

Office of Pediatric Therapeutic Policy
Center for Policy, Pediatrics and International Collaboration
Health Canada

December 2, 2024

To Whom It May Concern:

RE: Response to Health Canada's Consultation on the National Priority List for Pediatric Drugs (NPLPD)

On behalf of The Hospital for Sick Children (SickKids), Canada's largest pediatric healthcare and research institution, we appreciate the opportunity to contribute to Health Canada's consultation on the National Priority List for Pediatric Drugs (NPLPD). As an organization dedicated to advancing the health and well-being of children across Canada, we commend Health Canada for prioritizing pediatric drug access and recognizing the unique challenges posed by this underserved population.

The creation of the NPLPD is a critical step in identifying and addressing gaps in pediatric drug availability in Canada. However, achieving its intended impact requires not only ongoing identification of priority needs but also active and sustained efforts to bring these drugs to market and achieve equitable access for Canadian children and youth.

We encourage Health Canada to take an active role in ensuring that drugs listed on the NPLPD progress from priority identification to availability and use. This will require concerted collaboration between Health Canada, health technology assessment organizations, provincial and territorial formulary managers, industry and clinicians to overcome critical access barriers including insufficient market incentives, cumbersome regulatory challenges, and the uniquely complex public listing and reimbursement landscape in Canada.

Moreover, we urge Health Canada to complement the NPLPD with a proactive policy framework that supports agile, flexible, and responsive pathways for ensuring all necessary pediatric medications are accessible in Canada. This could include:

1. **Enhancing regulatory flexibility:** Building on international harmonization initiatives, Health Canada should streamline regulatory review processes for paediatric medications. This includes establishing expedited pathways for licensing pediatric drugs approved in peer jurisdictions, especially for pediatric conditions with limited treatment options and for those medications and formulations with longstanding safety and efficacy data.
2. **Streamlining reimbursement decision-making:** Market approval alone is insufficient. Ensuring timely public coverage of appropriately priced pediatric medications and child-friendly formulations is

required to optimize equitable access to essential drugs. Early engagement with and facilitated discussions between manufacturers, regulators, and health technology assessment organizations is necessary to encourage new and supplemental drug submissions, and to integrate approaches to the generation and appraisal of evidence on the value of pediatric drugs.

3. **Implementing pediatric regulations to secure critical pediatric drug data:** Canada continues to lag behind comparable jurisdictions in terms of requiring the submission of pediatric drug data when pediatric use can be expected or anticipated. Health Canada should mandate the submission of pediatric drug data and require the submission of pediatric-friendly dosage forms, in alignment with international best practice.

SickKids stands ready to collaborate with Health Canada in refining and operationalizing the NPLPD. Together, we can address unmet needs, reduce reliance on off-label prescribing, and ensure that all children in Canada have access to safe, effective, appropriate medications.

Thank you for your leadership on this critical issue. We look forward to further discussions on how Health Canada can enhance its efforts to improve pediatric drug access and development.

Yours sincerely,



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