



**International Pharmaceutical Federation
Fédération Internationale Pharmaceutique**

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**FIP STATEMENT OF POLICY
Quality Use of Medicines for Children**

Preamble:

This policy statement focuses on improving children's health by ensuring that medicines for use in children are of good quality, have been subjected to ethical scientific research and have been authorised by appropriate agencies. This policy complements the objectives articulated in the FIP policy "The Pharmacist's Responsibility and Role in Teaching Children and Adolescents About Medicines," adopted in Singapore in 2001, which is intended to improve communication and the availability of information on the use of medicines for children.

Background:

A world can be envisioned in which all children have access to good health care that includes access to good quality, safe and effective paediatric medicines. Pharmaceutical scientists, pharmacists and other health-care professionals have special roles and opportunities in advancing this vision.

Health care in children poses special challenges to families, pharmacists and other health-care practitioners, as well as to policy makers. The paediatric population is particularly vulnerable because of developmental, physiological and psychological characteristics that are unique to children and which change rapidly over time. Many children live in increasingly complicated environments where adequate parental (or similar) care, nutrition, sanitation, clean air and water and opportunities for education and play can be the exception rather than the rule. For the healthy child, such conditions can be daunting; for the sick child they can be devastating.

About ten million children die every year from preventable or treatable infectious diseases such as malaria, TB, HIV/AIDS, diarrhoea, and acute respiratory infections. The critical need for action has been recognised by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF).

Maintenance of health and treatment of disease in children are part of a comprehensive set of approaches that require good diagnostic capabilities and evidence-based treatment. For various reasons, including their susceptibility to infectious diseases, treatment with medicines is a major component of paediatric health care. However, as has been noted, the use of medicines in children can be complicated due to the developmental changes occurring over the course of childhood, which can alter the response to medicines in ways that significantly impact safety and efficacy outcomes.

Special formulations are needed for the paediatric patient in order to deliver the proper dose with ease of administration, and to assure adherence. The majority of medicines available in the marketplace have been developed for use in adults and at times lack even rudimentary information about the therapeutic benefit and/or risk in children.

Clinical trials in paediatric populations are difficult to perform and require special approaches. Pharmaceutical manufacturers may be reluctant to invest in paediatric medicines development because the market is relatively small and the needed studies are challenging in terms of cost, time and technical issues. Even if the safety and efficacy of a medicine has been established in a paediatric population, suitable dosage forms may be lacking to allow optimal therapy.

As in all patient groups, medicines must be readily available at the point of care, having been packaged and stored properly to assure maintenance of strength, quality, and purity throughout their shelf-life. In addition, they must be packaged and labelled in ways that promote their proper use and reduce the incidence of medication errors and adverse drug reactions.

Most uses of paediatric medicines occur in the home; therefore accompanying instructions provided by the pharmacist should be understandable to family members or other caregivers. Continuing availability of a health-care professional is important in assuring desired therapeutic outcomes are reached and, if not, that treatment is adjusted.

A particular role for the pharmacist in making useful medicines available for children may lie in extemporaneous compounding. Compounding of medicines by the pharmacist is an appropriate and important response to the frequent lack of appropriate formulations. In addition to professional compounding, dilution of liquids and injections, strategies to improve taste and splitting of tablets are valuable services that pharmacists can provide.

Against this background FIP undertakes to:

- Support WHO and UNICEF in their efforts to promote the health of children and the ready and wide availability of child specific medicines through such guidelines as the Essential Medicines List
- Support WHO and medicines regulatory authorities in efforts to encourage pharmaceutical manufacturers to address the need for appropriate paediatric formulations
- Be an advocate for the ethical, societal and scientific imperatives that will bring good health care to children and their families, including good pharmaceutical care.
- Support research on compounding formulations to ensure optimal product quality.
- Disseminate information about the need for rational use of medicines in children through optimal training, education and other appropriate approaches
- Through genomic and genetic studies promote research that better identifies developmental changes in children that impact drug response and clinical outcomes
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- Encourage collaborative efforts among governments, pharmaceutical industry, academia, and health-care professional associations to develop policies and action plans specifically to improve clinical outcomes and quality of life in children through the availability and appropriate use of quality medicines.
- Call for enacting legislation that provides further incentives to bring quality medicines for children to the market, including better research approaches and facilities for clinical trials.
- Work with governments, manufacturers and others to identify ways to gain useful and reliable information where clinical trials are difficult or impossible to perform.
- Encourage development of appropriate paediatric formulations and medicines information.
- Strengthen compounding by pharmacists for individual patients, based on best practices, to fill gaps for needed medicines and dosage forms.
- Encourage the recognition of the pharmacist's unique role in caring for the medicines therapy of paediatric patients
- Advocate for minimum and maximum doses, dose concentrations and dosing units which are standardised for parenteral medicines used in neonatal and paediatric patients.
- Encourage documentation and reporting of adverse drug events in children.

And, against this background, the FIP continues its recommendations of its 2001 Statement of Principle:

- Pharmacists, with the cooperation, and normally in the presence, of a parent, guardian or carer should communicate directly with children of school age about their medicines, both prescription and non-prescription, in an appropriate area of the pharmacy. Pharmacists should, in addition to any printed information required by law or professional standards, provide written material, which in their professional judgment is appropriate for children and adolescents of the relevant age group, to supplement information given orally.
- Pharmacists should encourage children and adolescents to ask questions about their medicines both at the time of supply and later.
- Professional associations should develop materials to assist pharmacists to help parents teach their children how to use medicines appropriately and where to find and evaluate information about medicines.
- Whenever possible, pharmacists should promote proactively the concept of educating children about medicines by speaking to teachers, parents and community groups.
- Pharmacy professional associations, in cooperation with other health professional associations, school health education authorities, teachers' organisations and the media, should coordinate education on medicines for children and adolescents, promoting the concept that this should be included in school health education curricula from the earliest school years.
- Research should be undertaken to identify and overcome barriers to pharmacists counselling children, adolescents, parents and carers about medicines.
- Communicating with children, adolescents and their parents, guardians or carers should be an integral part of undergraduate and continuing education programmes for pharmacists. In addition, externships, internships, and post-graduate placements should, whenever possible, incorporate experiences in communicating with children and adolescents about their medicines.
- Governments should recognise the benefits that will accrue if children learn to treat medicines responsibly and use them properly from as early an age as possible. Governments should therefore include provision for such an initiative in their health plans, the initiative to include support for pharmaceutical associations to assist them and their members in implementing these recommendations.

This Statement Originated with the FIP Board of Pharmaceutical Sciences