

Consultation for CADTH Common Drug Review and pan-Canadian Oncology Drug Review Programs Regarding Submitted Price

Purpose

CADTH is inviting stakeholder comments and feedback on a proposed revision to the CADTH Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR) procedures that would require disclosure of the submitted price (i.e., the submitted price will no longer be considered confidential). This revision would enhance transparency for both the CDR and pCODR processes.

Background

CADTH's jurisdictional customers¹ have encountered a variety of issues due to different interpretations by pharmaceutical manufacturers when the "submitted price" for a drug is filed as a confidential price for review through the CDR or pCODR process. The following are examples of issues that have emerged regarding confidential submitted prices:

- There is a misconception that confidential submitted prices automatically become transparent following a positive listing decision by one or more of CADTH's jurisdictional customers.
- A number of manufacturers have asked why further price negotiation is required at the jurisdictional level despite having already filed a confidential reduced price with CADTH.
- A number of manufacturers have refused to offer the confidential submitted price to CADTH's jurisdictional customers and have indicated that a "product listing agreement" is required to obtain the confidential submitted price.
- Several manufacturers have attempted to include details of confidential product listing agreements in pharmacoeconomic evaluations submitted to CDR. The CDR and pCODR processes do not assess product listing agreements as part of the recommendation process.

These situations have led to confusion between individual manufacturers, CADTH, and CADTH's jurisdictional customers.

CADTH's Proposal for Disclosure of Submitted Price for Both the CDR and pCODR Programs

For all drug applications filed for review through either the CDR or pCODR process on or after January 1, 2016, CADTH is proposing that the submitted price be disclosed in all applicable CDR and pCODR review reports, as well as Canadian Drug Expert Committee (CDEC) and pCODR Expert Review Committee (pERC) recommendation documents posted on the CADTH website. If, however, an application is voluntarily withdrawn by the submitter/manufacturer during the review process in accordance with CDR or pCODR procedures, the submitted price will not be publicly disclosed by CADTH (unless it is already in the public domain).

Next Steps

CADTH will carefully assess all stakeholder feedback from this consultation before announcing any final decisions regarding changes to current CDR and pCODR procedures regarding submitted price. Any future changes will be applied to and implemented for both the CDR and pCODR programs simultaneously.

¹ The term "CADTH's jurisdictional customers" refers to the federal, provincial, and territorial drug plans that participate in the CDR process and the provincial and territorial Ministries of Health and provincial cancer agencies that participate in the pCODR process.