

Formulating better medicines for children

7th 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



16 to 17 September 2015
Antwerp, Belgium
Course No. 6606

Preconference Workshops

How to construct/evaluate Paediatric Investigation Plans (PIPs)
Nasir Hussain, MHRA, London, UK

Challenges of administration of medicines to neonates
Virginia Aguado Lorenzo, Evelina London Children's Hospital St Thomas' Hospital, London,
UK

Soap box sessions – Poster session – Exhibition



International Association for Pharmaceutical Technology



Formulating better medicines for children

Dear Colleagues,

It is a great pleasure for European Paediatric Formulation Initiative to invite you to the 7th annual conference on "Formulating Better Medicines for Children", which will be held in Antwerp, Belgium, September 16th to 17th 2015 in partnership with APV (International Association of Pharmaceutical Technology).

The steady growth in importance of paediatric drug development has made it our mission to share expertise and interactive discussion between industry, academia, clinical and regulatory professionals to promote and facilitate preparation of better & safer medicines for children.

To achieve this goal, our 2015 programme is highly participant driven. This years preconference workshops will provide hands-on session on 'How to construct/evaluate Paediatric Investigation Plans (PIPs)' and an interactive session on 'Challenges of administration of medicines to neonates'.

The plenary session will focus on key efforts to expedite the crucial development of paediatric formulations in a global context. The talks include 'Refocusing research and development of paediatric HIV treatments on the needs of children in resource-poor settings' and 'Opportunities and challenges in paediatric product development outside of the EU/US'.

Paediatric research still encounters everyday a constant challenge of formulation, biopharmaceutical and other barriers. Focus sessions & Case studies are devised around these challenges, which in turn match the EuPFI workstreams on Excipients, Age appropriate formulations, Taste masking & Testing, Administration devices and Biopharmaceutics.

We continue to host a vibrant poster session with many selected for oral presentation. Also an 'Innovation Show Case' will give an opportunity for companies to present relevant technologies for children medicines.

This conference offers a unique opportunity for paediatric formulation specialists or interested parties, to exchange and present recent accomplishments as well as discuss remaining challenges for the future towards better medicines for children.

Don't miss this unique opportunity! We are looking forward to welcoming you in Antwerp with its beautiful historical city centre.



Catherine Tuleu,
UCL School of Pharmacy, London, United Kingdom



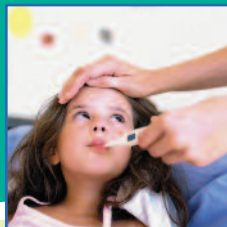
Jörg Breitreutz,
Heinrich Heine University, Düsseldorf, Germany

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, CROs, 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, biopharmaceutics, and administration devices.

Mainz, September 2015



Wednesday, 16 September 2015
09:00 to 18:00

Workshops (additional registration)

Workshop 1: How to construct/evaluate Paediatric Investigation Plan (PIPs)
Nasir Hussain
MHRA, London, United Kingdom

Workshop 2: Challenges of administration of medicines to neonates
Virginia Aguado Lorenzo
Evelina London Children's Hospital St Thomas' Hospital, London, United Kingdom

Both workshops running twice

Lunch (for WS participants), exhibition and poster presentations

Programme

Set-up and poster mounting

Welcome and introduction
Catherine Tuleu, Chair of EuPFI
UCL School of Pharmacy, London, United Kingdom
Jörg Breitzkreutz
Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany

Refocusing R&D of paediatric HIV formulations on the needs of children in resource poor setting
Marc Lallemand
Drugs for Neglected Diseases initiative, Geneva, Switzerland

Opportunities and challenges in paediatric product development outside of the EU/US
Daniel Schaufelberger
Janssen R&D LLC /J&J Pediatric Center of Excellence, Raritan, NJ, United States

Soap box session 1

Evaluation of the need for and criteria within a paediatric biopharmaceutics classification system: results of a survey
David Storey, MSD, United Kingdom

Assessing the bitter taste of medicines: a comparison between rat taste panels (via the brief-access taste aversion (bata) model) and human taste panels
Jessica Soto, UCL School of Pharmacy, United Kingdom

Multiple-unit orodispersible mini-tablets
Anna Kira Adam, Heinrich-Heine-University, Germany

Development of matrix type and coated prolonged release minitables with carbamazepine
Magdalena Czajkowska, Medical University of Gdansk, Poland

Tribology can be used to assess texture perception of oral medicines
Hannah Batchelor, University of Birmingham, United Kingdom

Coffee break, exhibition and poster presentations

Focus session: Age appropriateness of formulations
Chair: Terry Ernest

Mixing medicines with food: food characteristics and potential food effects in paediatric patients
Sandra Klein, University of Greifswald, Germany
Hannah Batchelor, University of Birmingham, United Kingdom

PIP submissions and clinical trial challenges for IV preparations: a case study with clonidine (the FP7 cloSed project)
Sara Hanning
UCL School of Pharmacy, London, United Kingdom

