



September 11, 2026

Response to pCPA's survey on expanding the early negotiation process

The Best Medicines Coalition (BMC) responded to the [survey](#) from the pan-Canadian Pharmaceutical Alliance (pCPA) on expanding the early negotiation process. The survey focused on two options:

- Option A: Health Canada's Priority Reviews
- Option B: Health Canada Advance Consideration under the Notice of Compliance with Conditions policy (AC-NOC/c)

Below are the responses the survey.

Feedback on Option A — Health Canada's Priority Review

To what extent would Option A — Health Canada's Priority Review meet your needs?

- Not at all
- Slightly
- Moderately
- **Mostly**
- Completely

Which aspects of Option A would be most beneficial from your perspective?

Option A directly addresses high unmet medical needs and accelerates patient access without adding significant evidentiary uncertainty. By relying on a well-established regulatory pathway, it provides higher confidence and clarity for interest holders.

Option A also applies to a broader and more inclusive set of products, meaning a larger share of high-need therapies would be eligible to benefit from earlier negotiation.

What concerns, if any, do you have about Option A?

While we recommend Option A, we want to also articulate the importance of Option B as most rare and cell gene therapies go through the AC-NOC/c pathway.

These are precisely the innovations that serve the smallest populations but with the highest unmet need, where patients have the fewest alternatives.

We'd recommend the pCPA not delay too long the expansion of Option B as these populations would benefit greatly from such an accelerated pathway.

What changes, if any, would improve Option A?

Increase opportunity for real-world experience to be factored into decision making by including a formal mechanism for patient engagement in negotiations.

Feedback on Option B — Health Canada's Advance consideration of Notice of Compliance with Conditions (AC-NOC/c)

To what extent would Option B — Health Canada's AC-NOC/c meet your needs?

- Not at all
- Slightly
- **Moderately**
- Mostly
- Completely

Which aspects of Option B would be most beneficial from your perspective?

Option B captures segments that Option A does not. AC/NOCc is vital for rare disease and C&G therapies.

What concerns, if any, do you have about Option B?

There is a lack of clarity on the pathway moving forward. Specifically, the uncertainty associated with Health Canada's planned transition to "Regulations with Terms and Conditions" (ToC) changes in April 2027 creates unpredictability for both manufacturers and payers.

What changes, if any, would improve Option B?

Provide a firm guarantee that the pathway - and the files within it - will not be negatively affected by the ToC regulatory changes in April 2027.

Additional questions

Which option do you currently favour?

- Option A – Health Canada's Priority Review
- Option B – Health Canada's AC-NOC/c

Which potential benefits are most important to preserve overall?

While BMC's strong preference is to expand the ENP to include both Option A and Option B simultaneously, if a single starting point is required, BMC would choose Option A. It provides more confidence and clarity, avoids the upcoming 2027 ToC transition complexities, and accelerates access without adding evidentiary uncertainty. However, this must be followed by a commitment to integrating Option B.

The most important benefits to preserve are:

- 1. Accelerating patient access without introducing evidentiary uncertainty*
- 2. Addressing high unmet needs for vulnerable patient populations*
- 3. Ensuring confidence, clarity and stability in the negotiation pathway*

Which risks or challenges are of greatest concern to you overall?

- 1. The current proposal to exclude cell and gene therapy for the next 6 months. C&G therapies represent some of the highest unmet needs, and excluding them delays critical care.*
- 2. The lack of clarity and uncertainty tied to the April 2027 ToC changes*
- 3. Treating the options as mutually exclusive rather than complementary*

As ENP is expanding, which implementation approach should be considered?

- Immediate expansion across all eligible drug types
- Phased expansion over time
- Unsure

Final comments

Is there another option the pCPA should consider?

Roll out both options at the same time. Implementing both Option A and Option B concurrently is the most effective way to capture the full spectrum of patient needs.

Please share any additional comments.

Given the potential impact of America's MFN pricing policies. Any measures that can incentivize pharmaceutical companies to seek reimbursement in Canada are valuable. Streamlining and improving the efficiency of the reimbursement process, as pCPA is proposing through the ENP, is therefore highly important.

The current reimbursement pathway is lengthy and sequential, with multiple regulatory and assessment bodies involved. Finding ways to make these processes more coordinated and synergistic could help make Canada a more attractive market for pharmaceutical companies, while also reducing delays and ultimately supporting faster patient access to medicines.

BMC appreciates the pCPA's leadership in executing and expanding the Early Negotiation Process (ENP) to accelerate patient access to innovative medicines. Expanding the ENP is an important step forward for the efficiency of the healthcare system.

The BMC also supports the recommendation from the July 2026 [Pharmaceutical and Life Sciences Sector Task Force Report](#) encouraging the pCPA to work with provinces and territories to review the processes regarding the Letter of Engagement and those following the signing of a Letter of Intent (LOI), with a target of achieving listing agreements in a timely manner, such as within 30 to 60 days, following the LOI.

BMC cares deeply about ensuring that patients facing severe, rare, and complex conditions — particularly those requiring next-generation therapies — have timely access to the treatments they need. We look forward to continued collaboration to make this expansion a success for Canadian patients.