October 23, 2026

Best Medicines Coalition: Feedback on the Proposed Interim Approach to Speed Up the Review of Certain Pediatric Drugs

We believe a fundamental barrier to improving pediatric drug access in Canada is the absence of a comprehensive pediatric drug regulatory framework. Establishing dedicated legislation or regulations, such as a Pediatric Drug Act, could provide greater consistency, predictability, and certainty, rather than relying on a series of individual pilots, plans, and interim measures.

That said, recognizing the opportunities within the existing framework, the Best Medicines Coalition (BMC), representing 33 patient organizations across Canada, offers the following practical recommendations to strengthen the proposed interim approach.

1. Connect the interim approach with the Pediatric Development Plans and Studies Pilot

In addition to leveraging foreign regulatory decisions and related information through the Ministerial Reliance Order, we recommend establishing a pathway to expedited review for submissions supported by pediatric studies completed through Health Canada's Pilot on Pediatric Development Plans and Studies.

Where a sponsor of a drug already approved for adult use in Canada submits pediatric clinical evidence that Health Canada determines is sufficient to support a safe and effective pediatric indication, the corresponding submission should be eligible for an expedited 180-day review.

This would build on the principle underlying the Ministerial Reliance Order: reducing unnecessary duplication and improving regulatory efficiency by leveraging existing, credible evidence. While this would not constitute deeming under the current Order, it could provide a complementary pathway that recognizes pediatric evidence generated through another Health Canada initiative.

2. Prioritize age-appropriate pediatric formulations and routes of administration

We recommend extending expedited review eligibility to submissions for new pediatric formulations or routes of administration that meaningfully improve the suitability, safety, accessibility, or administration of existing therapies for children.

For example, a new oral formulation that eliminates the need for injections could substantially reduce treatment burden for children and caregivers, even when the active medicinal ingredient is already approved.

Such child-friendly improvements should be recognized as addressing unmet pediatric needs and considered for expedited review.

3. Expand eligibility to orphan drugs and drugs vulnerable to supply disruptions

We recommend explicitly considering drugs for rare pediatric diseases, as well as drugs at risk of shortages, discontinuation, or other supply chain disruptions, for expedited review.

Children with rare diseases often have limited treatment options, while disruptions to essential medicines can have disproportionate consequences for pediatric populations.

Including these considerations in eligibility criteria would help ensure that regulatory prioritization reflects both unmet therapeutic needs and the risks associated with interrupted access to essential treatments.

4. Incorporate patient perspectives into priority-setting

We strongly encourage Health Canada to establish meaningful opportunities for patient organizations to inform the identification and prioritization of pediatric drugs for expedited review.

Patient groups bring firsthand insights into unmet treatment needs, challenges with age-appropriate formulations, drug shortages, discontinuations, and the real-world impacts of delayed or interrupted access.

Their perspectives should help inform both the criteria for expedited review and the ongoing identification of priority drugs, including future updates to the National Priority List of Pediatric Drugs.

Taken together, these recommendations would help strengthen the proposed interim approach, improve alignment across existing Health Canada initiatives, and move Canada toward a more coordinated, responsive, and patient-centred regulatory framework for pediatric medicines.

About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of 33 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.

Member Organizations

- 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
- Pulmonary Hypertension Association of Canada
- the cancer collaborative