Stakeholder Feedback on CADTH's Proposed Revisions to the Therapeutic Review Framework and Procedure for the CADTH Common Drug Review

To submit your feedback, please complete this form and email it to feedback@cadth.ca by **August 11, 2017 at 5:00 p.m. EDT.**

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

Where appropriate to your organization, please provide comments specific to the sections of the proposed process, as discussed in the following consultation document:

- Revising Common Drug Review Recommendations in the CADTH Therapeutic Review Process

In your feedback, please note whether any proposed requirements or considerations are clear and appropriate.

General comments on the proposed process:	
Feedback	Diabetes Canada strongly feels there has not been adequate patient consultation or opportunity for patients to ask questions about implications of the proposed changes to the patient community. General stakeholder feedback is insufficient. Patients are important constituents and ultimately the recipients of policies that result from CDR and Therapeutic Review recommendations. Unfortunately, they have been sidelined here in this process review.
Proposed plan for notifying manufacturers that the CDEC recommendation for an individual drug has been revised as a result of the therapeutic review:	
Feedback	Patient groups should also be made aware of any changes that may impact their care. Patients will experience, first hand, the implications of any policy change and should not only be included in the decision making process but also be explicitly informed of changes to recommendations.
Proposed process for manufacturers to provide feedback regarding a CDEC recommendation that has been revised as a result of the therapeutic review:	
Feedback	
Duration of the feedback period for providing input on a revised CDEC recommendation:	
Feedback	
Proposed format for a CDEC recommendation that has been revised as a result of the therapeutic review:	
Feedback	

Please provide any other comments on the proposed process.

Other:	
Feedback	It is not clear how new CDR recommendations will be regarded when published after the Therapeutic Reviews. Will new CDR recommendations published take precedence over the therapeutic review or will a Request for Clarification be required in that case? Will a disclaimer will be added to the Therapeutic Review Final Recommendation stating that it has been superseded by the revised CDR Recommendation. Close attention must be paid to the methodology in Therapeutic Reviews. The evidence generated from a head-to-head clinical trial is regarded as the highest quality. Clearly however, not all comparisons are made by this design and meta-analyses and network meta analyses allow some insight into multiple comparisons. When the evidence is very strong or very weak, the resultant conclusions from RCTs and NMAs may be similar. It is when the data are not black and white and when there are nuances in the interpretation that these results must be handled with caution and deep expertise. The potential contradiction of NMA with clinical trial data should be not be taken lightly and further changes to CDR recommendations based on NMA data requires careful consideration on the impact on patients. Therapeutic reviews are currently a long and cumbersome process. These reviews are not amenable to incorporating new evidence while the review is underway and there is also no process to incorporate new evidence soon after the review is complete. However, evidence is always emerging and significant clinical trials should impact recommendations. Therefore, it is essential that Therapeutic Reviews are 'living' and can incorporate emerging evidence as it becomes available. CADTH should commit to making Therapeutic Reviews more nimble and responsive to the current pace of research and discovery. The implications could be profound and there must be an opportunity for patients to be part of this whole HTA process, not just providing input at one junction. Diabetes Canada recommends that CADTH consider patients experts to be review team and added in parallel to clinical and economic reviewers. The amount of time for patients to be able to access evidence based therapies through public plans in Canada is already too long. Given the length of time it takes for a Therapeutic Review to be completed, it is important that provinces do not wait for the recommendations from a Therapeutic Review before implementing CDR recommendations. Many CDR and Therapeutic Review recommendations are based on cost, and the costs modelled in the analysis are not the actual costs to provinces. Therefore recommendations in the Therapeutic Review may not reflect the budget impact reality. Further, the implementation of Therapeutic Review recommendations that would change existing listings which were based on CDR recommendations, may mean that patients need to switch from existing therapy based on cost data that is not real. This needs to be considered both in light of true cost effectiveness and impact on the patient. Some of these patient impacts cannot be described by a clinical trial or an NMA.

	The selection of topics for Therapeutic Review should be transparent. Currently it is not clear how topics are selected.