



CRI

Centre for Regulatory Innovation

Regulators' Capacity Fund

Pediatric Incentives

QUICK GLANCE

Lead Organization:

Health Canada (HC)

Timeline:

Nov 2021 – Mar 2022

Funding:

\$252,000

ABOUT THE RCF

The CRI's Regulators' Capacity Fund empowers federal regulators to better consider economic, competitiveness, and resilience factors in regulatory design and implementation.

PROJECT OVERVIEW

The project aimed to develop and implement incentives to encourage pharmaceutical companies to conduct research and development (R&D) for pediatric medicines to address the gap in pediatric drug development and improving access to safe and effective medicines for children.

The Challenge:

Children often have limited access to appropriately tested and approved medicines, as pharmaceutical companies prioritize adult drug development due to higher profitability. This gap in pediatric R&D poses significant risks to children's health and safety.

The Approach:

Health Canada collaborated with industry stakeholders, pediatric experts, and international regulatory bodies to develop a framework for pediatric incentives. The project included the creation of financial and regulatory incentives, such as extended market exclusivity and priority review vouchers, to encourage companies to invest in pediatric R&D. The initiative also involved stakeholder consultations and pilot programs to test the effectiveness of these incentives.

The Impact:

The project successfully developed a set of pediatric incentives that were well-received by the pharmaceutical industry. Initial pilot programs resulted in an increase in pediatric R&D

activities, with several new pediatric medicines entering the development pipeline. These incentives have the potential to significantly improve access to safe and effective medicines for children, addressing a critical gap in healthcare.

Lessons Learned:

Targeted Incentives: Well-designed incentives can effectively encourage investment in pediatric R&D.

Stakeholder Engagement: Engaging industry and experts are crucial for developing practical and impactful incentives.

Pilot Testing: Testing incentives through pilot programs helps refine and validate their effectiveness.

This project demonstrates the importance of targeted incentives in addressing gaps in drug development, ensuring that children have access to safe and effective medicines.