Formulating better medicines for children
Meeting the needs of the children

19th to 20th September 2012
Prague, Czech Republic
Course No. 6440

4th conference of the
European Paediatric Formulation Initiative EuPFI
A conference organised by the International Association for Pharmaceutical Technology in partnership with the European Paediatric Formulation Initiative

Keynote Speakers

Mansoor A. Khan, PhD
Director of Division of Product Quality Research, CDER, FDA, United States

Diana Van Riet-Nales, PharmD
Quality Working Party, EMA, UK and RIVM, The Netherlands

Dr Clive Ondari
WHO, Geneva, Switzerland

Dr Benedicte Ricci
F. Hoffmann-La Roche, PDCCB Clinical Pharmacology CNS, Switzerland

Soap box sessions – Poster session – Exhibition

International Association for Pharmaceutical Technology
Wednesday, 19th September 2012   10.00-18.00 h

**Set-up and poster mounting**

**Welcome and Introduction**
Catherine Tuleu, PhD, Chair of EuPFI
UCL School of Pharmacy
London, United Kingdom
Prof. Jörg Breitkreutz, PhD
Heinrich-Heine-University Düsseldorf,
Düsseldorf, Germany

**Comments on the EMA draft guideline: final steps towards a harmonized view between regulators and industry**
Diana van Riet-Nales, PharmD
Co-ordinator, Section Chemical Pharmaceutical Assessment (CFB), Medicines Evaluation Board (MEB), Bilthoven, The Netherlands

**AAPS paediatric task force and its White Paper**
Georgia Charkoftaki, PhD
University of Athens, School of Pharmacy, Laboratory of Biopharmaceutics and Pharmacokinetics, Athens, Greece

**Question and Answer session**

**Reflection on the achievements of the ‘Make Medicines Child Size’ programme: what next?’**
Clive Ondari, PhD
Coordinator, Medicine Access and Rational Use (MAR), Essential Medicines and Pharmaceutical Policies (EMP) World Health Organization (WHO), Geneva, Switzerland

**Soap box session 1**

**Lunch, exhibition and poster presentations**

**Focus Session: Extemporaneous preparations**
Chair: Professor Tony Nunn, Liverpool, United Kingdom

*The MODRIC (manipulation of drugs required in children) study*
Cerin Barker
Alder Hey Children’s NHS Foundation Trust, Liverpool, and Cheshire Merseyside & North Wales Medicines for Children Local Research Network, Liverpool, United Kingdom

*What is extemporaneous and how to control it?*
Terry Ernest, PhD
GlaxoSmithKline, Harlow, United Kingdom

*Mixing medicines with foods and drinks - latest regulatory considerations*
Caroline Le Barbier, PhD
EMA QWP and FWG PDCO, London, United Kingdom

**Focus Session: Excipients**
Chair: Professor Jörg Breitkreutz, PhD

*Safe drugs for neonates: the European Study of Neonatal Excipient Exposure (ESNEE) project*
Mark Turner BSc, PhD, MBChB, MRCP(UK), MRCPCH, DRCOG
Department of Women’s and Children’s Health, Institute of Translational Medicine and School of Reproductive & Developmental Medicine University of Liverpool, Liverpool, United Kingdom

*Launch of the STEP (Safety and Toxicity of Excipients for Paediatrics) database*
Smita Salunke
EuPFI, London, United Kingdom
and
George P. Giacoia, MD
Eunice Kennedy Shriver NICHD, NIH, Bethesda, MD, United States

**Discussion**

**Afternoon break and exhibition**

**Focus Session: Administration Devices**
Chair: Herbert Wachtel, PhD, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany

*EuPFI activities: Administration devices for children*
Jenny Walsh, BPharm (Hons), PhD, MRPharmS
Jenny Walsh Consulting Ltd, Nottingham, United Kingdom

