

Formulating better medicines for children

Meeting the needs of the children



21st to 22nd September 2010
Berlin, Germany

2nd Conference of the European Paediatric Formulation Initiative

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



Conference programme including

- Keynote presentations of
George P. Giacoia, Eunice Kennedy Shriver NICHD
Sue Hill, WHO headquarter
Siri Wang, Head of EMA PDCO Formulation Subgroup
Julie Williams, Pfizer, EFPIA
- Soap box sessions
- Poster session
- Exhibition – present your company with a table top presentation

Formulating better m

Programme

Tuesday, 21st September 2010 10.00-18.00 h

Set-up of the poster session

Welcome and introduction

Catherine Tuleu, PhD, Chair of EuPFI
The School of Pharmacy, University of London,
London, United Kingdom
Prof. Jörg Breitzkreutz, PhD
Heinrich-Heine-University Düsseldorf, Düsseldorf,
Germany

Formulation issues in PIPs and update on regulatory framework

Siri Wang, PhD, Head of EMA PDCO Formulation
Subgroup
Vestfold Hospital Trust, Tønsberg, Norway

Industry experience with PIPs through case studies

Julie Williams, PhD
Pfizer PGRD European Headquarters, Sandwich,
United Kingdom

Soap box session 1

Chairs:
Catherine Tuleu, PhD
Prof. Jörg Breitzkreutz, PhD

Individual dosing and controlled drug delivery with matrix-minitablets for paediatric use

Hermann, Julia et al.
Freie Universität Berlin, Berlin, Germany

Bitterness comparison of original and generic products using ASTREE Electronic Tongue

Aranyos, Attil et al.
Alpha MOS, Toulouse, France

Pilot database addressing safety and toxicity aspects of excipients for paediatric medicines development

Salunke, Smita et al.
EuPFI, London, United Kingdom

Assessment of quality and clinical performance of unlicensed liquid captopril formulations used in the treatment of children with heart failure

Mulla, Hussain et al.
University Hospitals of Leicester, United Kingdom

Paediatric doses from effervescent formulation delivered by the solid dosage pen

Wening, Klaus et al.
Heinrich-Heine-University, Duesseldorf, Germany

Paediatric formulations- Information needs of developing countries

Woods, David
Pharminfotech Consultancy, Dunedin, New Zealand

Focus Session: Extemporaneous preparations

Chair:
John Hempenstall, PhD
GSK, Harlow, United Kingdom

Reflection paper: Extemporaneous dispensing

Prof. Anthony J. Nunn
NIHR Medicines for Children Research Network,
University of Liverpool, Liverpool, United Kingdom

Dutch pharmacists mind the gap. The bridge between commerce and care

Doerine Postma, PhD
KNMP, Den Haag, The Netherlands

Discussion

Focus Session: Taste masking and taste testing

Chair:
Richard Kendal
MSD, London, United Kingdom

Taste perception in children and taste blockers

Julie A. Mennella, PhD
Monell Chemical Senses Center, Philadelphia,
United States

Challenges of developing palatable oral paediatric formulations

Anne Cram
Pfizer Ltd. Sandwich Laboratories, Sandwich, United
Kingdom

Discussion

Afternoon break, exhibition and poster presentations

Focus Session: Administration Devices

Chair:
Maryvonne Chariot-Goulet
Sanofi-Aventis R&D, Chilly-Mazarin, France

Reflection paper: Challenges and recent developments in delivery devices

Jenny Walsh, PhD
AstraZeneca, Loughborough, United Kingdom

Novel approaches in pulmonary administration

Deborah Bickmann, PhD
Boehringer Ingelheim Pharma GmbH & Co. KG,
Ingelheim, Germany

Discussion

edicines for children

Wednesday 22nd September 2010 08.30-15.00 h

US PFI research considerations

George P. Giacoia, MD
Eunice Kennedy Shriver NICHD, NIH, Bethesda, United States

Focus Session: Age-appropriateness of formulation

Chair:

Prof. Chris Vervaet, PhD
Ghent University, Ghent, Belgium

Acceptability of solid dosage forms

Catherine Tuleu, PhD

Formulation factors influencing medication adherence?

