

Media Release

2 December 2003

## Ensuring better medicines for children

Children are being prescribed medicines that have not been properly studied for paediatric use and which are not licensed by regulatory authorities for use in children, according to Dr Madlen Gazarian from the Sydney Children's Hospital, Randwick, and the University of New South Wales. She examines the problems of unapproved use of medicines ("off label" or "unlicensed" use) and describes new initiatives in overcoming a lack of drug studies in children in this month's *Australian Prescriber*.

In her editorial Dr Gazarian highlights that 40%-90% of paediatric prescribing worldwide is for unapproved use, and notes "it is difficult to practice evidence-based medicine when there is little (or no) evidence". Doctors face the challenge of deciding whether to prescribe a medicine with little supporting evidence, or deprive a child of the potential benefits of a medicine.

Although prescribing medicines outside of the specifications of the product licence is not illegal, Dr Gazarian notes that children are disadvantaged in many ways by this situation - stressing the importance of conducting more research so that better information is available to doctors when prescribing for children.

Unapproved use of medicines leaves children exposed to potentially ineffective or unsafe medicines or effective medicines at an ineffective dose. Ineffective or unspecified dosage can also lead to a heightened risk of harm to children.

The shortage of research into medicines use in children is partly due to the lack of incentives for the pharmaceutical industry to test drugs for paediatric use. Dr Gazarian believes low profitability deters companies from undertaking this research.

The editorial examines initiatives undertaken in the USA where new laws have been introduced to increase paediatric drug research. These 'global initiatives' have started to improve the evidence base for prescribing in children but much more work needs to be done, according to Dr Gazarian.

Dr Gazarian emphasises the need for collaboration between consumers, researchers, clinicians, the pharmaceutical industry and policy makers to ensure paediatric drug research and quality use of medicines for children receives high priority.

Other topics in this issue are good nutrition for surgery, traditional Chinese medicines and calcium.

To view the complete article visit the *Australian Prescriber* web site [www.australianprescriber.com](http://www.australianprescriber.com). *Australian Prescriber*, an independent review providing critical commentary on therapeutic topics for health professionals, is published by the National Prescribing Service Ltd (NPS). NPS is an independent Australian organisation for Quality Use of Medicines. For further information about the NPS visit the web site [www.nps.org.au](http://www.nps.org.au)

For more information about therapeutics health professionals can contact Therapeutic Advice and Information Service (TAIS) on 1300 138 677, Monday to Friday, between 9am and 7pm EST.

**For further information or expert commentary about this article please contact Miriam Fletcher at NPS on (02) 8217 8700 or 0417 422 420 or by email at [mfletcher@nps.org.au](mailto:mfletcher@nps.org.au).**

CP/TP 02.12.03

**An independent, Australian organisation for Quality Use of Medicines**

National Prescribing Service Limited | ACN 082 034 393 | ABN 61 082 034 39  
Level 7/418A Elizabeth Street Surry Hills NSW

PO Box 1147 Strawberry Hills NSW 2012 | Phone: 02 8217 8700 | Fax: 02 9211 7578 | net: [www.nps.org.au](http://www.nps.org.au)