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Dr Suzanne Hill  
WHO  
Policy, Access and Rational Use  
Medicines Policy and Standards

Re: WHO Proposal for formal sub-committee of the Expert Committee on the Selection and Use of Essential Medicines

The Paediatric Sub-Committee of the Clinical Pharmacology Division of IUPHAR, International Union Of Basic And Clinical Pharmacology, warmly welcomes the proposal for establishment of a formal sub-committee of the Expert Committee on the Selection and Use of Essential Medicines, as we suggested during the August 2006 Joint WHO-UNICEF expert consultation on essential medicines for children. The proposal for more attention to children's medicines by the Essential medicines program seems very appropriate and timely in view of the 'Better medicines for children' –initiative recently adopted by the WHO Executive Board and put on the agenda of the World Health Assembly.

The problem with children's medicines is that a significant part of the medicines we have to use every day to treat patients in the paediatric age groups even in the most developed countries do not have adequate evidence of efficacy and safety from clinical studies, are not available in an age appropriate formulation of proper quality, and their use is not well established. As all of the criteria required for inclusion in Essential Medicines List are not fulfilled by a significant part of current paediatric medicines, special adopted criteria have to be developed so that the EML can meet the needs of children.

As long as many medicines which are essential for treatment of children are not approved by competent authorities, the data available on their quality, safety and efficacy has not been properly assessed. Consequently considering them for selection to the EML will require not only adopted criteria, but also a more thorough review of the risk-benefit ratio than is needed for medicines already appropriately authorized for use. Based on our experience with children's medicines from regulatory environments we believe that the Paediatric sub-committee of the Expert Committee needs more than the two meetings indicated by the Secretariat to meet all the proposed, and justified, terms of reference suggested in the proposal.

We urge the Expert Committee on the Selection and Use of Essential Medicines to recommend to the WHO Executive Board the establishment of an Expert sub-committee on the Selection and Use of Essential Medicines for Children. We are pleased to collaborate with the WHO and the future Expert sub-committee to give all children access to safe and effective essential medicines.



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