# Consultation to Increase Opportunity for Clinician Input and Feedback in CADTH pan-Canadian Oncology Drug Review Process

**New Call for Feedback Deadline**:

**November 30, 2015 at 5:00 p.m. ET** via email to info@pcodr.ca

CADTH is inviting stakeholder comments on proposed changes to the pan-Canadian Oncology Drug Review (pCODR) program that would allow for broader clinician participation in the pCODR process.

CADTH continues to foster relationships with the clinician community and believes that increasing the opportunity for clinicians to provide input and feedback into the pCODR process will provide and enhance value-added information, not only for the pCODR program, but also for the broader discussion of drug funding decisions in Canada.

## Background

Currently for every submission, the pCODR process involves three oncologists reviewing clinical data, providing context, and developing the main conclusions of the Clinical Guidance Report.

Additional clinician input and feedback beyond that of the three Clinical Guidance Panel clinician members is not presently eligible for reconsideration by the pCODR Expert Review Committee (pERC), as there is no formal process for clinicians to comment on issues specific to the local level.

The current pCODR process involves formal steps for submitting both stakeholder input and feedback. Eligible groups presently include the submitter, the manufacturer (if different from the submitter), registered patient advocacy groups, and the Provincial Advisory Group (PAG). Eligible feedback on the Initial Recommendation is provided to pERC for re-deliberation, and if appropriate, reconsideration of the Final Recommendation.

In view of the above, CADTH is proposing to develop a pilot mechanism that would increase opportunities for clinicians to provide input and feedback and participate in the pCODR process. CADTH intends to evaluate this pilot after 25 cancer drug submissions with clinician input received by pCODR or sooner as may be appropriate, and will consult with stakeholders on any significant changes to the pCODR process.

# Summary of Proposed Clinician Input and Feedback Under the pCODR Process

## 1. Proposed Process and Timelines

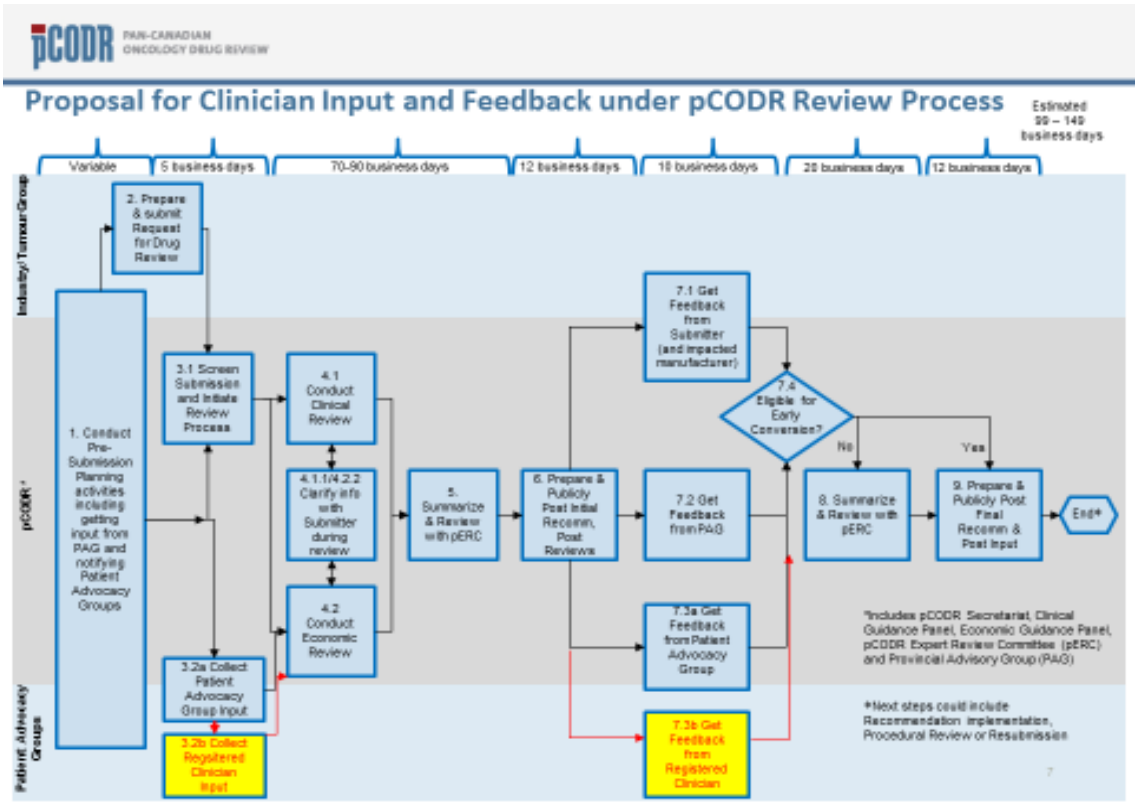
The proposed process for eligible clinicians to submit their input and feedback is similar to the requirements set for current eligible participants. It is proposed that existing mechanisms and timelines apply to eligible clinicians.

