Reducing Wait Times for Life-Saving Treatment

Submission to the 2025/2026 Horizontal Red Tape Review
Theme 2: Getting Products to Market Faster

End the Neglect: Children in Canada should no longer be Regulatory Orphans.

Over the past several decades, children in Canada have largely been ignored in health-related regulations, leading to unacceptably long wait-times for evidence-based medications, higher off-label drug use, fewer opportunities for research, and undue burdens on frontline medical staff.[1] The recommendations outlined below address this regulatory neglect while building a stronger Canadian healthcare and health research system.

This brief responds to Theme 2 – Getting products to market faster. As a small market, Canada is not always an attractive destination for new products or research. Our recommendations provide opportunities to facilitate market access while also ensuring that Canadian patients have access to innovative treatments and research opportunities regardless of delays in market authorization.

Cut Unnecessary Regulations on Clinical Research.

Currently, Health Canada regulates clinical trials studying routine, everyday treatments that are not technically 'on label' for pediatric use. This means that studies examining the use of drugs with longstanding safety and efficacy data, like oxygen, salt water, ibuprofen and acetaminophen must comply with the same regulations as studies involving brand new molecules or novel gene-based therapies. These regulatory requirements increase trial costs by an average of 20%, create unnecessary bureaucratic requirements for researchers, and based on recent Canadian data, do nothing to increase patient safety.[2]

Health Canada should immediately establish a full exemption pathway for low-risk pediatric clinical trials involving drugs routinely used in clinical practice.

This exemption would bring Canada in line with peer jurisdictions including the United States, Australia and United Kingdom, saving time and research dollars while attracting new trials to Canada.

Stop Denying Canadian Families Access to Lifesaving Treatments.

In part because of longstanding regulatory neglect, and in part because of Canada's small market size, fewer drugs – particularly those with pediatric indications - are available in Canada than in peer jurisdictions like the United States and European Union. As a result, pediatricians and pharmacists caring for critically ill children must frequently import medications and medical devices from other countries.

Under current regulations, medical professionals must first apply for and receive Health Canada approval to access medical treatments that are not available in Canada. In cases where treatments are deemed too innovative, medical professionals are forced to develop clinical trials for individual patients in order to treat them – significantly delaying treatment, and wasting both health care dollars and staff time.

In comparator nations like Australia, qualified medical staff are free to import medications not domestically available for any patient with a critical illness, *without waiting for government approval*. When days, or even hours, can mean the difference between life and death, streamlining access is essential, while mandatory reporting ensures government can monitor gaps in treatment availability.[3]

Health Canada should reform the Special Access Program in line with international best practices to ensure that critically ill Canadians can access lifesaving treatments. This should include establishing a list of commonly-accessed medications pre-approved for importation. In addition, Health Canada should reduce the regulatory burden associated with Single Patient Studies operating only for treatment, rather than research purposes. As an immediate first step, Health Canada should publish its case review criteria so clinicians can better understand if their applications will be denied.

Fast-track Market Approval for Safe Pediatric Drugs not Available in Canada.

In 2024, Health Canada released the draft National Priority List of Pediatric Drugs (NPLPD).[4] It identifies forty-two essential drugs that are either unavailable in Canada, or lack appropriate pediatric labelling or formulation, despite being accessible in the United States and European Union. Drugs that are not available in Canada must be imported through the pathway outlined above, while drugs that are available but neither labelled nor formulated for children are less safe, and often not eligible for reimbursement from provincial health plans.

To close the gap, **the Minister of Health should implement reciprocal reliance pathways using existing authorities[5] under the *Food and Drugs Act*, and approve drugs identified on the NPLPD.** This approval provides a powerful incentive to manufacturers to bring these essential treatments to market in Canada, while also making them eligible for review through Canada's Drug Agency for eventual public funding.

Going forward, the Minister should expand use of the reliance authority to fast-track approvals for any drug or device approved, and proven safe, in peer jurisdictions.

Make the Pediatric Rule Permanent.

Canada is currently more than three decades out of step with international best practice in terms of mandating pediatric data with new drug submissions. Health Canada is currently running a pilot to enable the voluntary submission of pediatric data, however there remains no regulatory requirement, nor commitment to reform regulatory requirements to align with peer jurisdictions.[6]

To ensure that all new drugs on the Canadian market are appropriately available to and labelled for children, **the "pediatric rule" should be made permanent, closing the longstanding reliance on "off label" prescribing for Canadian children.**

Alternatively, Canada could use existing reliance authorities to review and accept pediatric data submitted in peer jurisdictions.

Cut Red Tape, Improve Child Health.

Canada has historically been slow to adopt policy reforms focused on pediatric patients. As a result, Canadian children and youth face longer wait times for treatment and have less access to lifesaving medications than their peers around the world.

As outlined in the recommendations above, Canada has viable policy options – many of which come a little or no cost – that could close this unacceptable gap. We urge the federal government act swiftly to implement these reforms, and give Canadian children and youth a fair chance at a healthy childhood.

About the Child Health Policy Accelerator at SickKids.

The SickKids Child Health Policy Accelerator is Canada's first hospital-based applied child and youth health and social policy initiative. It aims to close the gap between what we know is effective in optimizing the well-being of children and youth, and what we do to attend to the needs of young people in the provincial and federal public policy space.

We work in partnership with clinicians, researchers, families and patients across Canada to identify barriers and develop policy solutions.

This brief is the first in a series outlining low- or no-cost policy changes that would improve the health outcomes of children and youth in Canada.

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Footnotes

1 Time for a regulatory framework for pediatric medications in Canada - CMAJ.
2 Based on study data collected on behalf of RareKidsCAN, 2024.
3 Special Access Scheme - Australian Government
4 About the National Priority List of Pediatric Drugs - Health Canada
5 Guide to precision regulating authorities under the Food and Drugs Act – Health Canada
7 Pilot on pediatric development plans and studies - Health Canada

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