

IMPORTANT NOTICE: CHANGES TO pCODR PROCEDURAL REVIEW GUIDELINES

April 17, 2014

Hello:

As a result of the transfer of the pan-Canadian Oncology Drug Review (pCODR) to the Canadian Agency for Drugs and Technologies in Health (CADTH) on April 1, 2014, we are writing to inform you of the process changes to pCODR's *Procedural Review Guidelines*. Please be advised that the changes to pCODR's *Procedural Review Guidelines* will take effect immediately as of April 17, 2014.

One of pCODR's Guiding Principles is an ethical review process. A fundamental component to having an ethical review process is a commitment to procedural fairness. Because the procedural review mechanism is an important cornerstone of the pCODR process and was included in response to stakeholder requests for a way to ensure pCODR adheres to its own processes and guidelines, it will be integrated into CADTH's governance structure.

The key change to the pCODR procedural review mechanism is in who conducts the procedural review and how a decision is made.

Previously, grounds for a procedural review were determined by the Steering Committee Co-Chairs by consensus. If grounds for a procedural review exist, a three-person panel consisting of individuals from the pCODR Steering Committee were appointed by the Steering Committee Co-Chairs. The Procedural Review Panel reviewed the submitted request for a procedural review and the supporting documentation and determined the outcome of the procedural review.

As of April 17, 2014 under CADTH's governance structure, it is the CADTH Chief Executive Officer, on the advice of the pCODR Advisory Committee (PAC) Chair and Vice-Chair, who will determine if the grounds for a procedural review exist. The grounds for review are assessed separately from the review itself.

If there are no grounds for a procedural review, this will be determined within 15 business days of the submitted date of an application for a procedural review, and it will be communicated on the pCODR website that the pERC Final Recommendation can be implemented. The party who made the request will be informed by the CADTH Chief Executive Officer in writing of the decision.

If, however, grounds for a procedural review exist, the CADTH Chief Executive Officer will appoint three (3) to five (5) members from the PAC, as needed. The PAC panelists will consider the evidence and make a recommendation to the CADTH Chief Executive Officer. The CADTH Chief Executive Officer will make the decision based on PAC's recommendation, and respond to the requester in writing.

As has always been the case, it is important to note that the outcome of the procedural review may or may not result in a change to the pERC Final Recommendation.

To learn more about the new changes to the pCODR *Procedural Review Guidelines*, please read *How will the procedural review mechanism work under CADTH?*

How will the procedural review mechanism work under CADTH?

A party (e.g., manufacturer, tumour group, patient group, or the Provincial Advisory Group) who participated in the pCODR review for a specific drug product may make a procedural review request to the CADTH Chief Executive Officer if the affected party believes that: (1) the process has not been followed as set out in the *pCODR Procedures* or (2) the pCODR Expert Review Committee (pERC) Deliberative Framework was not applied **within 10 business days** of a pERC Final Recommendation being issued. No extensions will be granted to the 10 business day period and all supporting documentation must be submitted within this period.

The requester must use the [pCODR Procedural Review Request Form](#) to initiate a procedural review request.

These grounds relate only to whether or not process was followed and not to the content of the pERC Final Recommendation. Differences in the interpretation and use of data during the review do not constitute grounds for a procedural review (e.g., the selection of comparators, the use of data sets, the place in therapy). In addition, disagreement with pCODR's approach to managing non-disclosable information that was provided in the submission, including use or non-use in the review process, does not constitute grounds for a procedural review, provided processes were followed as outlined in the *pCODR Procedures* and the *pCODR Disclosure of Information Guidelines*.

Upon receiving a request for a procedural review, the CADTH Chief Executive Officer, on the advice of the pCODR Advisory Committee (PAC) Chair and Vice-Chair, will determine if the grounds for a procedural review exist. The grounds for review are assessed separately from the review itself.

The party who made the request will be informed by the CADTH Chief Executive Officer in writing if the procedural review request has been accepted or not accepted.

If there are no grounds for a procedural review, this will be determined within 15 business days of the submitted date of an application for a procedural review, and it will be communicated on the pCODR website that the pERC Final Recommendation can be implemented.

If, however, grounds for a procedural review exist, the CADTH Chief Executive Officer will appoint three (3) to five (5) members from the PAC, as needed. The PAC panelists will consider the evidence and make a recommendation to the CADTH Chief Executive Officer.

The PAC panelists may recommend that:

1. No changes are required to the pERC Final Recommendation and a *Notification to Implement* a pERC Final Recommendation should be issued by the pCODR Secretariat.
2. Steps in the pCODR review process must be revisited and/or the submission must be re-deliberated by pERC at the next possible pERC meeting. A re-deliberation may result in the pERC Final Recommendation being maintained or being changed.

During this period, P/T Ministries of Health and Provincial Cancer Agencies would not implement the pERC Final Recommendation while a procedural review is being conducted.

The CADTH Chief Executive Officer will make the decision based on PAC's recommendation, and respond to the requester in writing. If steps in the pCODR review process must be revisited and/or the recommendation re-deliberated, the submission receives priority placement on the pERC meeting agenda at which it would be re-deliberated and work on the submission would be prioritized within the pCODR Secretariat.

- If the pERC Final Recommendation is maintained following the re-deliberation, a *Notification to Implement* a pERC Final Recommendation will be issued by the pCODR Secretariat.
- If the pERC Final Recommendation is changed following the re-deliberation, a new pERC Final Recommendation will be publicly posted and a *Notification to Implement* a pERC Final Recommendation will be issued by the pCODR Secretariat.

As has always been the case, it is important to note that the outcome of the procedural review may or may not result in a change to the pERC Final Recommendation.

How are decisions on procedural reviews communicated?

High-level details of any submitted procedural review request will be publicly posted on the pCODR website.

When a pERC Final Recommendation can be implemented, the pCODR Secretariat will issue a *Notification to Implement* a pERC Final Recommendation and this will be communicated on the pCODR website.

The party who made the request will be informed by the CADTH Chief Executive Officer in writing of the following key procedural review decisions:

- After a procedural review request has been submitted, if the procedural review request has been accepted or not accepted.
- Whether the Procedural Review Panel determines if the submission will be re-deliberated by pERC or if a *Notification to Implement* a pERC Final Recommendation will be issued without a re-deliberation of the submission.

The details and outcomes of the procedural review will be communicated in the pERC Final Recommendation.

How long does the procedural review process take?

A decision on whether or not to conduct a procedural review will take place within 15 business days of the submitted date of an application for a procedural review. The duration of the procedural review may vary, depending on the complexity and nature of the request.

pCODR Procedural Review Request Form

Date Procedural Review Request Submitted: _____

Final Recommendation for which Procedural Review is being Requested

Drug Name: _____

Indication: _____

Date pERC Final Recommendation Issued: _____

Information on Party making the Request

Organization: _____

Role in pCODR Review Process: _____

Contact Name: _____

Contact Email: _____

Contact Phone: _____

Grounds for the Procedural Review Request

Please check the following grounds that may apply:

- pCODR failed to act in accordance with its procedures in conducting the review
- pERC failed to apply its deliberative framework in formulating recommendations.

Provide a detailed description and any relevant documentation of how pCODR failed to act in accordance with its procedures or how pERC failed to apply its deliberative framework. Relevant pCODR process steps and components of the pERC deliberative framework should be clearly identified (see the *pCODR Procedures Document*, which is available on the CADTH website, www.cadth.ca/pcodr). This section should not exceed five pages.

Signature: _____

Date: _____