February 26, 2026

***Input to CDA-AMC on Improvements to the Drug Reimbursement Reviews Process***

***Introduction:***
The Best Medicines Coalition (BMC), a national alliance of 32 patient organizations, welcomes the opportunity to provide input to Canada's Drug Agency's consultation on proposed improvements to the drug reimbursement reviews process. This submission was informed by current BMC position documents developed in consultation with BMC's member organizations. Statements and recommendations expressed here reflect areas of consensus among the member organizations listed here.

As its mission, the BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. In its advocacy on related national issues, the BMC seeks policies and frameworks which recognize and embody patient-driven principles while valuing and investing in both incremental and breakthrough advancements in care. Related to this, the BMC seeks improved pathways to timely access to all medically necessary drugs and related treatments, and systems which are efficient, streamlined, transparent and accountable.

In its ongoing work, the BMC provides recommendations on selected issues within the context of policies, programs, legislation and regulations related to pharmaceutical care for patients in Canada, including broad pharmaceutical care reform, pharmaceutical review, assessment and pricing, strategies to support patients with rare diseases and drug supply initiatives.

The Best Medicines Coalition believes that national leadership, with cooperation from all jurisdictions and at all levels, along with stakeholders, is necessary to streamline infrastructure, including review, assessment, negotiation and decision-making processes, reducing timelines at every step, including at Health Canada, the Patented Medicine Prices Review Board (PMPRB), Canada's Drug Agency (CDA-AMC), the pan-Canadian Pharmaceutical Alliance (pCPA) and at drug programs.

We applaud CDA-AMC for its continued and most recent efforts to improve its drug reimbursement review procedures and processes. However, we do have some concerns, detailed in our feedback below. In particular, we are extremely concerned with the removal of patient group and clinician feedback on draft recommendations and see this as a step backward at a time when the CDA-AMC has spent considerable time and resources to improve patient engagement, driving meaningful outcomes and system-level impact through evidence-informed guidance.

Recent procedural reforms proposed by CDA-AMC reflect sustained efforts to improve the efficiency, predictability, and transparency of the drug reimbursement review process. These changes respond to real operational pressures and demonstrate a willingness to refine existing approaches over time. From a patient perspective, however, the reforms also highlight an important opportunity to step back and consider whether incremental adjustments alone are sufficient to achieve meaningful, patient-centred decision-making within health technology assessment.

Despite repeated adjustments to timelines, templates, and stages of consultation, CDA-AMC has not undertaken a fundamental re-examination of how patient input is understood, valued, or used in decision-making. Patient engagement remains positioned as a supplementary activity rather than as a core source of evidence shaping deliberation. Experiential evidence – rooted in lived experience, treatment burden, quality of life, and real-world trade-offs – continues to be subordinated to technical clinical and economic evidence, rather than considered alongside it as a complementary and necessary form of knowledge.

The reforms also do little to shift underlying power dynamics. Patients are asked to provide input, but rarely to share authority over framing questions, defining value, or influencing how evidence is interpreted. Engagement occurs primarily through structured, written submissions, often after key analytic and deliberative work has already taken place. As a result, patient perspectives are introduced too late in the process to meaningfully shape outcomes and are more often reactive than formative.

Taken together, these changes suggest that CDA-AMC is refining the mechanics of an existing model rather than rethinking the model itself. While procedural improvements may enhance administrative efficiency, they do not address long-standing concerns about patient engagement, limited feedback loops, or the absence of shared decision-making. Without broader systemic change – one that rebalances the relationship between technical and experiential evidence and meaningfully redistributes influence – patient engagement risks remaining symbolic rather than transformative.

***1.2. New streamlined review processes***

The process for new drugs and related treatments to move through review, approval, assessment and decision-making processes is complex and lengthy. In many cases it takes an extended period of time until patients are able to access the medications they need. This is a critical issue with implications for patient care and health outcomes, sometimes with dire consequences, especially for those with unmet needs and life-threatening illnesses.

The Best Medicines Coalition has consistently raised the need for coordinated, transparent and easily accessible reporting and tracking of progress on the full review and reimbursement pathway for each drug under consideration. The proposed expedited review timelines to support new streamlined drug reviews offer patient groups up to 88 days to provide input, which could help in this regard. However, they also propose to eliminate the ability to provide feedback on draft recommendations – a highly valued opportunity for patient and clinician engagement – to help achieve faster review times. The proposal to proceed to the final recommendation without providing another, more meaningful feedback method revokes this opportunity and it should not be implemented as presented.

