

A NATIONAL PHARMACARE THAT DOES NOT LEAVE KIDS BEHIND



ISSUES

1. **Children do not benefit from the same regulatory protection for drugs as do adults.**
 - 70 per cent of paediatric prescriptions are off-label vs 30 per cent for adults.
2. **Our regulatory system is two decades behind our international partners.**
 - Changes in the EU and US modernized their systems in the early 2000s.
3. **Between 2007 and 2016, only 25 per cent of new drugs had paediatric indication.**
 - Our paediatric drug pipeline is dry.

CONSEQUENCES

1. **We fail to uphold children's substantive right to a safe and healthy childhood.**
2. **Drugs for children are not as safe as drugs for adults.**
3. **Children outside of major city centers struggle to access safe drugs.**
4. **New drug technologies are rarely accessible to Canadian children.**

National pharmacare must include a focus on children.

RECOMMENDATIONS

1. Allow access to currently available paediatric drugs through trusted foreign decisions.

Health Canada's 2022-24 Forward Regulatory Plan¹ includes an intention to "create a streamlined application pathway that allows manufacturers of certain drugs that address an unmet medical need to rely on the authorization of a trusted foreign regulator."

THIS PATHWAY MUST INCLUDE PAEDIATRIC DRUGS.

In addition a survey of different stakeholders in clinical and pharmaceutical paediatrics, done by the Goodman Paediatric Formulations Centre in collaboration with the Canadian Paediatric Society during a virtual workshop held on February 3, 2021, shows that 67 per cent believe that 0-2 years of experience on a foreign market is sufficient for a drug to be approved in Canada while the remaining feel 5 to 7 years is enough. The proposed pathway requires 15 years of experience in trusted jurisdictions. According to a recent study², trusted foreign decision could increase access to safe formulation for up to 48 per cent of commonly used paediatric drugs, in one major setting.

If trusted foreign markets like the United States and Europe have approved paediatric drugs, Canada should not delay in doing the same, based on their trusted assessment.



1. Health Canada, "Forward Regulatory Plan 2022-2024."

2. Litalien et al., "Providing Suitable Pediatric Formulations for Canadian Children."

2. Ensure future access to drugs for kids through a Paediatric Rule.

In the United States and Europe, manufacturers must submit paediatric data if their drug is likely to have paediatric applications. **Canada does not require manufacturers to do the same.**

Health Canada must implement a paediatric regulation that requires manufacturers to submit paediatric data for approval, if there is a possibility a drug would have paediatric applications.

These measures are the two most important steps we can take to get safe drugs to kids, according to the survey held in February 2021.

ADDITIONAL STEPS

1. Formulary
2. Incentives to commercialize
3. Strong domestic market
4. Paediatric expert drug center in Health Canada and Canada Drug Agency

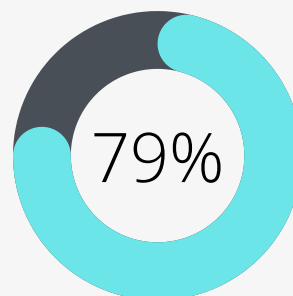
CHILDREN REQUIRE AND DESERVE SAFE ACCESS TO DRUGS.

THE TIME IS NOW!

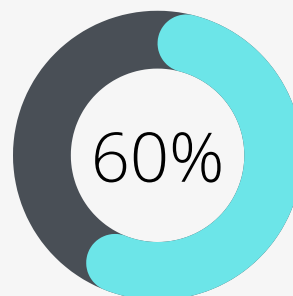
SURVEY RESULTS

What are the most effective steps that Canada can take to increase access to safe medication for children? (Participants chose their top 3 options, and shown below are the top 2 overall options.)

FOREIGN TRUSTED DECISIONS



PAEDIATRIC RULE



L'HONORABLE | THE HONOURABLE
Rosemary Moodie
SÉNATRICE | SENATOR
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