

***eSymposium* Phytotherapeutics in Children:**
Rationalizing optimal Dosing for use in Children:
Current Situation – Potential Solutions – Activities needed

Science for Children at the border between paediatrics, regulatory affairs,



17 May, 2022, 10.00 AM to 5.00 PM (CEST)

A joint symposium of



Society for Medicinal Plant and
Natural Product Research



Gesellschaft für Arzneipflanzen-
und Naturstoff-Forschung e.V.



Gesellschaft für Phytotherapie e.V.

“Children are no small adults with respect to the treatment with medicinal products”

– as stated by WHO. This understanding has been the basis for the initiative of the European Commission to build the Paediatric Committee (PDCO) as a scientific board of the European Medicines Agency (EMA).

A Paediatric Regulation came into force in the European Union (EU) on 26 January 2007. Its objective was and still is to improve the health of children in Europe by facilitating the development and availability of medicines for children aged 0 to 17 years. 15 years later we have to realize, that the results are moderate.

This eSymposium will give opportunity to analyse the reasons and to present prospects for alternatives to establish proof of safe and efficacious herbal medicines for children's use. The eSymposium is intended to be the starting point to discuss actions to be initiated as soon as possible to find suitable ways for establishing rationalized dosage regimes for phytotherapeutics for the use in children.

This eSymposium is a joint initiative of the Society of Medicinal Plants and Natural Products Research (GA), the Gesellschaft für Phytotherapie (GPT) and the Foundation Plants for Health (PfH) with the aim to facilitate research in this neglected area of healthcare, including future funding opportunities of research for phytotherapeutics in children.

Scientific Committee

Prof. Dr. Rudolf Bauer, Graz
Dr. Olaf Kelber, Darmstadt
Dr. Barbara Steinhoff, Bonn

Prof. Dr. Michael Heinrich, London
Dr. Bernd Roether, Neumarkt

Prof. Dr. Andreas Hensel, Münster
Prof. Dr. Judith Rollinger, Wien

09:30 Arrival and Preparation

10:00-11:00 **Session A: Impulse Cluster**

Welcome
Prof. Dr. Rudolf Bauer, University of Graz, Austria

10:05-10:20 **The academic viewpoint**
Prof. Dr. Karin Kraft, University of Rostock, Germany
Prof. Dr. Judith Rollinger, University of Vienna, Austria

10:20-10:35 **The paediatric viewpoint**
Dr. med. Karl Rüdiger Wiebelitz, Perleberg, Germany

10:35-10:50 **The regulatory viewpoint**
Dr. Reinhard Länger, Austrian Federal Office for Safety in Health Care, Vienna, Austria

10:50-11:00 **Moderated Discussion**

11:15-13:20 **Session B: The International Situation**
Chair: Prof. Dr. Michael Heinrich, UCL School of Pharmacy, London, U.K.

11:20-11:40 **The situation in the DACH region (Germany, Austria, Switzerland)**
Dr. Birka Lehmann, Paediatric Committee (PDCO) of EMA

11:40-12:00 **The situation in U.K.**
Dr. Melanie Pires, and Dr Liz Griffiths, Medicines and Healthcare Products Regulatory Agency, London, U.K.

12:05-12:25 **The situation in Spain**
Montserrat Mesegué, MD, Spanish Society of Phytotherapy (SEFIT), Barcelona, Spain

12:25-12:45 **The situation in Eastern Europe**
Dr. Bernd Roether, Bionorica SE, Germany

12:45-13:00 **Moderated Discussion**

Programme Day 2

14:00-16:45 **Session C: Potential Solutions**
Chair: Prof. Dr. Andreas Hensel, University of Münster, Germany

14:00-14:20 **Safe use of herbal substances in children – experiences with paediatric use in HMPC monographs**
Dr. Jacqueline Wiesner, BfArM, Germany

14:25-14:45 **Safety aspects within ICH, lessons learned from dosage for children for chemical entities**
Dr. Robert Skip Nelson, Johnson & Johnson, Member of ICH E11A Group, Senior Director, Pediatric Drug Development (CHILD), Pediatric Strategy Lead, Pediatric Development Team, Immunology

14:50-15:05 **Methods to predict adequate dosing in children using knowledge from adults**
Prof. Dr. Georg Hempel, University of Münster, Germany

15:10-15:30 **Controlled clinical studies with children - a review on European level**
Prof. Dr. Karin Kraft, University of Rostock, Germany

15:35-16:05 **PhytoVIS data base as a pharmacoepidemiological tool for getting real world data on paediatric use**
Prof. Dr. Karen Nieber, University of Leipzig, Germany
Dr. Olaf Kelber, Steigerwald Arzneimittel GmbH, Bayer Consumer Health, Germany

16:10-16:45 **Moderated discussion, wrap-up, summary and conclusion**
All Speakers of the Symposium – one key message in one sentence per speaker!

Prof. Dr. Andreas Hensel, University of Münster, Germany



Organization

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Registration

Please use [this link](#) to register.
Your registration will be checked manually and you will receive a Zoom link via email afterwards – please check your spam-folder.

This eSeminary series is free of charge.