**Regulatory and HTA Status**

**Instructions for Sponsors**

In this template, the sponsor is required to provide details and links to decisions and/or recommendations regarding the status of the health technology under review in other jurisdictions.

Sponsors are required to provide the completed template at both of the following timepoints:

1. Initial copy provided at the time of filing the application package.
2. Updated copy when filing their comments on the draft reports.

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 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:

Complete the status column of the tables using the following options:

* **Table 1:** Under review; Not recommended; Recommended; or Not filed for review.
* **Table 2:** Under review; Approved; Not approved; Not filed for review.

Please focus only on the indication(s) which are under review by Canada’s Drug Agency (CDA-AMC). If there are multiple indications under review, please use separate tables for each indication and clearly label the indication that is summarized in each table.

When the template is complete, delete this cover page with the instructions.

Filing the Completed Template:

Save the completed template as a Microsoft Word document.

As noted above, sponsors are required to provide the completed template at the time of filing the application package and provide an updated copy when filing their comments on the draft reports. CDA-AMC may update the information provided by the sponsor with new information, as required.

**Regulatory and HTA Status**

**Brand (non-proprietary):**

**Indication:**

**Sponsor:**

Table 1: Health Technology Assessment Agencies

|  |  |  |  |
| --- | --- | --- | --- |
| **Agency**  | **Region** | **Status** | **Link to decision** |
| Institut national d'excellence en santé et services sociaux (INESSS)  | Quebec | *Under review**Not recommended* *Recommended**Not filed for review* | *Please paste in URL* |
| National Institute for Health and Care Excellence (NICE) | NHS England |  |  |
| Scottish Medicines Consortium | NHS Scotland |  |  |
| All Wales Medicines Strategy Group (AWMSG) | NHS Wales |  |  |
| Pharmaceutical Benefits Advisory Committee (PBAC) or Medical Services Advisory Committee (MSAC) | Australia |  |  |
| PHARMAC | New Zealand |  |  |
| Haute Autorité de Santé  | France |  |  |
| Institute for Clinical and Economic Review (ICER) | United States | *N/A* |  |

Table 2: Regulatory Agencies

|  |  |  |  |
| --- | --- | --- | --- |
| **Agency (region)** | **Region** | **Status** | **Link to decision** |
| Food and Drug Administation  | United States | *Under review**Approved* *Not approved**Not filed for review* | *Please paste in URL* |
| European Medicines Agency | European Union |  |  |
| Therapeutic Goods Administration | Australia |  |  |
| Medicines and Healthcare products Regulatory Agency | United Kingdom |  |  |