PAN-CANADIAN ONCOLOGY DRUG REVIEW

Update on pCODR Procedures and Guidelines Consultation

May 16, 2014

Hello:

On February 11, 2014, we invited stakeholder comments on our proposed changes to the pan-Canadian Oncology Drug Review (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").

We would like to take this opportunity to thank all those who submitted feedback on the pCODR Documents.

Summary of Stakeholder Feedback

We received a total of 13 submissions from stakeholders, including from the pharmaceutical associations, individual pharmaceutical manufacturers and patient advocacy groups. Key comments related to:

- reducing the timelines for pre-submission process
- integrating of Checkpoint Meeting Template Requirements into pCODR Procedures
- administrative changes to the submission requirements, including:
    - setting a new deadline for providing Category 2 submission requirements for pre-NOC submissions
    - submitting a template letter with a signed statement indicating there is a confidential price as a Category 1 submission requirement, if applicable
    - submitting a table of contents
    - removing the requirement to provide copies of the clarifaxes for a pre-NOC submission; 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 certain submission requirements, including: letter confirming ability to supply, drug notification form, patent expiry information for both pre-NOC and post-NOC submissions
- public posting of the Structured Summary of Economic Information for Disclosure

- publishing the incremental cost-effectiveness ratios ("ICERs") in the pCODR Reports
- request for additional clarification on a number of different topics, including molecular diagnostic tests, options for conducting checkpoint meetings, reporting requirements, among others

Decisions: Removing certain submission requirements effective June 1, 2014

Stakeholders who submitted comments unanimously supported the removal of the submission requirements for the letter confirming ability to supply, drug notification form and patent expiry information for both pre-NOC and post-NOC submissions. In view of this, **effective June 1, 2014**, pCODR will **not require** a **letter confirming ability to supply**, the **drug notification form** and the **patent expiry information** to be provided as part of the submission to pCODR. For greater clarity, this requirement will apply to all submissions that are currently or will be under review by pCODR. Please be advised that this change does not imply that the submitted information meets the requirements of the individual participating provincial drug plans. If any of the participating provincial drug plans have needs relating to these previous submission requirements, they will contact manufacturers directly.

pCODR Documents Under Review

As a result of the in-depth feedback, pCODR is giving due consideration to all comments. A number of the comments have policy and technical implications. pCODR must take a balance approach to ensure that the application of these comments would be made in the best interest of patients and the public. This work will be ongoing and is anticipated to be finalized by Summer 2014.

pCODR will issue a notice prior to the implementation of any applicable changes to the pCODR Documents, so as to reduce the impact of timing on those working on submissions to the process.

If you have any questions, please contact us at info@pcodr.ca.