Submission to the House of Commons Health Committee: Study on Children's Health

Pharmascience Inc.
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Improving Access to Pediatric Formulations in Canada: A Blueprint for Action

We are pleased to have the opportunity to submit our feedback to the ongoing House of Commons Standing Committee on Health study on Children's Health in Canada. As a Canadian pharmaceutical manufacturer, we have particular expertise on the challenges to manufacture and market medications that are appropriate for the pediatric population.

The following submission summarizes the main challenges blocking pediatric formulations as well as offers solutions to increase the availability of pediatric medicine formulations in Canada.

Introduction

Despite the general acknowledgement that children require care standards adapted to their unique needs, there are remarkably few drugs formulated specifically for the pediatric population in Canada. An essential component of patient care, drug therapy, continues to be poorly adapted to the needs of sick children.

The absence of approved pediatric formulations appears to be worse in Canada than in other comparable countries (US, UK, Europe, Australia). Drug manufacturers are introducing fewer pediatric formulations in Canada than in these countries.

Up to 80% of all medications currently being prescribed in Canadian pediatric hospitals are being administered off-label, meaning that the use of the pharmaceutical deviates from the dose, method of administration, patient age, and indication in the Health Canada-approved monograph.

This situation is unanimously described as problematic by health care practitioners (pediatricians, pharmacists, nurses) and organizations advocating for child health care. It results in significant barriers to optimal drug therapy in children. This Canadian gap appears to result primarily from numerous economic barriers and market disincentives that prevent pediatric formulations from being offered commercially. The lack of pediatric formulations is a critical gap in our healthcare system.

About Pharmascience

Founded in 1983, Pharmascience Inc. is the largest pharmaceutical employer in Quebec with 1,500 employees proudly headquartered in Montreal. Pharmascience is a full-service, privately owned pharmaceutical company with strong roots in Canada and a growing global reach with product distribution in over 50 countries.
Ranked 47th among Canada's top 100 Research & Development (R&D) investors in 2020, with 40-50 million dollars invested each year, Pharmascience is the second largest Canadian-owned drug manufacturer.

As a proudly Canadian company, we believe our contributions to Canada are substantial:

- We create more than 2,620 jobs in Canada (direct, indirect, and induced, 2021). This includes approximately 1,500 workers in our Montréal, Candiac and Dorval manufacturing R&D and distribution sites;
- All our R&D and manufacturing activities are conducted in Canada, at our Montreal and Candiac sites;
- We encourage youth employment, partnering with local post-secondary institutions across disciplines to employ 15 to 20 student interns each summer, with a fast track to full employment;
- We support quality jobs: the average Pharmascience employee salary is 2.1 times the Quebec average at $104,457; these are productive jobs, averaging 1,5 times the productivity of Quebec jobs; and
- In 2021, we contributed $355 million to Canada's GDP, including $27 million in federal tax revenue and $42 million in tax revenue in Quebec.

Barriers to Introducing Pediatric Formulations

The gap in availability of pediatric formulations in Canada appears to result primarily from both economic barriers and market disincentives that prevent pediatric formulations from being offered commercially.

Market Size
The size of pediatric drug markets, regardless of the disease treated, is usually small. Since the pediatric population is small compared to the adult population, pharmaceutical companies test and design their products based on adult physiology. This results in neglecting to consider the differences in children's size, development, physical condition, and metabolism.

Manufacturing different types of formulations (smaller tablets, oral solutions) for the patient population requires the same efforts as manufacturing adult formulations, making it a lot of extra effort to meet a small need. Most drugs identified by pediatricians as missing a pediatric formulation (98%) are off-patent.

Despite being off-patent, they still require significant development in formulation research, manufacturing, and in the preparation of scientific submissions to Health Canada as well as Health Technology Assessment (HTA) authorities. As pediatric markets are very small, recovery of these large investments without patent protection becomes very challenging.

Off-label usage
Because new drugs are rarely developed primarily for pediatric indications, most of the resulting usage in pediatric formulations is off-label; that is, an adult formulation is prescribed in generally a lower dosage for a pediatric patient. Because of this, there is little incentive to market a separate, more appropriate pediatric formulation of the same products.

Lack of Patent Protection
Most (98%) drugs identified by pediatricians as missing a pediatric formulation are off patent This makes additional R&D investments by manufacturers risky, especially if one considers that off patent adult drugs are available at low generic prices that were not established to provide a R&D incentive, like those of patented medicines.

If prices of pediatric formulations are benchmarked against those of high-volume adult generics, the resulting introductory price of the new formulation may well not yield a viable margin to cover the additional development and commercialization costs.

High Regulatory Fees

Any new pediatric formulation requires significant development in formulation research, manufacturing, and in the preparation of scientific submissions to Health Canada as well as Health Technology Assessment (HTA) authorities such as CADTH and INESSS. There are no reduced fees based on the smaller patient population for Health Canada or HTA agencies. For drugs for which there is no exclusivity, these costs are an unsurmountable barrier.

Solutions to Improving Access

The following presents a blueprint of actions to improve access to pediatric formulations:

Finalize and Implement the Pediatric Drug Action Plan

Health Canada has created a Pediatric Drug Action Plan (PDAP) to address the lack of marketed pediatric formulations; work on this plan is in progress, with no definite finalization date.

Solution: Finalize recommendations in the PDAP and implement a new regulation to improve access to pediatric formulations within the next year.

Eliminate Submission Fees for Pediatric Formulations

Pediatric patient populations are much smaller than their adult equivalents, making it difficult to recoup the costs of regulatory and administrative fees.

Solution: Eliminate Health Canada submission fees for pediatric formulations. New submission fee schedules should be considered by Health Canada, CADTH, and INESSS to allow for reduced fees to incentivize repurposing, especially for pediatric formulations, where the problem is more acute.

Regulatory Exclusivity for Pediatric Formulations

Although Canada provides a six-month extension of regulatory exclusivity for a product that has a patent, this does not exist for generic products, which are most acutely in need for pediatric populations. Other countries provide regulatory exclusivity for products regardless of patent status.

Solution: Health Canada should allow for a three-year period of patent restoration, and/or offer a limited period of reimbursement exclusivity for the new indication to manufacturers undertaking generic drug repurposing or creating pediatric formulations, like what's offered in other jurisdictions.

Adopt Specific Pediatric Pricing for Public Payers

Recognizing that new formulations made specifically for children would replace existing marketed products as well as the time and expertise required to compound these products, pricing should reflect the unique aspect of these formulations.

Solution: The pCPA should introduce a specific pricing framework for pediatric formulations that accounts for the cost of pediatric formulations, the small patient population served, and the time saved from compounding these formulations.