CDA Consultation on the Procedural Changes for the Drug Reimbursement Review Process

February 26, 2026

Innovative Medicines Canada (IMC) and BIOTECanada are the primary associations representing the innovative medicines industry in Canada. We thank you for the opportunity to provide feedback on Canada's Drug Agency's (CDA-AMC) proposed improvements to the Drug Reimbursement Review Process. We appreciate the CDA-AMC's efforts towards ongoing modernization of the health technology assessment (HTA) process and positive intent for streamlining its review process so that it becomes a catalyst for accelerating access to innovative medicines for Canadians.

The current set of unprecedented policy directives emerging worldwide, namely the May 2025 U.S. Executive Order on Most-Favored Nation (MFN) and related policies, carry significant implications for Canada's access to new medicines. All interested parties within the life sciences ecosystem must be engaged in policy responses to mitigate risk and maintain Canada's access to innovative treatments. IMC and BIOTECanada would like to emphasize the importance of discussing system-level challenges and the ways in which CDA-AMC can improve Canadians' access to innovative medicines in this context.

The pressing issues for HTA in Canada are the clinical and economic methodologies that undervalue innovation, and as a result, lead to unrealistic pricing pressure by payers and protracted access negotiations. Given these pricing recommendations are also made public, our industry is increasingly facing pressure to adjust prices in other markets, further complicating the entry of novel, life-saving medicines into Canada.

The industry proposes to keep the current model for draft and final recommendations and refocusing the CDA-AMC reform effort on potential changes that would more directly address the current global pharmaceutical policy dynamics. While there is a need to streamline negotiation and payer processes in Canada, the CDA-AMC itself already provides parallel review opportunities (with Health Canada) and CDA-AMC review timelines are not the critical issue.

Health technology assessments play a critical role in mediating access to innovative therapies. As U.S. policies heighten global scrutiny on pricing and access, national HTA approaches require adaptation. In this context, the innovative medicines industry would appreciate dialogue on advancing a modernized value-based HTA that includes a **broader definition of value and discontinue practices that publish unrealistic price reduction recommendations**. For example, other countries have begun reforming aspects of their reimbursement systems, including HTA processes, to respond to the evolving global policy environment. We encourage CDA-AMC to

collaborate externally and become a thought-leader and innovator on incorporating non-traditional value elements in their assessments.

The current proposals do not represent the bold change needed and may also have unintended consequences. IMC and BIOTECanada anticipate that the CDA-AMC proposed revisions will shift critical discussions to the reconsideration process and will ultimately increase the need for reconsiderations.[i] This could ultimately delay review and reimbursement processes for many innovative therapies.

We also note that there are diminished opportunities for patients and clinicians to comment on recommendations as they will now only have opportunity to have their opinions heard by the expert review committee once a reconsideration has been requested thereby decreasing the quality and appropriateness of decisions and prolonging the process. Sponsors, patients and clinicians should all have opportunity and adequate time to comment on both the Review Reports and this feedback should be provided to the committee members well in advance of their meeting. CDA-AMC proposed changes to patient and clinician input to the reconsideration process provides a template upon which to base meaningful improvements to the review process by providing feedback on CDA-AMC's appraisal to decision makers *earlier* in the process.[ii] CDA-AMC process changes could focus on direct sponsor and interested party engagement with the expert committees and reforms to better reflect the value of innovative treatments. We are confident that implementing broad, quality input into the existing review processes would lead to fewer requests for reconsideration and shorter average review times.

Thank you for the opportunity to comment. Notwithstanding our view that the current international moment calls for a more fundamental review of processes and methods, we do appreciate CDA-AMC's ongoing efforts to modernize its approaches and the highly collaborative dialogue in recent years. Building on this collaborative approach, **we propose that CDA move forward with establishing a working group with the innovative industry and interested parties** to find ways to adapt CDA's HTA processes and methods to optimize patient access and respond to broader global pharmaceutical shifts.

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[i] See individual member submissions for additional challenges. For example, for multinational companies that must coordinate local and global reviewers on detailed documents, up to 200 pages, decreasing the window for feedback on Reviewer Reports by any number of days is detrimental. Additionally, the proposal to label a recommendation "final" upon posting is inconsistent with its procedural status, as the decision remains open to reconsideration requests from the sponsor. Reconsideration is a highly valued mechanism that must reflect a transparent, evidence-responsive, and scientifically grounded process. Terminology should accurately reflect this openness and minimize confusion. Therefore, we recommend replacing "Final Recommendation" with "Posted Recommendation (Subject to Reconsideration)" or equivalent language for all recommendations where a sponsor has indicated an intention to pursue reconsideration would reflect their ongoing status. The proposal removes the existing opportunity to include new analyses or clinical studies within reconsideration requests for complex reviews. This represents a step backward, as it limits the ability to efficiently address identified uncertainties.

[ii] Additionally, we support the proportional approach to Testing Procedure Assessments and the distinction between required companion diagnostics and broader clinical pathway tests. Pharmacoeconomic submission requirements should be proportionate to the TPA classification and avoid duplicative modelling requirements where diagnostics are already embedded within standard of care