

April 1, 2015

**Important Notice: Implementation of Guidelines for Manufacturers on Application Fees for pCODR**

Hello,

CADTH invited stakeholder comments and feedback on the *Guidelines for Manufacturers on Application Fees for the pan-Canadian Oncology Drug Review* (pCODR) on March 5, 2015.

We would like to thank all stakeholders who responded to the consultation. Feedback was received from two industry association groups and three pharmaceutical companies. We carefully considered all stakeholder feedback. The key changes made in response to stakeholder feedback received are as follows:

- An **application fee** will apply to a drug manufacturer submitting an application for a submission or resubmission of cancer drugs (including a submission or resubmission of new indication that is not likely to be submitted to Health Canada for review) to the pCODR program for review **received on or after April 1, 2015**.
- We recognize that there is a need for some flexibility to ensure that the needs of cancer patients are met; and therefore, we will continue to make the priority review mechanism available under the pCODR program; however, a fee will not apply to a request for priority review. We'll continue to work closely with submitters to make the most of this mechanism.
- In addition, there will be no fee charged for a procedural review request.
- We also received a number of recommendations in regards to making changes to the submission processes. It is important to note that the purpose of the application fees is to off-set some of the costs of a drug review and to help finance an increase in the number of cancer drugs that are reviewed by CADTH on an annual basis. We appreciate receiving these helpful ideas and will continue to consider process changes as part of the CDR-pCODR alignment work and through existing mechanisms such as the stakeholder engagement sessions and the Industry Liaison Forum.

CADTH will re-evaluate the fee structure after 1 year of experience or earlier, as deemed appropriate by the CADTH Board.

Please review the complete [Guidelines for Manufacturers on Application Fees for the pan-Canadian Oncology Drug Review](#) for additional information. We have also included a list of [FAQs](#) to provide some guidance on the new application fee structure for a review through the pCODR process.

Should you have any questions, please contact us at [requests@cadth.ca](mailto:requests@cadth.ca)