*Needle free parenteral administration for children: current status and future trends, an industry perspective*
Catherine Curdy, PhD
Parenteral and Topical Platform Leader, Technical R&D, Novartis Pharma, Basel, Switzerland

*Evidence Based Design Of Face Masks For Infants & Young Children*
Israel Amirav, PhD
Pediatric Department, Sieff Hospital, Safed, Israel

**Discussion**

**End of scientific programme**

**Guided castle tour and networking dinner**
Thursday, 20th September 2012  08.30-15.00 h

Introduction day 2

Challenges and opportunities for developing pediatric products: A FDA Perspective
Mansoor A. Khan, R.Ph., PhD
Director of product quality research in the Center for Drug Evaluation and Research at the US Food and Drug Administration, Silver Spring, United States

PK & bridging studies in pediatric drug development
Benedicte Ricci, PhD
F. Hoffmann-La Roche, Basel, Switzerland

Question and Answer session

Focus Session: Taste masking and Taste assessment
Chair: Catherine Tuleu, PhD

Assoc. Prof. Mario G. Bianchetti, MD
Medical director at the integrated Department of Pediatrics, Bellinzona-Mendrisio, and associate Professor at the University of Bern, Bellinzona, Switzerland

Potentiometric sensor array for the assessment of taste-masking of APIs
Prof. Wojciech Wroblewski, PhD
Warsaw University of Technology, Department of Microbioanalytics, Warsaw, Poland

Discussion

Coffee break, exhibition and poster presentations

Soap box session 2

Lunch, exhibition and poster presentations

Successful case studies from industry

Case study 1: Buccolam®: The 1st Centralized Paediatric Use Marketing Authorization (PUMA)
Susan Conroy, PhD
Therakind Ltd, London, United Kingdom

Case study 2: Successful development of orphan drugs for the paediatric population
Pierre Mambrini, Lucane Pharma, Paris, France

Discussion

Focus Session: Age-appropriate formulations
Chair: Sabine Desset-Brethes, PhD, Novartis Pharma, Basel, Switzerland

Microparticulates as drug carriers for paediatric use
Frédéric Gerber, PhD
Glatt, Binzen, Germany

Gastrointestinal models (TIM) with high predictive power, even for children?
Robert Havenaar, PhD
TNO, Zeist, The Netherlands

Discussion

General Discussion

Closing of conference

Restaurant Vikárka in Prag
Dear Colleagues,

In September 2012, the European paediatric Formulation Initiative (EuPFI) will convene its 4th annual conference ‘Formulating Better medicines for Children’. Yet another significant milestone in its mission to scope issues and challenges in paediatric formulation in order to raise awareness and consider ways towards better medicines for children.

Join us for the 4th annual conference of the EuPFI which will take place at the Centre of the Institute of Molecular Genetics, in Prague, Czech Republic, September 19th – 20th, 2012. The Conference is again organised in partnership with APV (International Association of Pharmaceutical Technology).

This conference will focus on challenges and opportunities for developing medicinal products and medicinal devices for paediatric use from EU and US perspectives. It will provide update on the comments on draft EMA ‘Guideline on Pharmaceutical Development of Medicines for Paediatric Use’, reflect on the achievements of the WHO ‘Make Medicines Child Size’ programme, discuss PK & bridging studies in paediatric drug development. You will hear case studies including the story of the 1st successful PUMA, illustrating lessons learned and strategies to develop clinically relevant paediatric formulations. The thematic sessions covering the five work streams of EuPFI (taste masking and testing, excipients, age appropriateness of formulations, extemporaneous formulations and administration devices) will provide an overview of the current practices and challenges in the aforementioned areas, to illustrate specific strategies put in place by paediatric drug development teams to overcome hurdles.

We also have a vibrant poster session with many peer review selected oral short communications in soap-box sessions. We encourage you to explore the EuPFI website which contains all the information you need to submit your abstracts.

