



## **Written Submission to the Health Canada Consultation: Improving access to drugs and other health products in Canada**

**August 2023**

## Summary

The Canadian Paediatric Society (CPS) is pleased to submit the following in response to the consultation on improving access to drugs and other key products in Canada. We thank you for the opportunity to highlight the unique needs of infants, children and youth in this important national discussion focused on building resilience in the supply chain for Canada's critical medications and other life-saving and life-sustaining products.

Following the events of the past few years, the paediatric community is acutely aware of the very real risks faced by patients and the significant stress placed on health systems following health product shortages. We are eager to contribute to strategies and policies that mitigate the negative clinical and operational impacts associated with these complex, and often unpredictable, supply chain and demand-related challenges. Given our experience and expertise, our response to this consultation will focus on the key issue areas of improved communication and transparency, and agile regulatory tools.

### Key Area 1: Improved communication and transparency

Most front-line paediatricians, including both those who work in hospital and community settings, are alerted to drug shortages only after supply has been critically disrupted (i.e., when pharmacy stocks are low and/or absent and alternative drugs must be dispensed). Proactive communication with paediatricians is limited, and often paediatric pharmacists are only made aware of a shortage when a hospital pharmacy attempts to place a re-order and is unsuccessful. This late-stage notification reduces or eliminates the possibility of early mitigation strategies (e.g., using second-line therapies in selected patients to preserve essential supply for the highest risk individuals, prescribing and/or dispensing alternate dosage forms). Early, proactive communication would be appreciated by all.

While many providers are aware of the requirement for drug shortages to be publicly posted on the Drug Shortages Canada webpage, it is not possible or reasonable for all paediatricians to regularly review the website. Health care providers are subject to constant "information overload", and communicating clear, direct, and time-sensitive messages is a perpetual challenge.

Given this chronic information overload, a direct, unsolicited communication from Health Canada to practicing physicians may, unfortunately, have little impact. We therefore recommend that Health Canada partner with effective pre-existing physician communication channels (including, but not limited to, communication channels provided by national professional societies) when attempting to disseminate time-sensitive information. When planning for joint communications with professional societies or organizations, we encourage early collaboration between communications experts to ensure alignment and understanding of target audiences, dissemination plans and timelines. Coupling information about the shortage together with information related to potential clinician-level mitigation strategies would be most appreciated, and information from a trusted source would be most likely to change practice.

The recent shortage of over-the-counter (OTC) pain analgesics and antipyretics highlighted the need to tailor all communication strategies to the most appropriate audience. This widespread and highly visible OTC shortage resulted in a significant increase in at-home dosing errors and a 40-60 percent uptick in the number of calls to the Ontario Poison Centre.<sup>1</sup> While the majority of drug shortages have been, and will likely continue to be associated with prescribed, “behind-the-counter” medication shortages, this recent experience highlights the importance of ensuring that Health Canada has the relevant policies and procedures in place to also address OTC drug shortages, and communicate effectively with the broader public, when necessary.

## Key Area 2: Agile regulatory toolbox

The drug needs of children are unique, and their specific drug requirements must be considered in any drug shortage situation. Due to longstanding regulatory deficiencies at Health Canada specific to the paediatric drug space, Canadian paediatricians rely heavily on off-label prescribing, which must be considered when contemplating the magnitude of any drug shortage. Moreover, indications for use for a significant number of essential paediatric medications vary from the indications in the adult population. Therefore, the appropriateness of alternatives (including tier assignment and possible second- and third-line drug choices) must always consider the specific and unique requirements for paediatrics.

Additionally, infants, young children, and children with sensory processing and/or neurodevelopmental difference often require child-friendly drug formulations (such as liquids, minitabs or sprinkles) specific to their weight, size, and developmental stage. Ensuring stable supply not only of the drug, but also the required drug forms, should be a policy priority for the Drug Shortages Task Force.

Unfortunately, given the distinct epidemiology of childhood illness, rare diseases are common in paediatrics. This makes the development of an “essential medicines stockpile” unfeasible. As such, we would strongly discourage a stockpile approach to the management or mitigation of drug shortages. However, should such a stockpile be contemplated, paediatric experts across the full range of disciplines should be engaged to inform necessary decisions.

Lastly, the recent shortages in non-drug essential health products, including infant and other specialized formulas, highlights the need for specialized response protocols, supported by the appropriate regulatory policy, to include all lifesaving and life-sustaining medical products, devices and supplies. This should include specific consideration for all specialized formulas (including those used in infancy and throughout childhood), paediatric medical devices, and supportive medical supplies.

## Conclusion

Recognizing and responding to the unique needs of children and youth in accessing paediatric drugs and health products should be a core component of this important consultation. We thank Health Canada

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<sup>1</sup> Zipursky JS, Brown KA, Khan S, et al. Pediatric Dosing Errors during a National Shortage of Fever and Pain Medications. N Engl J Med. 2023;388(22):2099-2101.

and the Drug Shortages Task Force for undertaking this crucial work to improve the availability of drugs and other health products in Canada and look forward to continued opportunities for collaboration.

## **About the CPS**

The Canadian Paediatric Society is the national association of paediatricians, committed to working together to advance the health of children and youth by nurturing excellence in health care, advocacy, education, research and support of its membership. Founded in 1922, the CPS is a voluntary professional association that represents more than 3,600 paediatricians, paediatric subspecialists, paediatric residents, and others who work with and care for children and youth. The CPS is governed by an elected Board of Directors representing all provinces and territories.