Simon Bryson
University of Brighton, Brighton, United Kingdom

Discussion

Coffee break, exhibition and poster presentations

Soap box session 2

Chairs:

Catherine Tuleu, PhD
Prof. Jörg Breitzkreutz, PhD

Gastro-resistant multiparticulate dosage form for mesalazine colon delivery in paediatric patients

Colombo, Gaia et al.
University of Parma, Parma, Italy

Rational development of a taste masked paediatric formulation guided by electronic tongues

Woertz, Katharina et al.
Heinrich-Heine-University, Duesseldorf, Germany

Odt-formulations: Fast dissolution not always follows fast disintegration

Ohrem, Leonhard et al.
Merck KGaA, Darmstadt, Germany

An investigation of drug manipulation for dose accuracy in paediatric practice

Richey, Roberta
Alder Hey Children's NHS Foundation Trust, Liverpool, United Kingdom

Transdermal iontophoresis: An opportunity in paediatric drug delivery?

Djabri, Asma et al.
University of Bath, Bath, United Kingdom

Steady state pharmacokinetics of the novel AZT/3TC FDC tablets in HIV-infected children

Kayitare, Egide et al.
University of Ghent, Ghent, Belgium

The European paediatric regulation- Is it making a difference? Experience from the UK

Branch, Sarah
MHRA, London, United Kingdom

Paediatric oral solid dosage form preferences: A quantitative analysis among children and their parents

Wiet, Stephan et al.
McNeil Consumer Healthcare, Neuss, Germany

Lunch, exhibition and poster presentations

Formulating medicines for developing countries

Sue Hill, PhD
WHO headquarter, Geneva, Switzerland

Focus Session: Excipients

Chair:

Carl Mroz
Colorcon Ltd., Dartford, United Kingdom

Preservatives in paediatric formulations

Piotr Kozarewicz
EMA QWP, PDCO formulation subgroup, London, United Kingdom

Exposure to excipients in preterms and neonates

Hitesh Pandya, PhD
Glenfield Hospital, Leicester, United Kingdom

Discussion

General Discussion

Social programme:

A guided city tour and a networking dinner will give the participants the opportunity to share knowledge and to throw a glance at the exciting capital city of Germany.

Exhibition and sponsoring:

For exhibition and sponsoring opportunities please contact the APV headquarters (Phone +49-6131-976930 or e-mail mb@apv-mainz.de)



EuPFI

The first conference of the “European Paediatric Formulation Initiative” (EuPFI) provided a useful overview of ‘the state of the art’ in the development of drug formulations, dosage forms, and drug delivery devices for the paediatric population. It was held in March 2009 in London and was a great success. Continuing this important theme, the International Association for Pharmaceutical Technology (APV) and the EuPFI announce a second conference in Berlin, Germany in September 2010.

Numerous medicines are currently unlicensed or prescribed off-label in paediatrics, and children have often been denied access to new or innovative medications. The Paediatric Regulation opened a new era of European drug regulatory history and offers a major opportunity to improve the situation through advancements in research and development. However, paediatric medications remain challenging for industry, academia, regulatory bodies and practitioners. The upcoming conference will shed light on key issues of paediatric drug development such as age-appropriateness of dosage forms and administration pathways, excipients, taste masking and taste assessment, administration devices, extemporaneous formulations, and new developments for the global market.

The conference will be held over two days with plenary sessions from outstanding speakers with experience on formulation issues in Paediatric Investigation Plans (PIPs) from both industry and European Medicines Agency; updates on the regulatory framework and reflection papers on topical subjects. Moreover, key speakers from North America and the WHO will report on global perspectives. In addition to these invited presentations, there will be five focus sessions comprising oral and poster presentations and a round table to facilitate discussion of each topic.

