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 (ESCOP), 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, DGPharMed e. V., 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, Paediatrician, Maria Enzersdorf, Austria
  Herbal Medicinal Products in Daily Paediatric Practice
- 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. Tamar Lasky, PhD, FISPE, Food and Drug Administration (retired), Silver Spring, MD, U.S.A.
  RWD and RWE to understand phytopharmaceuticals in children
- 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

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PROGRAM

Chairman: Prof. Dr. Rudi Bauer, Foundation Plants for Health

13:30 – 13:45	Prof. Dr. **Andreas Hensel** GA, PfH, University of Münster, Germany	Rationalizing the use of (T)HMPs in children: Current situation and new approaches
13:45 – 14:05	Univ.-Doz. Mag. pharm. DDr. med. **Ulrike Kastner**, Specialist in pediatrics and adolescent medicine, Austria	Herbal Medicinal Products in Daily Paediatric Practice
14:05 – 14:25	**Angela Müller** Chair AESGP Committee Herbal Medicinal Products, Dr. Willmar Schwabe, Germany	RWD on herbal medicinal products in children – industry food for thought
14:25 – 14:45	Prof. Dr. **Karel Kostev** IQVIA Inc., Scientific Principal, Germany	Unmet need for real-world studies on the effectiveness of phytopharmaceuticals in children
14:45 – 15:05	Dr. **Simone Breitkopf**, Medical Consulting, Germany	Capturing use of HMPs in patient registries and electronic medical records
15:05 – 15:20	**Coffee Break**	
15:20 – 15:40	Dr. **Tamar Lasky** PhD, FISPE Food and Drug Administration (retired) Silver Spring, MD, U.S.A.	RWD and RWE to understand phytopharmaceuticals in children
15:40 – 16:00	Dr. **Jacqueline 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
16:00 – 16:20	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’
16:20 – 16:55	**Open Discussion**	
16:55 – 17:00	Prof. Dr. **Rudi Bauer** GA, PfH, University of Graz, Austria	Summary and Outlook: The way towards next steps and potential pilot projects

Abstracts:

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.

Univ.-Doz. Mag. pharm. DDr. med. Ulrike Kastner

Herbal medicinal products (HMPs) are frequently used in paediatric patients to treat common and moderate diseases and to maintain health. However, paediatricians and practitioners have to cope with lack of authorized herbal medicines, especially for infants and toddlers. In addition, recommendations of HMPC restrict the use of many herbals under the age of four years because of lack of adequate data [1].
The discrepancy in urgent need of HMPs for paediatric patients (also requested by parents) and the possibility to prescribe legally, leads to a dilemma for practitioners and frequent off-label use. Since children are not small adults when it comes to drug treatment, emphasize should be put on further clinical studies (rather hypothetical for HMPs – because of moderate diseases, small numbers of patients, different age groups) or datasets derived from post marketing surveillance and Real World Data. In consequence, authorities, companies and health care professionals should work together to generate such databases. Harmonizing the access to plant derived products including food supplements and medical devices (given by self-medication or medical advice) and recording prescriptions and dosage recommendation of herbal remedies in dependence of age and disease could be feasible initial steps. Considering that about 85% of German children receive at least one HMP per year [2], this would be a practical way to quickly achieve appropriate data. More transparency in quality, efficacy, dosage and safety of HMPs for doctors, pharmacists and consumers will definitely help to maintain this important treatment option with long tradition for paediatric patients in future.

Conflicts of Interest: ----

Keywords: Herbal medicinal products, paediatric patients, off-label use, generation of data
References
1. European Union herbal monographs: Overview of recommendations for the uses of herbal medicinal products in the paediatric population. EMA/HMPC/228356/2012, Rev. 2, 2023
2. Hümer, M., Scheller G., Kapellen T., et al, 2010. Use of herbal medicine in German children - prevalence, indications and motivation. Dtsch. Med. Wochenschr. 135(19), 959-964

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. 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.