Patients are the end users of the therapies that CDA-AMC reviews, and many have few to no treatment options. Their needs and voices should be included in every step of the review and reimbursement process. Patient and clinician groups play a key role in reviewing and providing input into draft recommendations to ensure the full impact that the therapies may have on the lives of patients have been considered and incorporated, as well as in identifying any challenges draft recommendations may have on patient access. Moreover, patient and clinician group input has resulted in important changes

to draft recommendations, such as the need for companion diagnostic testing to support access to therapies, and has led to greater clarity of sub-populations that should be eligible for access, both of which are specific aims of CDA-AMC's proposed improvements to its reimbursement process in this current consultation.

It was through feedback on the draft recommendation that BMC member organization Cystic Fibrosis Canada and clinicians from its Health Advisory Council and clinical trials network demonstrated that the proposed renewal criteria for the life-changing therapy Trikafta focused solely on lung function outcomes and did not include all of the clinical endpoints measured in clinical trials, such as increases to weight and height, reductions in pulmonary exacerbations and hospitalizations, decreases in the number of days treated with oral and IV antibiotics, as well as improvements to the CFQ-R respiratory scale, a standard measure of lung function.

As a result, the renewal criteria were changed to reflect all of these clinical outcomes in the final recommendation. Without this change, some people with cystic fibrosis may not have been renewed for a therapy that showed significant health improvements simply because only one of these measures was considered in the draft recommendation. If this patient group and its associated clinician groups were not given the opportunity to provide input into the draft recommendation, this revision – which is significantly improving and extending the lives of thousands of people with cystic fibrosis in Canada – may not have happened.

The importance of patient input in general should not be overlooked. Consider the case of Okedi, a long-acting injectable treatment for schizophrenia, which initially received a "Do Not Reimburse" draft recommendation that was revised to "Reimburse with Conditions" in the final recommendation. Although no patient organization submitted feedback specifically in response to the draft recommendation, CDA-AMC indicated that it considered the Institute for Advancements in Mental Health's prior patient perspectives from earlier reviews of risperidone. This demonstrates that when patient organization input is absent/missing in the process, CDA-AMC still requires and desires it to inform its final recommendation.

Another example of the importance of patient and patient group engagement is the CDA-AMC's treatment of Vraylar, an atypical (second-generation) antipsychotic medication that treats schizophrenia and helps to manage manic, mixed, or depressive episodes associated with bipolar I disorder in adults. The initial submission received a negative draft recommendation. Mood Disorders Society of Canada (MDSC) provided patient feedback at the draft recommendation stage, highlighting unmet needs and lived-experience perspectives.

The first submission ultimately resulted in a negative final recommendation. The manufacturer subsequently resubmitted the therapy, with MDSC providing a patient submission. Following resubmission, the therapy received a "Reimburse with Conditions" final recommendation. The final recommendation referenced considerations such as the need for additional treatment options and the heterogeneity of patient response, despite remaining uncertainty in the clinical evidence. These themes were consistently emphasized in MDSC's input across both the draft feedback from the first submission and the submission supporting the resubmission. This case illustrates how patient perspectives can meaningfully inform reassessment processes and contribute to changes in reimbursement outcomes.

Clearly CDA-AMC considers patient input to be of great value to the drug review process, which makes it even more perplexing that CDA-AMC wants to take our voices away from the draft recommendation. In fact, streamlining the process from draft to final recommendation by removing patient input may have the opposite effect of what CDA-AMC hopes to achieve in the long run. Removing patient input at the draft recommendation stage is intended to streamline the HTA process and accelerate access to medications. However, this change may unintentionally have the opposite effect in practice.

The transition from draft to final recommendation is a critical stage where lived-experience perspectives help contextualize evidence and real-world impact. Without patient insight at this juncture, important perspectives may be overlooked. This absence of input could contribute to negative or conditional recommendations that do not fully reflect patient realities. Such outcomes may result in patients having no access to a therapy, prompting reconsideration requests or resubmissions. These additional procedural steps may ultimately extend timelines rather than shorten them. Reducing input in the name of efficiency does not necessarily guarantee faster access and may instead risk delaying access for patients the system aims to serve.

Removing patient group input into the draft recommendation entirely may signal that feedback previously collected from patient organizations on draft recommendations was not sufficiently valued. Patient organizations have historically invested significant time and resources to provide responses to draft recommendations, voluntarily and without compensation. Eliminating this opportunity creates the perception that these contributions were not considered important enough to retain within the process. If the rationale is that this feedback was not formally returned to committees or critically appraised, this raises questions about why such input was requested in the first place.

It also raises concerns about why mechanisms were not established to ensure this feedback was systematically communicated back to decision-making committees.