Focus session: Excipients
Chair: David Storey

The European Study for Neonatal Excipient Exposure (ESNEE) research initiative update
Mark Turner
University of Liverpool, Liverpool, United Kingdom

Experiences with excipients in paediatrics/lessons learned from PIPs
Smita Salunke
UCL School of Pharmacy, London, United Kingdom

Focus session: Administration devices
Chair: Jenny Walsh

Little users pose large challenges: Aerosolized drug delivery in infants and toddlers
Thomas Gallem
PARI Pharma GmbH, Starnberg, Germany

Round table discussions with all speakers

Social programme with city tour and networking dinner

Main
Sponsor

Janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson



Thursday, 17 September 2015
09:00 to 16:00

Introduction Day 2

Catherine Tuleu, Chair of EuPFI
UCL School of Pharmacy, London, United Kingdom
Jörg Breitzkreutz
Heinrich-Heine-University Düsseldorf, Düsseldorf,
Germany

Focus session: Taste masking & taste testing

Chair: Roy Turner

Taste perception in children

Judith van der Horst and Gertrude Zeinstra
Wageningen University and Research Centre,
Wageningen, Netherlands

Pediatric patient-reported outcome instruments for
research to support medical product labeling: Report of
the ISPOR PRO Good Research Practices for the assess-
ment of children and adolescents task force

John Chaplin
University of Gothenburg, Gothenburg, Sweden

Adaptive processes and clinical trials for developing paediatric formulations

Peter Scholes
Quotient Clinical Ltd., Nottingham, United Kingdom

Innovation show cases

Improved outcomes with patient-centric pharmaceutical design

Vincenza Pironti, Adare Pharmaceuticals

Developing an age appropriate pediatric formulation and overcoming the challenges of dose uniformity

Skylar Wolfe, Bristol-Myers Squibb

Evaluation of emerging and existing taste masking tech- nologies for paediatric drug development

Eunice Afriyie, University of Birmingham

Coffee break, exhibition and poster presentations

Case studies

The development of a pediatric formulation for a poorly water soluble compound

Albertina Arien, Janssen, Belgium

Taste assessment for pediatric formulation development case studies

Gesine Winzenburg, Novartis, Switzerland

Soap box session 2

Evaluating new biorelevant media for simulating post- prandial gastric conditions in infants

Elisabeth Kersten, University of Greifswald, Germany

Pharmacy and formulation support for paediatric clinical trials in England

Hannah Batchelor, University of Birmingham, United
Kingdom

Development of an extemporaneous 'hydroxyurea in sim- ple syrup' for paediatric use

Stuart Charlton, Bristol-Myers Squibb, United Kingdom

A pan-European paediatric formulary

Dirk Leutner, EDQM / Council of Europe, France

Mucoadhesive oromucosal films of desmopressin acetate for paediatric use

Sandra Lindert, Heinrich-Heine-University, Germany

Lunch, exhibition and poster presentations

Influence of excipient on drug absorption in the gut (from transit to permeability)

Abdul Basit
UCL School of Pharmacy, London, United Kingdom

Focus session: Biopharmaceutics

Chair: Hannah Batchelor

Strategies and examples to improve pediatric formulation development through early implementation of PBPK modeling and simulation

David Good
Bristol Myers Squibb

Clinical pharmacological considerations in the design of studies in children

Paulien Ravenstijn
Janssen R&D LLC/J&J, Beerse, Belgium

Round table discussion with all speakers

Closing remarks

Programme is subject to change

Introducing a new component to our annual conference –

" Career Network - Your Way to a New Job "

Mark your calendar now to meet with prospective
employees/employers in informal "table talk" settings to
discuss new job opportunities. It will provide the perfect
backdrop for professionals looking to discover potential
career opportunities in paediatric drug development,
make industry contacts and sharpen networking skills"

Dedicated Careers
Networking session

will take place on
Wednesday 16
Sept. 2015 from
18.15 - 18.45 h
and on Thursday
17 Sept. 2015 from
08.15 - 08.45 h



Important Dates

Call for abstracts –
24 May 2015 submission deadline for oral presentations
24 June 2015 submission deadline for poster presentations
Notification of acceptance – **3 July 2015**
Conference early bird registration – **15 July 2015**

For more information go to www.eupfi.org

Topics for oral and poster presentations

1. Developing paediatric drug formulations
2. Excipients
3. Taste masking and taste testing
4. Administration devices
5. Modification of dosage forms required for children
6. Age appropriateness of formulation/compliance-adherence issues
7. Formulating paediatric medicines for developing countries
8. Lessons learned from PIP submissions
9. Biopharmaceutics



Exhibition and Sponsoring

We are glad to tailor a sponsor package (starting from 1000 EUR) according to your wishes.

