IMPROVING MEDICINES FOR CHILDREN IN CANADA

FINDINGS OF THE EXPERT PANEL ON THERAPEUTIC PRODUCTS FOR INFANTS, CHILDREN AND YOUTH

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ABSTRACT

With children being largely orphaned from the benefits of drugs, and being managed mostly by medications unapproved by Health Canada, a landmark document was published in September 2014 by the Council of Canadian Academies (CCA) to serve as a blueprint to change this grim reality. It is now the task of governments, academia and the public at large to ensure that we follow this new road map and take care of our children as they deserve and expect us to do.

The main findings of the panel included:

1. *Children take medications, many of which have not been proven safe and effective for their use.*
2. *Children respond to medications differently from adults; thus, medicines must be studied in children and formulated for children.*
3. *Studying medicines in children is always possible and in their best interests.*
4. *In the United States and the European Union, pediatric medicines research is encouraged, required and monitored in ways that offer lessons for Canada.*
5. *Pediatric medicines research is a Canadian strength, but it requires reinforcement and sustained capacity and infrastructure to realize its full potential.*

In 2010, Dr. Stuart MacLeod, a pre eminent Canadian pediatric pharmacologist, presented to Health Canada's Pediatric Expert Advisory Committee the vision of creating a blueprint to change the unacceptable reality, where children are orphaned from the advents of science and do not benefit from new medications. In Canada, similar to other countries, the majority of drugs have not been tested for their safety and effectiveness in children and hence have not been approved for use in children by Health Canada using regulatory standards for approval. In reality, academia uses most drugs in children, based on experience and a variety of study designs. These are published in clinical guidelines and hospitals' formularies and are generally accepted as standard of practice even by the courts.

However, there are glaring differences between the USA, where the Clinton administration enacted rules that empowered pharmaceutical companies to study medicines in children in return to extension of their market exclusivity[1], and Canada, where similar actions were not initiated. Similarly, the European Union has initiated several moves to make studies in children compulsory.

This reality is in a sharp contradiction to the very rich capacity of the pediatric academic institutions in Canada and their track record in performing such studies.[3]

Stuart MacLeod's conviction and leadership received unanimous support of the Pediatric Expert Advisory Committee, which has led Health Canada to request the Council of Canadian Academies (CCA) to convene a task force to author a report depicting the issues and suggesting solutions to the challenge.[2]

A panel of 14 leading Canadian and international scientists in areas related to pediatric therapeutics were asked to address the following questions:

- How does human development from infancy to youth alter clinical pharmacology and therefore inform pediatric drug investigations?
- What are best practices to ethically conduct scientifically sound but adaptive drug studies to confirm the safety and effectiveness of drugs for infants, children and youth?
- When the participation of infants, children and youth in drug studies is not feasible, what are the best practices to confirm drug safety and effectiveness in these populations?
- What are Canada's strengths to contribute to global pharmacovigilance efforts for drugs that may benefit infants, children and youth?
- The 266 page volume tackles these questions in a very complete manner that can be used, in addition to its public health task, as an excellent resource for learners of pediatric therapeutics.[2]

While it is beyond the scope of this short report to cover every aspect, the members of the panel highlighted 5 critical points:

1. *Children take medications, many of which have not been proven safe and effective for their use.*
2. *Children respond to medications differently from adults; thus, medicines must be studied in children and formulated for children.*
3. *Studying medicines in children is always possible and in their best interests.*
4. *In the United States and the European Union, pediatric medicines research is encouraged, required and monitored in ways that offer lessons for Canada.*
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Out of their suggestions, I wish to highlight here two findings that I believe, are critical:

- Compared to the USA, Britain, Australia and the EEC, Canada spends almost nothing in creating infrastructure for pediatric trials. This situation cannot be justified, not for a country claiming to put its children first, but also not as a fair player in doing its share in the international effort.
- The Panel suggests to develop comprehensive repository of all peer-reviewed reports on use of medications in children, in all age groups, would close a gap created by the lack of labeling. Similar initiatives in Europe and Oceania have been shown effective. While it is acknowledged that the regulator itself cannot do this work, Health Canada can empower other institutions to do so, as is the case in Britain.

"Improving Medicines for Children In Canada" is a commendable document. It is now the task of each one of us to ensure that it does not collect dust, as many such documents have done, but rather inspire action and serve as a road map to empower our commitment to our children.

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