

Safe prescribing information for children in Canada often hard to find

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Accurate, safe prescribing information for children is often unavailable to doctors in Canada because pharmaceutical companies will not disclose information to Health Canada, states an editorial in *CMAJ* (*Canadian Medical Association Journal*).

Health professionals in Canada as well as other countries such as Japan and Australia, unlike their colleagues in the United States and Europe, do not have access to the same body of evidence regarding pediatric dosing.

"As a consequence, Canadian children and youth may fall victim to medication errors and mistreatment simply because of limited access to information about pediatric drugs," writes Dr. Paul Hébert, Editor-in-Chief, <u>CMAJ</u>, with coauthors.

Many drugs in the US that have specific pediatric labeling are described in Canada as having "insufficient evidence."

"Children are not little adults," state the authors. "Pediatric labelling should go well beyond simply adjusting adult doses to a pediatric weight, because this is inappropriate and potentially dangerous."

They cite as an example the increased suicide risk from early off-label prescribing of selective serotonin reuptake inhibitors guided only by data in adults.



While the pharmaceutical industry maintains that pediatric markets are small and not profitable, the US and Europe have introduced financial incentives to encourage research in children. The US Pediatric Research Equity Act requires drug companies to conduct studies and submit results to the US Food and Drug Administration for drugs they expect will be used in children.

"In line with recommendations of the World Health Organization, we need international harmonization of laws to ensure that appropriate incentives are in place to promote pediatric research necessary for pediatric indications and prescribing information," write the authors.

They conclude with a call to politicians to enact strict legislation similar to that in the US to protect Canadian children.

More information: www.cmaj.ca/cgi/doi/10.1503/cmaj.110563

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