Confédération Européenne des Spécialistes en Pédiatrie
Section Monospécialisée de Pédiatrie de l'U.E.M.S.

Confederation of European Specialists in Paediatrics
Monospecialist Section of Paediatrics of U.E.M.S

Avenue de la Couronne, 20 B-1050 BRUSSELS, BELGIUM ☎ 32-2-649 21 47 Fax 32-2-649 26 90

Regulation on new medical products for paediatric patients
Statement from the paediatricians in Europe

Dear Member of the European Parliament

The **European Confederation of Specialists in Paediatrics (CESP**)
is the official European Representative of all National Societies, Syndicates and European Scientific Societies in Paediatrics. **CESP** has followed the development of the regulation on medicinal products and has discussed this intensively over the last two years. In addition to that **CESP** has organized meetings on this topic as well has be been actively involved in several meeting, i.e. EFGCP meeting etc.

The European paediatricians unanimously support this new regulation.

We are convinced that our statement is important since the paediatric doctors are the interphase between any regulation or research plans and the child.

The proposal in our view is a good example of the Commission actively working to improve life for European citizens. In this case, by promoting the availability of new and better medicines specifically designed for our children. We believe that our proposal achieves the right balance between these objectives and the need to strengthen the competitiveness of the pharmaceutical industry.

More than 50% of the medicines used to treat children have not been tested and authorised for use in children. The health of the children may suffer as, when a doctor writes a prescription for a child for an untested, unauthorised product, that doctor can not be sure the medicine will be truly effective, what dose is appropriate or exactly what the risks and side effects may be. This is unacceptable for all paediatricians.

Market forces have failed to stimulate the pharmaceutical industry to adequately development of medicines for children. The market is too small relative to that for adults and studies in children are judged to be too complex.

The key objectives of the proposed regulation are to increase the development and authorisation of medicines for use in children while ensuring that children's

medicines are subject to high quality research and children are not subjected to unnecessary clinical trials. The proposal also aims to improve the information available on medicines for children.
The example of the FDA regulation (i.e. 6 months patent extension) which is very simple and clear has turned into a success story leading to an impressive list of new information with a significant impact on dosing, efficacy, and safety issues in paediatric medication.

CESP underlines the moral imperative for all governments to promote the health of their children and to create child health research especially on drug safety.
Therefore, we as the representatives of European paediatric doctors expressed our hope that you as a Member of the European Parliament are highly motivated to support the new regulation which will be a major step towards better health for European children.

Peter F. Hoyer
Professor of Paediatrics
President of CESP

Jose Ramet
Professor of Paediatrics
Secretary General of CESP