

# Formulating better medicines for children

Meeting the needs of the children

19<sup>th</sup> to 20<sup>th</sup> September 2012

Prague, Czech Republic

Course No. 6440



## 4<sup>th</sup> 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



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## Programme

Wednesday, 19<sup>th</sup> 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

Catrin 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

#### Discussion

#### 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

# ng better medicines for child

Thursday, 20<sup>th</sup> 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

#### Palatability assessment in children: Why? When? How?

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

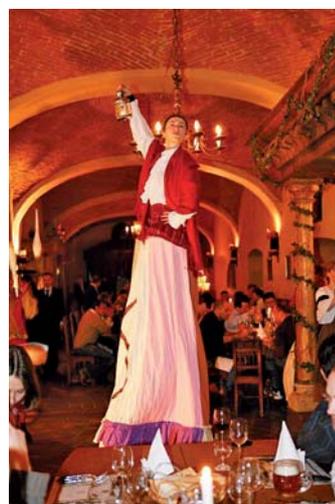
TNO, Zeist, The Netherlands

## Discussion

## General Discussion

## Closing of conference

## Restaurant Vikárka in Prague





## EuPFI

Dear Colleagues,

In September 2012, the European paediatric Formulation Initiative (EuPFI) will convene its 4<sup>th</sup> 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 4<sup>th</sup> annual conference of the EuPFI which will take place at the Centre of the Institute of Molecular Genetics, in Prague, Czech Republic, September 19<sup>th</sup> – 20<sup>th</sup>, 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 1<sup>st</sup> 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**

The European Paediatric Formulation Initiative (EuPFI) is a consortium of members working in a pre-competitive way on paediatric drug formulations. It was founded in 2007 with the aim of raising awareness of paediatric formulation challenges. Members are from academia, hospitals and the pharmaceutical industry (innovators, generics, CRO's, specials and excipient manufacturers), with EMA as a continuous observer.

The main objective of the EuPFI is to resolve scientific, technological and regulatory issues associated with paediatric formulation development by writing reflection papers, organising conferences, developing knowledge repositories and promoting dialogue through its website.

Currently, there are five EuPFI workstreams, covering pharmaceutical excipients; age appropriateness of formulations; taste masking and taste assessment methods; extemporaneous formulation and dispensing; and administration devices.

# 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](http://www.eupfi.org) to submit your abstracts. Detailed information for authors and submission are available online on the website.

### Deadlines:

Call for Abstracts – Open 5<sup>th</sup> March 2012

Abstract Submission – Deadline 1<sup>st</sup> June 2012

Notification of Acceptance – 1<sup>st</sup> 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 15<sup>th</sup>, to take advantage of the early bird fee!).

Please contact the APV headquarters  
Phone +49 6131 9769-85  
e-mail [sp@apv-mainz.de](mailto:sp@apv-mainz.de)



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Website: [www.eupfi.org](http://www.eupfi.org)

## Date

Course No. 6440  
from 19<sup>th</sup> Sept. 2012 10:00  
to 20<sup>th</sup> Sept. 2012 15:00

## Location

Congress Center: Institute of Molecular  
Genetics of the ASCR, v.v.i. (IMG)

Videňská 1083  
142 20 Prague 4  
Czech Republic  
Phone: +42 241 063-215  
Phone: +42 224 310-234  
Fax: +42 224 310-955

## Hotel reservation

Residence 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.

Deadline for special conference rate: 25<sup>th</sup> July,  
2012.

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.

Deadline for special conference rate: 25<sup>th</sup> July,  
2012.

Special rate:  
Single room incl. breakfast buffet and shuttle  
to/from IMG from EUR 101,00 excluding VAT  
per night.

Mainz, March 2012

Register by Friday 15<sup>th</sup> 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)

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

## Course No. 6440

### Formulating better medicines for children

in Prague, Czech Republic, 19<sup>th</sup> to 20<sup>th</sup> September 2012

Title, First Name, Name

Company/institution name

Company/institution address

Phone

Fax

e-mail

Order no.

Position in Company/institution

Department

APV member

Non-member

Date

Signature

## Registration

All correspondence regarding  
the conference should be  
addressed to:

Conference Scretariat  
Kurfürstenstraße 59  
55118 Mainz/Germany  
Phone: +49 6131 9769-0  
Fax: +49 6131 9769-69  
e-mail: apv@apv-mainz.de  
Website: www.apv-mainz.de

You will receive a confirma-  
tion of your registration with  
the invoice.