

There's a shortage of info on drugs for children in Canada

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Samira Samiee-Zafarghandy is an assistant professor of pediatrics at McMaster University and a neonatologist and a pediatric clinical pharmacologist at McMaster Children's Hospital. Credit: Hamilton Health Sciences

Newly approved drugs in Canada lack important pediatric drug

information in their product monograph, according to an analysis led by McMaster University and McMaster Children's Hospital.

This absence of pediatric information perpetuates "off-label" [drug use](#) which could be dangerous for this vulnerable population, say the authors. They add that Canadian regulatory mechanisms are needed to ensure submission of pediatric data by manufacturers when use in [children](#) is anticipated.

The findings were published today in *Canadian Medical Association Journal (CMAJ) Open*.

"Less than one-third of new Canadian drugs are approved for [pediatric patients](#)," said senior and corresponding author Samira Samiee-Zafarghandy, assistant professor of pediatrics at McMaster and a neonatologist and pediatric clinical pharmacologist at Hamilton Health Sciences' McMaster Children's Hospital.

"Dosing information was missing for the majority of pediatric age groups, but most concerningly for newborns. In addition, we found that many important drugs that treat critical diseases are not approved for use in newborns or children."

Diseases with no new drug development approved for children include, among others, inflammatory bowel disease, diabetes, [human immunodeficiency virus](#) (HIV), seizure, depression and severe pain.

The detailed analysis was conducted of product monographs, which are intended to provide the necessary information, especially for health professionals, for the safe and effective use of a new drug.

The research team manually reviewed monographs of all new drugs approved by Health Canada between 2007 and 2016. During this time,

Health Canada approved 281 drugs, 270 of which had clear benefit for children.

However, only 75 (28 per cent) of the drug monographs were approved for children and there were only 10 (4 per cent) drugs approved for use in newborns.

For a few oral drugs with approval in children (15), only nine (60 per cent) were available in child-friendly, age-appropriate dosage forms.

"Although we were aware that information present in the drug labels are usually more focused on [adult patients](#), the extent of the absence of prescribing information available for children was much, much greater than we anticipated," said Samiee-Zafarghandy.

"We were also confounded by how many drugs used in critical conditions for pediatric and newborn patients did not have any information for their proper use in these children. Many of these drugs are being prescribed to children anyway, and the lack of pediatric data in their monograph can make it difficult for physicians and pharmacists to optimize treatment. The result may be inadequate treatment or increased side effects."

Samiee-Zafarghandy said regulatory mechanisms to require the submission of pediatric data by manufacturers to Health Canada are urgently needed to promote both neonatal and pediatric drug development.

"Our study is the first to report this severe lack of necessary information in labeling of Canadian drugs for pediatric patients," she said.

"The results of this study will serve as a foundation for future comparisons of pediatric drug [information](#) availability between Canadian

drug labels, and [drug](#) labels of medications approved in other advanced countries."

Provided by McMaster University

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