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:	**Innovative Medicines 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that all the required information has been provided • letter authorizing sharing of information • list of published and unpublished studies, including any non-randomized observational studies to support switching • copy of the Notice of Compliance (NOC) or NOC With Conditions (NOC/c), dated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	These information requirements look reasonable and are generally consistent with existing requirements. We would note that 'Drug Benefit Listing Table' requires further clarification. Is this the same as *Appendix 2: Listing Status for Reference Product and Other Biosimilars* of the current CDR Biosimilar Submission Template?
#2	CADTH has developed the draft *Biosimilar Summary Dossier Template* that is intended to address the key questions for a biosimilar review.

1. Proposed Revisions to the Biosimilar Review Process for CADTH's CDR and pCODR Programs	
	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	The template should be revised to remove references to innovator and biosimilar prices internationally (comparators in the reference countries used by the Patented Medicine Prices Review Board (PMPRB)). This information is not readily available and is a highly onerous requirement, particularly given that this information will not actually be used in the review processes (i.e. 'for information purposes only'). CADTH has not clarified the procedural consequences in the event that manufacturers are not able to fulfill these requirements. This pricing data would not be directly comparable to Canada due to different market dynamics and circumstances. It would also require considerable effort to prepare (data sources; exchange rate conversions, etc). Presenting this information as part of the public biosimilar dossier could lead to considerable confusion and delays. International pricing information will not always be available to Canadian companies. This is an unreasonable requirement for a drug that is not patented and that operates in highly competitive marketplace. Furthermore, CADTH should remove the section on implementation considerations where details on patient and provider support programs are requested. The biosimilars market is highly competitive and these details are typically commercially confidential, particularly in the pre-launch phase. These details may also change as negotiations with jurisdictions unfold. Public disclosure of this information could interfere with competitive markets and should not be part of the CADTH submission. The *Biosimilar Summary Dossier Template* is lacking some key information included in the current *CDR Biosimilar Submission Template*. a) Section 1 (page 4): for clarity, the *Manufacturer's Reimbursement Request* should be renamed *Manufacturer's Requested Listing Criteria*; and b) With the *Manufacturer's Requested Listing Criteria*, the Manufacturer should be allowed to include its rational for the requested listing criteria, as in the current template (section 3.2).
#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	We support robust mechanisms for patients to provide input into CADTH processes. As such, we suggest CADTH continue to use the current template (i.e., for patient groups and registered clinicians) for each biosimilar review. We also support an option to respond to questions that

1. Proposed Revisions to the Biosimilar Review Process for CADTH's CDR and pCODR Programs	
	address issues specific to the biosimilar under review. CADTH could use the current template and perhaps add a section for additional questions to address any specific issues/concerns that may be applicable. In general, we are open to different options and defer to patients and patient group to comment on how best to capture their input.
#4	Please provide any other comments specific to the proposed biosimilar process.
Feedback	Above all, it is important that all review processes are based on the best available evidence. Any information or evidence in a biosimilar review should be reviewed with the same level of rigor as other reviews. The choice of therapy should always remain a shared decision made between physicians and patients, based on informed knowledge of the clinical efficacy and safety data of a product. The industry appreciates CADTH's efforts to reduce duplication to optimize resources. However, it is unclear why CADTH is only pursuing review efficiency initiatives for biosimilars when all products could also benefit from process efficiency enhancements, particularly in situations of high unmet clinical need. CADTH should clearly identify the protocol and circumstances under which a CDEC/pERC review *would* be conducted. In absence of clear protocol, there will be considerable uncertainty for manufacturers and drug plans. We recommend that CADTH work to make all review processes more efficient and reduce overall review times. We look forward to working with CADTH to identify solutions to achieve this objective for all products.

2. Proposed Revisions to the Resubmission Criteria for CADTH's CDR and pCODR Processes	
#1	Please provide comments specific to the proposed revisions.
Feedback	We do not see the rationale for not allowing non-randomized control trials (RCT) data for an original submission (i.e. for any submission). We recommend that CADTH harmonize allowable evidence for submissions and resubmissions and consider non-RCT data for any submission. CADTH should articulate a set of clear and consistent evidence criteria for this purpose. We are supportive of efforts to expand the conditions under which a resubmission is possible. There is a clear need in the current review system to allow for the consideration of evidence beyond RCT such as Real-World Evidence (RWE). We would note that any new data used as part of a resubmission be considered in addition to the full body of evidence. In some situations, there may be RCTs that were previously considered by CADTH for which new data (study results) are available. Resubmissions should consider any and all data available at the time of the resubmission.

2. Proposed Revisions to the Resubmission Criteria for CADTH's CDR and pCODR Processes	
	The proposed *Eligibility Criteria for Resubmission* do not address the possibility to resubmit based on new cost Information. In such a case, new clinical studies would not be required. This should be clearly stated in the proposed eligibility criteria. We have concerns with the proposal that 'the final decision regarding whether or not a resubmission will be accepted for review will be determined by CADTH,' and 'there is no provision for requesting reconsideration of the decision.' There are many procedural and evidentiary reasons why the underlying justification for a resubmission could be misinterpreted as part of a paper-only process. Manufacturers should always be permitted to request reconsideration of a CADTH decision to limit resubmissions.

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	We support this proposal.