Canada's Drug Agency has made positive process changes that have improved patient engagement over time, such as the recent incorporation of the participation of people with lived experience at expert committee meetings to amplify patient perspectives, experiences and values for complex reviews. The CDA-AMC could go even further in expanding patient and patient group input by providing us with the opportunity to provide live input for classes of drugs, not just complex files. Eliminating input into draft recommendations is not in keeping with the spirit of the important improvements CDA-AMC has made to its patient engagement practices, nor does it recognize the important and unique roles that patient groups play in ensuring that patient perspectives are considered and represented in final recommendations and in CDA-AMC's patient engagement processes in general.

***The Best Medicines Coalition strongly opposes the removal of existing patient engagement opportunities unless more inclusive and meaningful opportunities are implemented in their place. The current proposal to remove patient and clinician group input from draft recommendations does not meet this requirement and is therefore not supported by the coalition.***

***Not only should CDA-AMC not implement this recommendation, it should leverage this opportunity to improve its reimbursement reviews in ways that encourage substantive feedback from patient and clinician groups on draft recommendations at expert committee meetings. This is time well spent if it leads to more thoughtful and inclusive recommendations that improve the lives of patients in Canada. If more time must be found to meet CDA-AMC's expedited timelines, it should be taken from other places in the review process, not those that provide patient perspectives, which are already limited.***

***The Best Medicines Coalition welcomes the opportunity to work with the CDA-AMC to develop more robust patient and clinician group consultations to enhance the draft recommendation feedback process.***

***1.3. New reconsideration procedures***

The Best Medicines Coalition generally supports changes to the reconsideration process that improve transparency, such as enhancing timeline predictability, as well as publicly posting reconsideration review reports and sponsor's rationale for reconsideration. We appreciate CDA-AMC's commitment to developing a new template for patient and clinician group input, including the addition of the questions to the existing standard review template, as described on page 11 in the consultation document.

With all of that said, the Best Medicines Coalition does have concerns about the proposed process, some of which build on our comments in the previous section. The proposed changes to the reconsideration process provides patient and clinician groups a formal, customized open call of 35 business days to provide "new targeted input for the reconsideration" that will "directly inform the reconsideration process and will be reflected in the reconsideration report and recommendation". But it also includes moving patient and clinician input from draft recommendations from these reviews to a single point of re-examination after final recommendations have been posted. This involves removing the opportunity for patient and clinician groups to provide feedback into draft recommendations, which we notably oppose in the section above. As previously stated, this does not enhance the patient voice. It limits it.

***The Best Medicines Coalition supports the addition of the open call for reconsiderations and inclusion of our input in the final report and recommendation. We strongly support more robust consultation with patient and clinician groups at expert committee meetings, including those for files under reconsideration. We recognize that the number of expert committee meetings currently held add time to existing and, potentially, to the new, more predictable timelines proposed. However, we stand firm on the need to hear our perspectives on draft recommendations, including those made through the proposed reconsideration procedures.***

***In its efforts to revamp its reconsideration procedures, CDA-AMC must ensure that the number and duration of expert committee meetings to support this work are structured in ways that include meaningful patient and clinician engagement. This extends to hearing our input on draft recommendations made through the reconsideration process in the ways outlined in section 1.2 of this submission. We would welcome the opportunity to work with CDA-AMC toward these ends.***

***1.4. New resubmission procedures***

The Best Medicines Coalition generally supports the objectives behind the proposed new resubmission procedures. Implementing the new resubmission categories outlined would provide additional clarity to determine which resubmissions may be streamlined, and the proposed target timelines seem reasonable. That said, we think CDA-AMC should put further consideration into how it might provide additional opportunities for streamlined resubmissions going forward.

Another area to explore is engaging patient groups that manage registries in reconsideration and resubmission processes. Some patient groups have clinical registries that track patient outcomes to medical interventions, including therapies reviewed by CDA-AMC. CDA-AMC used recent funding from the National Strategy for Drugs for Rare Diseases (NSDRD) to lay the foundation for improved generation of, and access to, real-world data from rare disease registries, highlighting the value of disease registries in generating high-quality, real-world data that may complement more traditional sources of evidence, such as randomized clinical trials, to help inform drug access decision-making processes. The goal of this work is to help generate fit-for-purpose, decision-grade, real-world evidence that addresses critical evidence gaps in regulatory, health technology assessment, and payers' decision-making needs throughout the drug life cycle.

As CDA-AMC works toward improving reimbursement reviews more broadly, it must continue to consider how registries may identify early indicators of the impact that reviewed therapies have on patient populations and how best to engage the patient groups that manage registries in this work. This is especially important when it comes to reconsiderations and resubmissions.

