# *Analyzing Incentives for Pediatric Medicines*

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Children can respond differently to health products; thus, medicines need to be studied in pediatric populations to ensure that they are safe and effective. These studies, however, are complex and challenging. Currently, around 75% of drugs prescribed to children in Canada are prescribed "off-label", meaning outside of the Health Canada approved use of the drug (Senate 2012). To address challenges around access to medicines for children in Canada, Health Canada developed a Pediatric Drug Action Plan (PDAP) that aims to increase access to medicines for pediatric populations in Canada (0-17 years). One component of the PDAP is to explore the implementation of a pediatric regulation, along with associated incentives to ensure that pediatric regulatory requirements do not make Canada an undesirable jurisdiction for pharmaceutical companies. These regulatory requirements will bring Canada into alignment with other major regulators such as the U.S. Food and Drug Administration (U.S. FDA) and the European Medicines Agency (EMA).

The purpose of this project was to analyze the success and/or gaps of Canada's existing pediatric incentives provided under the Food and Drug Regulations (FDR) to inform the development of new incentive models to support the implementation of a new pediatric regulation. The project was organized into the themes of stakeholder engagement, feasibility analysis, and economic impact analysis. Stakeholder engagement was used to obtain feedback from targeted stakeholders regarding the current pediatric incentives and ideas regarding proposed alternative models. An analysis of the available data needed to assess feasibility of the economic impact analysis was conducted, along with a complete national and international environmental scan. Finally, economic impact analysis was conducted to analyze the impact of Canada's current pediatric incentive in terms of achieving its goal and any impact on both the pharmaceutical industry and the downstream payers. The economic impacts of any incentive models Health Canada is considering implementing were also examined.

The project aims to lay the groundwork for moving forward on a particular incentive(s) that could be expected to be most impactful in improving access to pediatric medicines in Canada. It was found that the existing incentive was likely moderately successful in bringing pediatric products to Canada. The difficulty in the design of the incentive was around the data protection laws in Canada. The current pediatric incentive requires that pediatric data be submitted within 5 years of the drugs' Notice of Compliance being granted. Five years is generally not enough time to complete the required pediatric studies. This has resulted in the submission of only partial data by the 5-year mark, often with no subsequent submission of data once the final pediatric studies were completed. While this incentive did increase Canada's knowledge of the use of certain drugs in pediatric populations, it was typically not sufficient to result in a label update, meaning that the product would still be considered "off-label" if used in children.

The results of this project provided Health Canada with a greater understanding of the economic impact of different incentives that Canada could implement in our regulatory framework. By harmonizing Canada's approach to pediatric drugs with other major regulators, where possible, this could make Canada a more competitive place for industry and may attract companies to market their drugs in Canada. This project also identified existing data gaps and encouraged engagement with internal and external stakeholders.