CADTH

Summary of Feedback from August 2018 CADTH Consultations on Pharmaceutical Review Programs

1. BACKGROUND

CADTH initiated stakeholder consultations in August 2018 on three proposals related to our Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR):

- addressing non-submissions by manufacturers
- strengthening the process for establishing reimbursement criteria in CDR recommendations
- the posting of CADTH responses to manufacturer feedback received for draft CDR review reports.

2. ADDRESSING NON-SUBMISSIONS BY MANUFACTURERS

The objective of the proposed initiative was to create a process to formally address situations where manufacturers with eligible products have declined to file submissions with the CDR or pCODR processes. Mixed feedback was received with respect to the inclusion of reasons for not filing a submission with CADTH. As decisions for not filing a submission are complex and may involve proprietary business information, CADTH will not post the manufacturer's reason for not filing a submission. CADTH will post information about the drug in question (drug name, manufacturer, and indication) and a statement that CADTH is unable to make a reimbursement recommendation because a submission was not filed by the manufacturer. There was no major opposition to this proposal and CADTH has implemented the proposed process for addressing non-submissions by manufacturers. The details of this new process have been incorporated into updated versions of the *Procedures and Submission Guidelines for the CADTH Common Drug Review* and the *pCODR Procedures*.

3. STRENGTHENING THE PROCESS FOR ESTABLISHING REIMBURSEMENT CRITERIA

Stakeholders were generally supportive of the objective and initiatives contained within the proposal. Feedback was largely focused on the following two areas of the proposal:

- Clinical engagement: There was support expressed for the inclusion of additional clinical experts in the review process and endorsement of CADTH's plan to establish clinical panels to provide input into the CDR review process.
- Proposing detailed criteria: Manufacturers did not favour the introduction of a new category 1 requirement focused on detailed reimbursement criteria. It was suggested that the proposal should be limited to "complex drugs" and that proposing criteria should be optional for manufacturers. Some manufacturers expressed concern about potential differences in the criteria that are detailed in the product label and those used to support a submission to CADTH.

Based on stakeholder feedback, CADTH has adopted a phased implementation approach with this initiative. CADTH has begun integrating clinical expert panels into the CDR review process and is currently reviewing options regarding the other aspects of the consultation (e.g., manufacturer-submitted criteria).

4. POSTING OF CADTH RESPONSES TO MANUFACTURER FEEDBACK

As described in the *Procedure and Submission Guidelines for the CADTH Common Drug Review*, manufacturers are given the opportunity to review the draft CDR review reports and submit written comments about the reports. CADTH provides written responses to the manufacturer comments and updates the reports, as required. These responses are currently forwarded to the manufacturer for reference prior to the targeted CADTH Canadian Drug Expert Committee (CDEC) meeting. The comments and responses are then incorporated into the CADTH CDEC brief and are shared with the CDR-participating drug plans. The objective of the proposal was to increase transparency in CADTH's Pharmaceutical Review processes by publicly posting feedback from manufacturers regarding the draft CDR review reports and the corresponding CADTH responses to this feedback. An additional component of the proposal was to shift the timing of the redaction process so that it occurs after CADTH's responses to the manufacturer's comments have been finalized and have been provided to the manufacturer.

CADTH received mixed feedback on this initiative, with many respondents having no objections, but others raising important concerns. The most notable concerns were:

- that posting comments related to content that is subsequently revised (e.g., error corrections or revised appraisals) could cause commercial harm if others are able cite the uncorrected passages (deliberately or inadvertently)
- that the current seven-day feedback period would be insufficient as companies would need to seek input and/or approval from global counterparts in order to post comments in the public domain.

Based on the feedback received from industry, CADTH believes that the proposed revision to begin posting comments and responses may be problematic to implement at this time and will engage in further discussion with stakeholders on this issue in the future. CADTH is planning to pursue the proposed changes to the redaction process in order to make this process more efficient; further details will be communicated at a later date.