***The proposed changes to reimbursement reviews outlined in this current consultation do not fully consider the role that registries, and the patient groups that manage them, could play in supporting and perhaps even initiating reconsideration and resubmission reviews. Both current and proposed processes leave patient groups with registries in the difficult position of having to advocate to drug manufacturers and/or public payers to consider submitting a reconsideration and/or resubmission request if registry data demonstrate a need or an opportunity to do so. A more effective method would be to provide a process through which patient groups that manage registries could flag real world findings that may influence a decision to start a reconsideration or resubmission review to CDA-AMC directly.***

***1.5. Testing procedure assessments***

The requirement for sponsors to incorporate clinical and economic consideration related to companion diagnostics with reimbursement reviews applications is important. Not only do these tests help determine treatment eligibility and initiation, they now inform multiple aspects of the clinical pathway, as CDA-AMC notes. ***The Best Medicines Coalition therefore welcomes the addition of a focused section within reimbursement reviews for testing procedure assessments (TPAs) to describe the health system-related implications of companion diagnostics associated with the therapies being reviewed.***

The proposed eligibility requirements of scope and relevance criteria outlined in the consultation document are clear and the timing predictability tactics presented, such as increasing the advance notice period from 48 to 80 days and the open call for patient/clinician input from 58 to 88 days, are appreciated.

***The Best Medicines Coalition appreciates CDA-AMC's distinction between eligibility for full TPA reports and abbreviated TPA reports. Production of a full TPA report is needed in scenarios in which companion diagnostic testing is not publicly funded across participating jurisdictions and would require new adoption and funding for integration into clinical practice. Not only do payers need to implement these tests to determine how best to assess initial and ongoing access, patients and patient groups deserve to know that recommendations on companion diagnostic testing have been made so we can hold public drug plans to account on implementation of recommended companion diagnostic tests.***

***Other comments***
In general, we ask that consideration be given to how CDA-AMC's deliberative processes align with the goals and needs of all the organizations and agencies involved in developing policy, recommendations and decision-making regarding drugs and related treatments. In the interest of efficiency, any opportunities to gather information to share and inform the work at other agencies, such as the pan-Canadian Pharmaceutical Alliance and the Patented Medicine Prices Review Board, should be considered and pursued. All agencies must be accountable for working together to inform and make pharmaceutical policy recommendations and decisions to benefit patients and improve patient outcomes in as efficient and timely manner as possible.

We are pleased that the changes to process and procedures of the Formulary Management Expert Committee allow people with lived experience and patient groups to stay after their presentations to the FMEC for the presentation of evidence. This enables us to provide timely feedback to the committee.

***The Best Medicines Coalition thanks Canada's Drug Agency for the opportunity to provide input into the proposed improvements to drug reviews. As an organization with over 30 member organizations, we recommend that CDA-AMC provide at least 60 days for feedback on public consultations going forward. Providing a feedback window of less than 30 days is an inadequate amount of time for us to meaningfully engage our members in developing submissions that directly impact the patients they represent.***

**About the Best Medicines Coalition**

The Best Medicines Coalition is a national alliance of 32 patient organizations. The BMC seeks timely access to a comprehensive range of medically necessary, safe, and effective drugs and related treatments, informed by patient-driven evidence and values, and delivered equitably and affordably to all patients in Canada. The BMC's areas of interest include drug approval, assessment, and reimbursement, as well as patient safety and supply issues. As an important aspect of its work, the BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's core activities include issue education, consensus-based position development, and advocacy, making certain that patient-driven positions are communicated to decision makers and other stakeholders. The BMC was formed in 2002 as a grassroots alliance of patient advocates. In 2012, the BMC was registered under the federal Not-for-profit Corporations Act and operates under the direction of a Board of Directors composed of representatives of member organizations and elected annually.


Asthma Canada
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Breast Cancer Network
Canadian Cancer Survivor Network
Canadian Council of the Blind
Canadian Cystic Fibrosis Treatment Society
Canadian Epilepsy Alliance
Canadian Hemophilia Society
Canadian PKU & Allied Disorders
Canadian Skin Patient Alliance
Canadian Spondyloarthritis Association
CanCertainty
Crohn's and Colitis Canada
Cystic Fibrosis Canada
Eczema Society of Canada
Family Alliance on Severe Mental Illnesses
Fighting Blindness Canada
Health Coalition of Alberta
Huntington Society of Canada
Kidney Cancer Canada
Lung Health Foundation
Lymphoma Canada
Medicines Access Coalition – BC
Migraine Canada
Millions Missing Canada
Mood Disorders Society of Canada
Ovarian Cancer Canada
Parkinson Canada
Platelet Disorder Support Association
Psoriasis Canada
the cancer collaborative