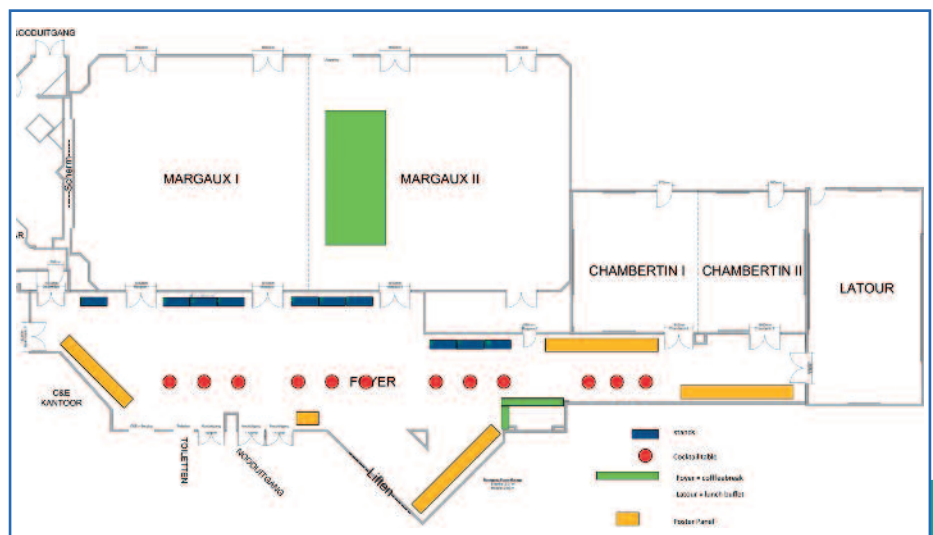
For general information, please go to www.apv-mainz.de/en/seminare/sponsoring-exhibition/

As an exhibitor you will be also invited to attend the sessions and network at the networking dinner in the evening. At the conference center the poster presentations will again be integrated in the exhibition, ensuring that participants are around the exhibition stands as much as possible. Price for a tabletop space with table, chairs and power supply is 990 EUR plus one mandatory full conference registration (register before July 15, to take advantage of the early bird fee!).

Please contact **Antonia Herbert**

Phone +49 6131 9769-90

e-mail ah@apv-mainz.de



Date

Course No. 6606
from 16 September 2015 09:00
to 17 September 2015 16:30

Registration times for workshop participants:
16 September 2015 08:00

Registration times for conference participants:
16 September 2015 12:00

Set up and poster mounting times:
16 September 2015 12:00

Location

RAMADA Plaza Antwerp
Desguinlei 94
2018 Antwerp, Belgium
Phone: +32 32448211
Fax: +32 32164712

Hotel reservation

RAMADA Plaza Antwerp
Desguinlei 94
2018 Antwerp, Belgium
Phone: +32 32448211
Fax: +32 32164712
email: info@ramadaplaza-antwerp.com

Participants should make their own hotel reservation referring to the APV seminar. For registration please use booking form.

Deadline for special conference rate:
11 August 2015.

Special rate:
Single room incl. breakfast buffet from
115 EUR per night.

Mainz, Mai 2015

Conference secretariat

For organisational questions

International Association for Pharmaceutical Technology (APV)
Kurfürstenstraße 59
55118 Mainz, Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
Email: apv@apv-mainz.de
Website: www.apv-mainz.de

For scientific questions

EuPFI
UCL School of Pharmacy
29-39 Brunswick square
London WC1N 1AX
Phone: +44 20 7753 5846
Fax: +44 20 7753 5942
Email: admin@eupfi.org
Website: www.eupfi.org

Register by 15 July 2015 to take advantage of the early bird fee

- Non-member (non academic, non governmental)
- Member of APV/EuPFI (non academic, non governmental)
- Non-member (academic, governmental)
- Member of APV/EuPFI (academic, governmental)
- Students (please enclose evidence)

Workshop prices additional to registration fee:

- Non-member + Member APV/EuPFI (non-academic, non-governmental)
- Non-member + Member of APV/EuPFI (academic, governmental)
- Students (please enclose evidence)

Do you want to participate in the Workshops: yes no

Course No. 6606

Formulating better medicines for children

in Antwerp, Belgium, 16 to 17 September 2015

Title, first name, name

company/institution name

company/institution address

Phone

Fax

e-mail address participant

Order no.

Position in Company/Institution

Department

APV/EuPFI member

Non-member

Date

Signature

Early bird	Full fee
1175 EUR	1275 EUR
1045 EUR	1145 EUR
475 EUR	525 EUR
410 EUR	460 EUR
215 EUR	245 EUR
300 EUR	350 EUR
150 EUR	175 EUR
75 EUR	100 EUR

Registration

All correspondence regarding the conference should be addressed to:

APV
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 confirmation of your registration with the invoice.

- pay via invoice
- pay via credit card (fill in below)
- Visa
- Mastercard
- Amex

Card holder: _____
Card no.: _____
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