CADTH

Proposal to Enhance Transparency of CADTH's Review Reports and Recommendations

1. Proposal Objective

As one of CADTH's core values, we are committed to further enhancing the transparency of our review processes. As such, CADTH considers it essential that any information submitted to CADTH for review be fully disclosable.

CADTH would like to invite stakeholder comments on a proposal to further strengthen transparency by requiring that clinical, economic, and other information submitted to the CADTH review processes be made disclosable at the time of publishing its reports and recommendations on its website.

CADTH believes increasing the transparency of its reports and recommendations will help to:

- provide better accessibility, comprehensiveness, and usefulness of information for all stakeholders
- reduce administrative burden for CADTH and manufacturers/submitters
- promote greater confidence in CADTH's recommendation process.

2. Background

As a key contributor in the Canadian health care system, CADTH receives clinical and economic information from a submitter, as well as perspectives from patients and clinicians. This information is used to evaluate and provide drug and other product reimbursement recommendations and advice to participating federal and provincial public drug and other programs.

In recent years, both national and international organizations have developed and implemented transparency initiatives to disclose data (e.g., trial data, Clinical Study Reports, etc.) to better support decision-making. CADTH adheres to the value of transparency by publishing the process steps, including a process to engage stakeholder input and feedback, status of reviews, timelines, reports, recommendation and reasons for the recommendation.

CADTH has formal procedures and guidelines in place to handle information submitted to the CADTH review processes, including non-disclosable information. As a result, CADTH currently spends a substantial amount of time and effort negotiating with the submitter and redacting information deemed to be non-disclosable by the submitter. Redacting means editing a document to delete or mask information that has been deemed as non-disclosable by the submitter.

Information that is deemed to be non-disclosable by a submitter is a barrier to transparency. It results in documents being published that contain, at times, significant amounts of relevant information that is rendered not visible at the request of the submitter. This, in turn, could hamper understanding of the issues outlined in the reports and the rationale for the recommendation.

Therefore, CADTH proposes to amend its existing procedures and guidelines with regard to how it will handle confidential or non-disclosable information in its reports and recommendations by making the information in its reports and recommendations fully disclosable at the time of publication on its website. The proposal would be

aligned with international policies and best practices,[1,2] as well as with Health Canada's recent regulatory changes. CADTH is of the view that information to support decision-making, as contained in its reports and recommendations, should be made fully disclosable to ensure that stakeholders and the public can better understand the evidence that supports the outcome of a recommendation made by CADTH's expert review committees.

3. Highlight of Proposed Changes

To enhance transparency of its drug review and recommendation processes, it is proposed that CADTH will seek to make information that is submitted to the CADTH review processes fully disclosable at the time of publication on its website by amending its respective procedures and guidelines (e.g., *Procedure and Submission Guidelines for the CADTH Common Drug Review*, *pCODR Procedures*, *pCODR Disclosure of Information Guidelines,* etc.). For greater certainty, the proposed amendments would allow CADTH to use and disclose information provided by a submitter (i.e., both clinical and economic) or from other sources (e.g., patient and clinician input) in its reports and recommendation that would be published to support decision-making. Table 1 contains a sample list of sources of information that CADTH uses to assess a drug or other product submission, and the disclosure status of these documents. Be advised this list is not exhaustive; the full documentation requirements are set out in the respective CADTH program's procedures and guidelines.

Table 1: CADTH Sample List of Sources of Information to Assess Submissions

Key Sources of Information Used by CADTH to Assess a Drug or Other Product Submission	Current Disclosure Status	Proposal
Clinical Study Report	Often non-disclosable	It is proposed that CADTH may use and disclose all relevant information provided by a submitter or from other sources at the time of publishing its reports and recommendations on its website.
Regulatory documents (e.g., Common Technical Documents, Reviewer's Report, Clarifaxes, etc.)	Often non-disclosable	
Other supporting documents (e.g., new data generated, quality of life data, resubmission eligibility form, etc.)	Often non-disclosable	
Indirect Treatment Comparison Technical Document Report	Often non-disclosable	
Patient Input	Disclosable	
Clinician Input	Disclosable	
Participating Jurisdiction Input	Disclosable	
Publication or other information in the public domain	Disclosable	
Pricing information (list price)	Disclosable	
Pharmacoeconomic Report	Partially disclosable	
Budget Impact Analysis Report	Partially disclosable (note: submitter's market share assumptions and results are currently non-disclosable)	

[1] European Medicines Agency. European Medicines Agency policy on publication of clinical data for medicinal products for human use, POLICY/0070, effective date: 21 March 2019 [cited 2019 July 12]. Available from: https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf

[2] Food and Drug Administration. Clinical Data Summary Pilot Program [cited 2019 July 12]. Available from: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm589210.htm

[3] Government of Canada. Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information): Canada Gazette, Part II, Volume 153, Number 6 – March 4, 2019 [cited 2019 July 12]. Available from: http://www.gazette.gc.ca/rp-pr/p2/2019/2019-03-20/html/sor-dors62-eng.html

4. How to Submit

To provide feedback on the proposals, please use the feedback template. The completed template must be saved in one of the following formats:

- Microsoft Word document (.doc or.docx)
- unlocked PDF document that permits copying and pasting of text.

The completed templates must be uploaded sent to feedback@cadth.ca.

Feedback should be presented clearly and succinctly in 11-point font and must be received by CADTH by **5:00 p.m. EDT on Friday, September 13, 2019**. For feedback to be considered, you must identify yourself to CADTH. Only one response per organization will be considered. If more than one response is received, only the first will be considered.

If you have any questions about the feedback process, please email us at feedback@cadth.ca. We thank you in advance for your interest.