The conference will provide a platform to exchange ideas among experts from academia, industry, hospitals, and regulatory authorities. It will bring together international leaders in the field of paediatric medicines development to discuss emerging topics in these areas.

Don’t miss this unique opportunity! We are looking forward to welcoming you in Prague, the magical city of bridges, cathedrals, gold tipped towers and church spires.

Catherine Tuleu, PhD, UCL School of Pharmacy, London, United Kingdom
Prof. Jörg Breitkreutz, PhD, Heinrich Heine University, Düsseldorf, Germany
Formulating better medicines for children

Key Plenary Topics

- Comments on the EMA draft guideline: final steps towards a harmonized view between academia, regulators and industry.
- Challenges and opportunities for developing paediatric products: A FDA Perspective
- AAPS paediatric task force and its White Paper
- Reflection on the achievements of the WHO ‘Make Medicines Child Size’ programme
- PK & bridging studies in paediatric drug development

Topics for Oral and Poster Presentations

- Developing paediatric drug formulations
- Excipients for paediatric use
- Taste Masking and Taste Testing
- Administration Devices
- Extemporaneous and Industry Verified Preparations
- Age Appropriateness/Compliance and Adherence Issues
- Formulating Paediatric Medicines for Developing Countries
- Lessons Learned from PIP Submissions

Abstract Submission:

You are kindly invited to submit abstracts for soap box sessions and poster presentations during the conference. Please use the submission procedure on our website www.eupfi.org to submit your abstracts. Detailed information for authors and submission are available online on the website.

Deadlines:
Call for Abstracts – Open 5th March 2012
Abstract Submission – Deadline 1st June 2012
Notification of Acceptance – 1st July 2012

Social Programme:

A guided tour at Prague castle and a networking dinner in a restaurant in a historic location will give the participants the opportunity to get together.

Exhibition and sponsoring:

Sponsoring and exhibition opportunities: We are glad to tailor a sponsor package (starting from 2000 EUR) according to your wishes. As an exhibitor you will be also invited to attend the sessions and network at the Get Together Dinner in the evening that is part of the conference programme. At the conference center the poster presentations will be again integrated in the exhibition, ensuring that participants are around the exhibition stands as much as possible. Price for a table top space with table, chairs and power supply is 990 EUR plus one mandatory full conference registration (register before July 15th, to take advantage of the early bird fee!).

Please contact the APV headquarters
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Register by Friday 15th July 2012 to take advantage of the early bird fee

Non-Member (Non Academic, Non Governmental)
Member of APV (Non Academic, Non Governmental)
Non-Member (Academic, Governmental)
Member of APV (Academic, Governmental)
Students (please enclose evidence)

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Formulating better medicines for children
in Prague, Czech Republic, 19th to 20th September 2012

Hotel reservation
Rezidence Emmy
K Zelené louce 2a
140 00 Prag 4 - Krč
Phone: +42 246 020-004
Fax: +42 246 020-155
E-mail: reservation@emmy.cz

Participants should make their own hotel reservation referring to the APV seminar.
Special rate:
Single room incl. breakfast buffet from EUR 56,00 excluding VAT per night.

Panorama Hotel
Milevska 7
14063 Prague
Czech Republic
Phone: +42 26116-1111
Fax: +42 26116-4141
E-mail: welcome@panoramahotelprague.com

Participants should make their own hotel reservation referring to the APV seminar.
Special rate:
Single room incl. breakfast buffet and shuttle to/from IMG from EUR 101,00 excluding VAT per night.

Mainz, March 2012

Early bird          Full fee
1075 EUR          1175 EUR
945 EUR          1045 EUR
425 EUR          475 EUR
360 EUR          410 EUR
195 EUR          225 EUR

Registration
All correspondence regarding the conference should be addressed to:
Conférence Scretariat
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
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E-mail: apv@apv-mainz.de
Website: www.apv-mainz.de

You will receive a confirmation of your registration with the invoice.