PAN-CANADIAN ONCOLOGY DRUG REVIEW
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CONSULTATION ON pCODR PROCEDURES AND GUIDELINES CHANGES

Call for Feedback Deadline: Friday, March 14, 2014 at 5:00pm ET

The pan-Canadian Oncology Drug Review ("pCODR") is inviting stakeholder comments on the proposed changes to the pCODR Procedures and related guidance documents including: *pCODR Procedures, pCODR Disclosure of Information Guidelines, pCODR Submission Guidelines, pCODR Pre-Submission Guidelines* and *pCODR Checkpoint Meeting Template* (collectively referred to as "pCODR Documents"). The purpose of the proposed changes to the pCODR Documents is intended to enhance the transparency and clarity of the cancer drug review process. Enclosed is a copy of the draft pCODR Documents with the proposed changes.

1. Draft pCODR Pre-Submission Guidelines
2. Draft pCODR Submission Guidelines
3. Draft Disclosure of Information Guidelines
4. Draft pCODR Procedures

A summary list highlighting the key changes that pCODR is proposing to the pCODR Documents are provided below. Additional clarifications and minor changes to the pCODR Documents are also included in this update. In order for your feedback to be considered by pCODR, please carefully read the *instructions* outlined below. pCODR has also included a *Stakeholder Feedback template* to assist stakeholders in providing feedback.

Following the consultation period, pCODR anticipates that the proposed changes to the pCODR Documents will be posted in May 2014. Please be advised that if pCODR receives comments that would require substantial policy or process changes, then pCODR may need to discuss these potential changes with the pCODR Steering Committee and pCODR Provincial Advisory Group. Therefore, such proposed changes may not be incorporated into this update of the pCODR Documents.

Highlights of Proposed Key Changes to the pCODR Documents

Proposed Key Changes for Consultation	
#1	**Reduce timelines for Pre-submission Process** It is proposed that the timeframe for notifying pCODR of an anticipated submission will be reduced to 4-8 months in advance of a target submission date from 6-12 months in advance of a target submission date.
#2	**Integration of Checkpoint Meeting Template Requirements into pCODR Procedures** It is proposed that the procedures contained in the pCODR Checkpoint Meeting Template will be integrated into the pCODR Procedures.
#3	**Changes to the Submission Requirements**

	The following changes are proposed for the submission requirements:
	
	<u>Proposed New Requirements:</u>
	- The deadline for providing Category 2 submission requirements have been changed to 5 days before the targeted pERC meeting for pre-NOC submissions.
	
	- Submitting a template letter for a signed statement indicating there is a confidential price as a Category 1 submission requirement, if applicable. Please note a submission will be deemed incomplete, if a submitter includes provisions to the template letter that would make the submitted price to pCODR contingent on the submitter's requested funding criteria (e.g., linking to a specific clinical criteria).
	
	- Submitting a table of contents outlining the files, folders and CDs included in the submission will be required.
	
	<u>Proposed Removal of Certain Requirements:</u>
	- Removing the requirement to provide copies of the clarifaxes for a pre-NOC submission. Note that pCODR retains the option to request this information as additional information, if needed. Notwithstanding, a listing of relevant clarifaxes will still be required (e.g., a table listing the responses during the Health Canada review, including clarification questions, date, response and date of responses, and any other clarifaxes that may be relevant to pCODR).
	
	- Removing the following requirements for both pre-NOC and post-NOC submissions:
	  - Letter confirming ability to supply
	  - Drug Notification Form
	  - Patent expiry information

#4	**Public posting of the Structured Summary of Economic Information for Disclosure** It is proposed that the Structured Summary of Economic Information that is provided by submitters to pCODR for disclosure purposes will be included as an appendix in Economic Guidance Report that is posted on the pCODR website.
#5	**Publishing the incremental cost-effectiveness ratios ("ICERs") in the pCODR Reports** Proposed changes to clause 3.4(b) of the *pCODR Disclosure of Information Guidelines* to clarify that the ICERs are not considered to be confidential even if it is associated with a confidential price; and as such, this information may be published in the pCODR reports.

Instructions for Providing Feedback

In order for feedback on these changes to be considered:

- Please submit your written comments in the *Stakeholder Feedback template*
- Only one response per organization will be considered. If more than one response is received, only the first response that is received will be considered.
- To provide feedback, you must identify yourself — feedback provided by individuals who do not identify themselves and/or the organization they represent will not be considered.
- Feedback should not exceed six (6) pages in length, using a minimum 11 point font on 8 ½" by 11" paper in Microsoft Word format. If comments submitted exceed six pages, only the first six pages of feedback will be considered.
- 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., guideline, page number, section title, and paragraph).
- Feedback should be specific to the changes being proposed and based on direct experiences with the pCODR process since its inception. If other changes are suggested, they should be provided in the last section of the template under "Other Suggested Changes"
- Feedback must be provided in English. Stakeholders should complete those sections of the template where they have substantive comments and should not feel obligated to complete every section, if that section does not apply. Similarly, stakeholders should not feel restricted by the space allotted on the form and can expand the tables in the template as required.
- Unless requested and otherwise agreed to by pCODR, all materials or comments received from organizations in response to the notice will be considered public information and may be used and disclosed by pCODR as part of its review. pCODR may disclose materials or comments, or summaries of them, to other interested parties during and after the feedback period.
- pCODR 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, pCODR may use and disclose the content of the individual's submission to assist pCODR in its review.

Submit your comments to:

Please submit your written comments by e-mail to: **info@pcodr.ca** by **March 14, 2014 at 5:00pm ET**