If given sufficient prior notice by the submitter, one month before the anticipated filing date, and after obtaining confirmation from the submitter to do so, CADTH will post details of the pending submission on the CADTH website and issue an email to stakeholders. This will allow eligible clinicians time to prepare their input on the submission.

Eligible clinicians must submit their input by the posted deadline date (within 10 business days of pCODR receiving the submission) in order for pCODR to make use of the information to develop the review plan (i.e., protocol) — a critical step that takes place early in the review.

Under paragraph B6.2 of the *pCODR Procedures*, the pERC Initial Recommendation will be publicly posted on the CADTH website 10 business days following the pERC meeting at which the pERC Initial Recommendation was made. Notification will be sent via email to stakeholders indicating the posting and calling for stakeholder feedback, including from eligible clinicians, on the pERC Initial Recommendation.

The proposed approach is illustrated as follows:



### 2. Proposed Eligibility Criteria

For a clinician to be eligible to provide input on a submission through the pCODR process, CADTH proposes that clinicians meet *all* of the following criteria:

- be registered with the pCODR program
- be a recognized expert in the specific tumour site (e.g., breast, colorectal, etc.) as evidenced by membership with a provincial cancer agency or a national cancer organization or similar body, such as the Communities Oncology Network, among others
- be an active practising clinician treating the cancer type for the drug under review
- submit a declaration of conflict of interests (COI).

### 3. Proposed Method of Submission and Questions

Similar to other eligible participants in the pCODR process, it is proposed that eligible clinicians be required to complete a set of questions (using a template) to:

- confirm their experience with using the treatment under review to treat the specific tumour type
- identify the current standard treatment for the defined patient population according to the funding request
- provide perspective on how the drug or indication under review is clinically superior than current treatments for the defined patient population
- provide perspective on the benefits and harms of the drug or indication under review
- identify any unmet needs that the treatment under review would fulfill
- describe how the drug or indication under review could be sequenced with current therapies, if appropriate.

CADTH strongly encourages collaboration among eligible clinicians and that feedback submitted for a specific drug or indication be made jointly.

Eligible clinicians would be required to submit their completed input and feedback templates through the CADTH Collaboration Space by the posted deadline date. Any submissions from eligible clinicians made after the posted deadline date will not be accepted.

Information received from eligible clinicians would be incorporated into the pCODR reports (i.e., similar to patient groups and PAG submissions) and posted on the CADTH website, including the COI declaration.

## Next Steps

Following the consultation period, CADTH will carefully assess all stakeholder feedback from this consultation before announcing any decisions regarding changes to the current pCODR process. Any future changes will be applied to the *pCODR Submission Guidelines* and *pCODR Procedures*.

## Instructions for Providing Feedback

To be eligible to provide feedback on this proposal, please note the following:

- You must identify yourself — feedback provided by individuals who do not identify themselves will not be considered.
- Only one response per submitter will be considered. If more than one response is received, only the first response that is received will be considered.
- Feedback should be provided in a Microsoft Word document using a minimum of an 11-point font.
- The maximum length of feedback is two pages.
- Feedback should be presented clearly and succinctly. The issue(s) should be clearly stated and specific reference should be made as appropriate to the section of the document under discussion (i.e., page number, section title, and paragraph).
- Unless requested and otherwise agreed to by CADTH, all materials or comments received from submitters in response to the notice will be considered public information and may be used and disclosed by CADTH as part of its review. CADTH may disclose materials or comments, or summaries of them, to other interested parties during and after the feedback period.
- CADTH will not disclose any personal information contained in a submission of an individual who does not specify an organizational affiliation in his or her submission without the individual's consent, unless required by law. However, CADTH may use and disclose the content of an individual's submission to assist CADTH in its review.

Please submit your written comments by email to **info@pcodr.ca** by **November 30, 2015 at 5:00 p.m. ET**.