



Workshop "Real-world data to document the use of phytopharmaceuticals in children"

Date: Sunday 14/07/2024, 13:30-17:00,

Venue: ICE Krakow Congress Center, Marii Konopnickiej 17, 30-302 Kraków, Poland

The workshop is organized during the International Congress on Natural Products Research in Krakow (<https://icnpr2024.org/>) by GA Foundation Plants for Health (GA PfH), Society for Medicinal Plant and Natural Product Research (GA), German Society of Phytotherapy (GPT), in cooperation with Austrian Society of Phytotherapy (ÖGPhyt), Swiss Medical Society of Phytotherapy (SMGP), Dutch Society of Phytotherapy (NVF), European Scientific Cooperative on Phytotherapy (ESCOMP), Kooperation Phytopharmaka and Komitee Forschung Naturmedizin e.V. (KFN).

Stakeholders from academia, industry and regulatory authorities will discuss ideas to advance the use of real-world-data/real-world-evidence (RWD/RWE) in order to support a more extensive use of HMPs in children and adolescents.

Invited Speakers (in alphabetical order):

- Dr. med. Simone Breitkopf, Medical Consulting, Germany
Capturing use of HMPs in patient registries and electronic medical records
- Prof. Dr. Andreas Hensel, GA PfH, University of Münster, Germany
- Univ.-Doz. Mag. pharm. DDr. med. Ulrike Kastner, Specialist in pediatrics and adolescent medicine, Austria
- Prof. Dr. Karel Kostev, Scientific Principal at IQVIA, Germany
Unmet need for real-world studies on the effectiveness of phytopharmaceutical in children
- Dr. Angela Müller, Dr. Willmar Schwabe, Chair AESGP Committee Herbal Medicinal Products, Germany
RWD on herbal medicinal products in children – industry food for thought
- Dr. Emiel Van Galen, Chairman of the Herbal Medicinal Product Committee (HMPC) of the European Medicines Agency, The Netherlands
RWD: what we want to know, need to know, can know and what is nice to know'
- Dr. Jaqueline Wiesner, Head of the Department of Herbal and Traditional Medicines, BfArM, Germany
RWD in the authorisation of herbal medicinal products for use in children - the perspective of the BfArM

Discussion Session

No Fees

Registration necessary:

Please register on the Foundation Plants for Health webpage

<https://www.plantsforhealth.org/registration-krakow>

Abstracts:

Prof. Dr. Karel Kostev

A large real-world study from Germany shows that in pediatrician practices, there was an increase in phytopharmaceutical prescribing for respiratory tract infections between 2013 and 2018 and then a slightly decrease between 2018 and 2022. Both increase and decrease in prescriptions of phytopharmaceuticals differed depending on diagnoses and age groups. The increasing trend in phytopharmaceutical prescription may further accentuate the decreasing trend in antibiotic prescription. Since the increasing trend may be explained by the fact that some scientific research has suggested that these drugs are effective treatments for respiratory tract infections, more real-world data are urgently needed on the effectiveness of phytopharmaceuticals in children. Prof. Kostev discusses the Unmet need for real-world studies on the effectiveness of phytopharmaceutical in children and possible analyses using databases from IQVIA.

Dr. Simone Breitkopf

The EMA is increasingly considering Real-World Data (RWD), collected in patient registries and electronic medical records, in the scientific evaluation of human medicines. The presentation gives an overview on real world data sources, the types of studies that can be performed and how EMA can help identify the best resources to address a research question.

Dr. Jacqueline Wiesner

For some years, it has become evident that RWD can make an important contribution to the assessment of the safety and efficacy of medicinal products and can complement evidence from other sources, including clinical trials. The possibilities and limitations of such studies must be carefully considered.

The challenge will be to balance how good the quality (and also the design in general) of studies on RWD needs be so that such data can serve as a basis for regulatory decisions or when the uncertainty in the RWD is too great to use them for decision-making.

Angela Müller

How to advance the use of real-world-data/real-world-evidence (RWD/RWE) in order to support a more extensive use of HMPs in children and adolescents?

Improved evaluation of data from paediatric clinical practice for the safe use of herbal substances in children is one of the topics of the HMPC 2024 workplan. In absence of sufficient clinical study data, a common understanding for the interpretation of clinical practice from herbal medicinal products on the market shall be developed for conclusions on acceptable indications for children, also taking new data resources into account, including RWD/RWE. Therefore, HMPC has started a pilot within the EMA's RWD/RWE project, to explore available data resources for the use in children's age groups of (traditional) herbal substances/preparations.

The presentation will discuss some thoughts on essential basic requirements and framework conditions of RWD on herbal medicinal products and suggest potential approach to best capture OTC Real-World-Data balancing both potential limitations and the given circumstances in the OTC Real-World situation.