CDA-AMC review process. Consent to the terms and conditions cannot be revoked by the sponsor at any time during or after the CDA-AMC’s review. |

**[Signature]**

**[Name and Title of Senior Company Official of Sponsor]**