CADTH Consultation on Time-limited Reimbursement Recommendations: Stakeholder Feedback Template

Thank you for your interest in contributing to CADTH’s consultation process. Your input is needed and highly valuable. The purpose of this consultation is to gather feedback on a proposal to integrate time-limited recommendations into CADTH's drug reimbursement review processes.

How to Participate in the Consultation

To provide comments on the proposal, please complete this feedback template and email it as a **Microsoft word document** to feedback@cadth.ca.

The deadline for feedback is **5:00 p.m. ET on May 1, 2023.**

Please use the following format for naming the file: “Organization name – CADTH TLR Feedback”

For your feedback to be considered, you must identify yourself to CADTH. Only 1 response per organization will be considered. If you have any questions about the feedback process, please email CADTH.

There is no limit on the number of pages for feedback. Please ensure that feedback is clear, concise, and relevant to the scope of the current consultation.

Contact Information

|  |  |
| --- | --- |
| **Organization providing feedback:** |  |
| **Contact person:a** |  |
| **Title:** |  |
| **Email address:** |  |

a CADTH may contact this person if comments require clarification.

Eligibility Criteria for Time-Limited Recommendations

|  |
| --- |
| 1. **Please add any comments regarding the proposed eligibility criteria for time-limited recommendations.**
 |
| **Response:** |

Presubmission Phase

|  |
| --- |
| 1. **Please add any comments regarding the opportunities to discuss potential time-limited recommendations during the presubmission phase.**
 |
| **Response:** |

Application and Screening Phase

|  |
| --- |
| 1. **Please add any comments regarding the proposed processes for a sponsor to identify potential time-limited recommendations and CADTH’s initial screening of eligibility.**
 |
| **Response:** |

Stakeholder Engagement

|  |
| --- |
| 1. **Please add any comments regarding the engagement of patient groups and clinician groups through the time-limited recommendation process.**
 |
| **Response:** |

Review Phase

Consideration of Evidence Gaps

|  |
| --- |
| 1. **Please add any comments regarding the proposal to discuss the potential importance of the gaps in the evidence within the clinical and economic reports.**
 |
| **Response:** |

Qualifying Notice

|  |
| --- |
| 1. **Please add any comments regarding the proposal to use the qualifying notice as the basis for informing CADTH about the sponsor’s plan to generate additional phase III evidence.**
 |
| **Response:** |

Recommendation Phase

Expert Committee Deliberations

|  |
| --- |
| 1. **Please add any comments regarding the process for deliberation on potential time-limited recommendations.**
 |
| **Response:** |

CADTH Recommendation Document

|  |
| --- |
| 1. **Please add any comments regarding the proposed process for communicating time-limited recommendations within the recommendation documents.**
 |
| **Response:** |

Implementation Phase

|  |
| --- |
| 1. **Please add any comments regarding the required status updates from sponsors.**
 |
| **Response:** |

Reassessment of a Time-Limited Recommendation

Proposed Timelines for Reassessment

|  |
| --- |
| 1. **Please add any comments regarding the proposed timelines for filing a reassessment following completion of the phase III clinical trial.**
 |
| **Response:** |

Initiating the Reassessment Process

|  |
| --- |
| 1. **Please add any comments regarding the proposed situations where a reassessment could be initiated by the drug programs that participate in the CADTH reimbursement review process (e.g., failure of the sponsor to file a reassessment application).**
 |
| **Response:** |

Application Requirements for Reassessment

|  |
| --- |
| 1. **Please add any comments regarding the application requirements for a reassessment.**
 |
| **Response:** |

Recommendation Phase

|  |
| --- |
| 1. **Please add any comments regarding the potential output of the expert committee’s deliberations on a reassessment.**
 |
| **Response:** |

Transparency

|  |
| --- |
| 1. **Please add any comments regarding the CADTH proposal that sponsors must consent that all information related to evidence generation plans be disclosable when the CADTH recommendations and reports are posted on the CADTH website.**
 |
| **Response:** |

Terminology

|  |
| --- |
| 1. **Please add any comments regarding the proposed nomenclature “time-limited recommendation” (e.g., does it appropriately capture the intent of these recommendations?).**
 |
| **Response:** |