CADTH

Stakeholder Feedback on CADTH's Proposed Revisions to the Biosimilar Review Process, Resubmission Criteria, and Other Operational Considerations for the CDR and pCODR Processes

To submit your feedback, please complete this form and email it to feedback@cadth.ca by **September 15, 2017 at 5:00 p.m. ET.**

Organization Providing Feedback:	**Diabetes Canada**
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[a] CADTH may contact this person if comments require clarification.

1. Proposed Revisions to the Biosimilar Review Process for CADTH's CDR and pCODR Programs	
#1	CADTH proposes a modified submission package for biosimilars. It is proposed that a submitter would be required to submit the following information: • completed Biosimilar Summary Dossier Template (only certain sections would need to be completed by the submitter). Other procedural requirements that are set out in the CDR and pCODR procedures will apply to a biosimilar submission; these include: • pre-submission notification requirements • signed cover letter confirming that all the required information has been provided • letter authorizing sharing of information • list of published and unpublished studies, including any non-randomized observational studies to support switching • copy of the Notice of Compliance (NOC) or NOC With Conditions (NOC/c), dated and signed by Health Canada • product monograph • drug benefit listing table. Please indicate if there is other information that should be included to support a biosimilar submission.
Feedback	
#2	CADTH has developed the draft *Biosimilar Summary Dossier Template* that is intended to address the key questions for a biosimilar review. Please indicate if the requirements in the template are clear. Please indicate if there is other information that should be included in the template to help inform the biosimilar review.
Feedback	

1. Proposed Revisions to the Biosimilar Review Process for CADTH's CDR and pCODR Programs	
#3	CADTH strongly believes that insights, perspectives, and experiences from stakeholders are integral to the process. CADTH wants to ensure that stakeholders' perspectives and experiences with biosimilars are considered as part of this new process, and have outlined the following options for comment: • continue with the use of the current template (i.e., for patient groups and registered clinicians) for each biosimilar review • respond to questions that address issues specific to the biosimilar under review • provide feedback on a draft CADTH Biosimilar Summary Dossier • contribute to a report on broader (or more general) expectations and concerns that could be used for biosimilar therapeutic class reviews rather than individual single biosimilar reviews. Please indicate if you have a preferred option along with your rationale, recognizing that there may be resource and time implications associated with each option presented. Please indicate if you think there may be another approach we should consider.
Feedback	In order for HTAs and policies to be patient centred, patients must be a partner in the development, implementation and evaluation. Diabetes Canada recommends that patients are included in the HTA process at multiple points including: responding to calls for patient input using the current template; having the opportunity to ask questions that address issues specific to the biosimilar under review; providing feedback on the draft CADTH dossier and contributing to a broader discussion about biosimilar reviews. Further, patient representatives should be considered to be part of a review team so that the patient voice can be heard along with other experts.
#4	Please provide any other comments specific to the proposed biosimilar process.
Feedback	Diabetes Canada welcomes a streamlined review process to improve the efficiency and timeliness of the HTA process so that new drugs and technologies can benefit Canadian patients as soon as possible. Patient group input should be summarized and provided explicitly in the dossier in a section explicitly for patient groups. As the biosimilar review is proposed to no longer go to the advisory committees, it is unclear how/if recommendations will be made. The rationale for any recommendations may not be clear and the transparency of considerations may be compromised. While the information within the dossier will be made public, the interpretation and discussion about this information is not public. It is important that the values of integrity and transparency are upheld.

2. Proposed Revisions to the Resubmission Criteria for CADTH's CDR and pCODR Processes	
#1	Please provide comments specific to the proposed revisions.
Feedback	

3. Proposed Changes to the Checkpoint Timeline for the pCODR Program	
#1	To allow the pCODR review team sufficient time to review the responses, CADTH is proposing to make changes to the pCODR procedures that would request the submitter responses to the clarifying questions and any applicable requests for additional information be provided to the team **at least one (1) business day** in advance of the scheduled Checkpoint Meeting. A submitter will still have 10 business days to prepare responses to the clarifying questions and the request for additional information to the pCODR program. Please provide comments specific to this proposed change.
Feedback	