European Academy of Paediatrics
Paediatric Section of U.E.M.S (European Union of Medical Specialists)

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9 December 2016

Dear G. La Via, F. Grossetête, E. Gentile, B. Piecha, F. Ries, S. Eck and J. Mélin, co-rapporteurs on The Regulation on Paediatric Medicines,

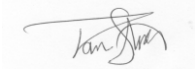
On December 8, the Committee on Environment, Public Health and Food Safety will vote on a draft motion for a resolution on the Regulation on Paediatric Medicines. This Regulation entered into force on 1 January 2007 with the objective of improving children's health through clinical studies, facilitating the research and development of safe and effective medicines intended for all children and adolescents and also increase their availability.

By means of this letter, the European Academy of Paediatrics (EAP) wishes to show its support to your call to the Commission and wishes to express several other points that warrant attention. The EAP is the official voice of children and paediatricians in Europe. It includes professional paediatric societies from all EU Member States and European paediatric sub-specialty societies. In addition, the EAP has a strong research network (the European Academy of Paediatrics Research in Ambulatory Settings network, EAPRASnet) and supports the development of medicines for children by being a partner of the European Medicines Agency. On behalf of European paediatricians and children, the EAP supports your call to the Commission to deliver the 10-year report on the application of the Paediatric Regulation on time and revise the Regulation accordingly to its results. The EAP also wishes to emphasize the following:

- The Regulation should facilitate cross-border paediatric drug research that is ethically and scientifically sound and feasible.
- The Regulation should ensure that development of medicines for paediatric population is stimulated in the areas where insufficient progress has been made, including (but not limited to) oncology and neonatology. Importantly, other areas with clear unmet needs, like rare diseases or those related to first-in-children indications, should not be neglected;
- Medicines (including vaccines) that are safe and effective in neonates, children or adolescents should become available without undue delay. Collected data should be communicated appropriately and timely to paediatricians, in order to benefit their patients;
- National authorities should monitor and document (preferably in a publicly accessible database) if medicines that are approved for use in children by EMA, are actually available in the market of the respective country.

The EAP wishes you a productive meeting today and is looking forward to future collaboration on this important topic.

Yours sincerely,



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