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Editorial

# 'Formulating better medicines for children' – Still paving the road

The 3rd conference of the European Paediatric Formulation Initiative (EuPFI) co-organised with the International Association of Pharmaceutical Technology (APV) took place on the 21st and 22nd of September 2011 in Strasbourg, France. With almost 200 delegates from 22 countries and 5 continents, it was yet another significant event, addressing the EuPFI mission to scope issues and challenges related to paediatric formulations, in order to raise awareness and consider ways forward towards better medications and dosage forms for children.

The purpose of this, now regular, conference is to bring together those with expertise and interest in the area of children's medicines: renowned scientists, researchers and students from industry and academia and also healthcare professionals, in order to share, reflect upon and discuss recent advances in pharmaceutical sciences, considering the needs of children for appropriate medicines. In the dedicated focus sessions, which included discussion time, the meeting offered a strong representation of 5 topics of interest corresponding to the EuPFI workstreams: *Age-appropriate formulations*, *Administration Devices*, *Excipients*, *Extemporaneous preparations*, *Taste masking and testing*. To set the scene the main plenary lectures presented the draft EMA guideline on "Pharmaceutical Development of Medicines for Paediatric Use", released for consultation in May 2011, as well as the "Development of Paediatric Medicines: Points to Consider in Pharmaceutical Development" proposed by WHO; two very important documents. In parallel on behalf of the European Federation of Pharmaceutical Industries and Associations (EFPIA) an industrial view point was given on the rationale to accurately define the paediatric target product profile and consider paediatrics very early on in development, to manage the risk. In turn, through case studies from the Paediatric Committee (PDCO) Formulation Working Group, the EMA gave an overview of formulation issues encountered in PIPs from almost 5 years of experience since the EU regulation implementation. The FDA also shared their activities in the field. Issues with quality of ingredients in paediatric medicines were also discussed, particularly appropriate for this conference held in Strasbourg, the headquarters for the European Directorate for the Quality of Medicines & HealthCare (EDQM). Papers presented in this IJP special issue resume the outcomes of all these sessions. It seems that stakeholders are still finding their feet with the regulations, and the regulators are responding by trying to set some guidance to help the pharmaceutical industry. Both are working to respond to the heterogeneous paediatric population subsets needs, within tight resource restrictions, and lack of evidence based indicators and precedent, while patients and their family are still waiting for new clinically relevant dosage forms to be available on the market. Forty-one posters displayed over the 2 days highlighted new findings and preliminary data, stimulating discussion in a relaxed atmosphere, 10 of which were showcased in short podium presentations. This provided a fruitful platform to exchange ideas amongst experts from the audience. *Peer reviewed abstracts can be found at* http://www.eupfi.org/new%20website%20template/index1.html.

In this IJP special issue the short papers provide a snapshot of all the oral presentations that took place over the 2 days:

- The EMA perspective: case studies from the PDCO Formulations Group (chemicals & biologicals).
- The EMA quality guideline on the pharmaceutical development of medicines for paediatric use.
- WHO guideline development of paediatric medicines: points to consider in pharmaceutical development.
- FDA: contribution to developing pediatric formulations and transatlantic collaboration.
- International initiatives on extemporaneous dispensing.
- Current administration practices and preferred formulations of children's medicines in Tanzania: summary of survey findings.
- Assessing taste without using humans: Rat Brief Access Aversion model and Electronic Tongue.
- Industry perspective on palatability testing in children – two case studies.
- Regulatory aspects of devices.
- Development of child-appropriate devices.
- Off-patent Oral Oncology Drugs for Kids (O3K FP7-project): from bedside to Paediatric Use Marketing Authorisation (PUMA).

In terms of selection of full length manuscripts, the emphasis was put on excipients with two papers covering topics from need assessment of a database on Safety and Toxicity of Excipients for Paediatrics (STEP data base under development by the EuPFI consortium) to the feasibility to study toxicokinetics in neonates with the propylene glycol research project from the Department of Neonatology, University Hospitals, Leuven, Belgium. Moreover recognising that there is some confusion about the types of paediatric pharmaceutical preparation (in a regulatory and pharmaceutical development context) that are acceptable for approval by medicines regulators, another EuPFI reflection paper on 'Preparation of medicines for children – a hierarchy of definition' has been selected.

Finally it was decided to address another important issue: the fine balance between benefit and risk factors associated with developing pharmaceutical product intended for paediatric use. In that

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respect 3 major global pharmaceutical companies got together and prepared a document to highlight 'A benefit/risk approach towards selecting appropriate pharmaceutical dosage forms – an application for paediatric dose form selection'.

The 4th EuPFI conference will be convened in Prague, Czech Republic, on 19th and 20th September 2012 at the Centre of the Institute of Molecular Genetics, organised again in partnership with APV. This conference is a real opportunity for international leaders in the fields of paediatric formulation development to come together and continue identifying issues, discussing possible solutions and then ultimately, to devise and successfully execute solutions to emerging related topics. This conference will focus on challenges and opportunities for developing paediatric products from a worldwide perspective. It will provide updates on final steps towards a harmonized view between academia, regulators and industry, following consideration of the comments on the EMA draft guideline "Pharmaceutical Development of Medicines for Paediatric Use", and also the FDA perspective on the challenges and opportunities for developing paediatric products; as well as the AAPS paediatric task force White Paper. The conference will reflect on the achievements of the WHO 'Make Medicines Child Size' programme, and discuss the value of PK & bridging studies in paediatric drug development. Case studies, including the 1st PUMA and how to develop orphan medicines, will illustrate lessons learned and strategies to develop clinically relevant formulations. The 1st live version of the Safety and Toxicity of Excipients for Paediatrics (STEP) data base will be unveiled. The thematic sessions covering the five aforementioned EuPFI work streams, complemented by a vibrant poster and podium session will provide an overview of the current practices and challenges in these areas, to illustrate specific evidence-based remedies, utilized by paediatric drug development teams, to overcome hurdles.

Abstracts can be submitted at http://www.eupfi.org/Conference%202012%20webpage/abs-topics.htm until 1st June 2012. Early bird registration closes by Friday 15th July 2012.

This special issue is dedicated to the late Dr John Hempenstall who was instrumental to the European Paediatric Formulation Initiative creation in 2007 and has continuously supported, helped, guided and enthused the group. His invaluable contribution towards formulating better medicines for children will be greatly missed.

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