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Commentary to Proposed Pharmacare with Regards to Pediatric Formulations

Dr. Hoskins,

The Goodman Pediatric Formulations Centre (GPFC) would like to provide its perspective regarding pediatric formulations vis-à-vis the proposed implementation of a National Pharmacare Program. We are pleased to have the opportunity to comment on this anticipated change.

[The Goodman Pediatric Formulations Centre](#)

The GPFC has the goal of improving access to child-friendly medicines. We are the only Centre in Canada whose mandate is to assist in the development and commercialization of safe and effective age-appropriate formulations for children. The GPFC operates as a **not-for-profit organization**, whose exclusive goal is to support the well-being of children by facilitating the availability of formulations adapted to their needs, for optimal treatment. Even though the GPFC works closely with hospitals, health care providers and industry, our positions and actions are completely independent of these third parties.

[The Problem: Canadian Children Do Not Have Access to Commercialized Pediatric Formulations](#)

We need to have commercial pediatric formulations available for Canadian pediatric patients. In many cases, commercialized pediatric formulations are available in other jurisdictions, such as in the United States and in Europe; however, these formulations are not commercialized in Canada for a number of reasons. Firstly, the Canadian pediatric market is small and unlike the programs in the United States and Europe, there are neither commercial incentives, nor regulatory protection granted to bring commercialized pediatric formulations to Canada. Secondly, the pediatric regulatory approval pathway is perceived as unclear. Thirdly, once marketing

approval is received, reimbursement groups may, or may not, recommend these medications to the provinces for public listing. All of these processes contribute to the complexity of the Canadian system and discourage commercialized formulations to be marketed in Canada.

When Commercialized Formulations are Not Available

When commercialized pediatric formulations are not available to Canadian children, adult forms need to be modified (i.e. crushing a tablet, dissolving it in water and diluting it in an oral vehicle) to suit the dosing needs of children. Although the exact percentage of compounding used in children is unknown, a common understanding is that many medications given to Canadian children have no commercially available, age-appropriate formulations resulting in the manipulation of adult dosage forms. As such these manipulated medications, fall outside of regulatory approval, with the efficacy and safety risk this presents¹. Using a safe and effective commercialized formulation is strongly preferred by healthcare providers, pharmacists, parents and patients.

The Proposed Pharmacare Program Would Provide Equal Access to Pediatric Formulations Across Canada

Currently in Quebec, l'Institut national d'excellence en santé et en services sociaux (INESSS) makes formulary decisions for the Quebec government while the Canadian Agency for Drugs and Technologies in Health (CADTH) makes listing recommendations for the rest of Canada. However, provincial, federal and territorial governments decide whether they follow the recommendations of CADTH and INESSS, leading to variations in drug listings decisions across the country. The unintended result is that patients may or may not have access to pediatric formulations depending on where the medicine is listed. The inequality of access to these pediatric medications across the country is unacceptable. In a country such as Canada, it is inconceivable that pediatric drugs would not be equally accessible to this vulnerable population.

A National Pharmacare Program Would Simplify the Health Care System and Increase Transparency in Decision-Making

The Federal Government needs to promote a regulatory and reimbursement system that is able to evolve and fit an economy where innovation and change are the norm, and where the pediatric drug market is small. The GPFC believes that it is imperative to provide special considerations for the Canadian pediatric population with respect to making pediatric formulations readily available in Canada. Increasing the number of commercialized

¹ [Improving Medicines for Children in Canada](#), 2014, Council of Canadian Academies.

formulations in Canada would address a clear unmet medical need. The proposed National Pharmacare Program would simplify the reimbursement and access of medicines, and decrease the time of review, by having one agency, CADTH, lead both.

[A Centralized Pharmacare Program Could Provide National Reimbursement Exclusivity for Pediatric Formulations](#)

The lack of pediatric incentives for manufacturers to submit their applications in Canada, along with the complex reimbursement and pricing processes, are barriers that discourage manufacturers from bringing pediatric formulations to Canada. Moreover, many of these pediatric formulations are generic medicines where there are no incentives available for commercialization in Canada. As stated above, a National Pharmacare System would simplify the process and would also make possible the development of incentives, such as providing reimbursement exclusivity. The ability to develop incentives specific to pediatric formulations would be a significant step forward to improving access to child-friendly medicines in Canada.

[Improved Quality Health Care Between Hospital and Community Pharmacies](#)

Discrepancies between in-hospital and out-of-hospital formularies may exist and could introduce errors for a pediatric patient. In situations where commercialized formulations may be listed on certain formularies, while the compounded drug are listed on others, may cause differences in concentrations between the two formulations which could potentially lead to medication errors if the dose conversion is not properly done. A National Pharmacare program would provide consistency between hospital and public drug plan sectors, reduce possible dosing errors and would ensure continued high quality patient care throughout the patient journey.

[Better Tracking of Utilization Rates of Pediatric Medicines at a National Level](#)

Currently there is very limited information available on drug use in pediatrics patients. Market Research data from companies such as Iqvia (formerly IMS Brogen Quintiles) can provide some insight on number of prescriptions and units of medications dispensed at the community pharmacy level but this information does not cover in-hospital use and does not provide any information on the indications, dosages used or safety. A National Pharmacare program would allow for a national utilization rate and therefore better understanding of the needs of the pediatric population across Canada.

The GPFC Supports a National Pharmacare Program

The GPFC urges all stakeholders, Health Canada, Reimbursement Agencies, Pricing Bodies and the Provinces and Territories, to coordinate and align as much as possible to improve access to pediatric formulations. Success is unattainable until this occurs.

The GPFC supports an expanded mandate of CADTH to maintain the common National Prescription Drug Formulary (including Québec) to ensure harmonization among the drug formularies. Guidelines and decision-making processes should be as transparent as possible. A significant step towards simplifying the reimbursement and listing processes would be achieved by having CADTH manage the National Prescription Drug Formulary, which should encourage more pediatric formulations to be commercialized in Canada.

Finally, and most importantly, a common voluntary National Prescription Drug Formulary would ensure equal access to pediatric formulations for all Canadian children.

Best regards,



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