This conference is tailored to maximise the sharing of knowledge and expertise in developing paediatric formulations from a global perspective. The meeting will also promote networking between the pharmaceutical industry, academia, health authorities and clinical practitioners and facilitate pharmaceutical advancements for the next generation. Take the opportunity to meet key stakeholders and opinion leaders in the field of paediatric drug formulations to learn and discuss the most recent developments in this evolving research area.

We look forward to meeting you in Berlin.

Catherine Tuleu, PhD, School of Pharmacy, London, United Kingdom
Prof. Jörg Breitzkreutz, PhD, University of Düsseldorf, Germany



EuPFI

THE EUROPEAN PAEDIATRIC FORMULATION INITIATIVE (EuPFI)

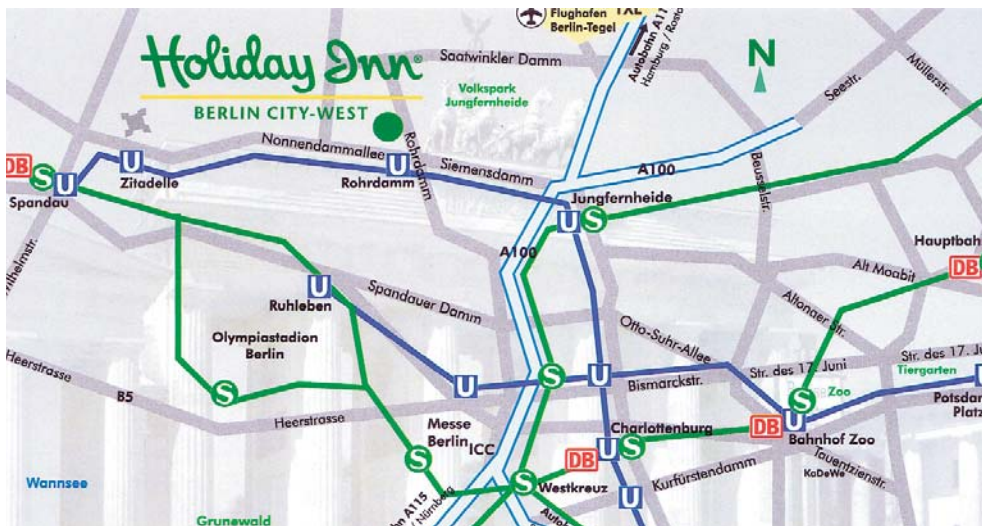
The development of paediatric medicines can be very challenging. This was recognised by the European Paediatric Formulation Initiative (EuPFI), a group consisting of experts predominantly from industry, as well as academia and clinical pharmacy. EuPFI was founded in 2007 with the aim of raising awareness of paediatric formulation issues. The current focus areas of the group include excipients, taste assessment, delivery devices and extemporaneous preparations.

Accommodation

Your hotel, **The Holiday Inn Hotel Berlin City-West**, is situated just about three km away from Tegel Airport. It is a perfect gate way for your city trips.

Enjoy excellent connections to the world famous sights, such as Alexanderplatz, Berliner Fernsehturm, Berliner Dom, Gendarmenmarkt, Museum Island, Schloss Charlottenburg, Spandau, Unter den Linden or the Zitadelle Spandau.

Never mind the season, Berlin with its lively cultural scene and diversity of sights is always worth a journey.



Date

Course No. 6330
from 21st Sept. 2010 10:00
to 22nd Sept. 2010 15:00

Location

Holiday Inn
Berlin City-West
Rohrdamm 80
13629 Berlin, Germany
Tel.: +49/30/38389-0
Fax: +49/30/38389-900

Hotel reservation

Holiday Inn
Berlin City-West
Rohrdamm 80
13629 Berlin, Germany
Tel.: +49/30/38389-888
Fax: +49/30/97808-450
reservation.berlin@
grandcityhotels.com

Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 31st August, 2010

Special rate:
Single room incl. breakfast buffet from EUR 145,00 per night.

Mainz, October 2009

Formulating better medicines for children



Register by Friday 1st July 2010 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
575 EUR	675 EUR
445 EUR	545 EUR
325 EUR	375 EUR
260 EUR	310 EUR
195 EUR	225 EUR

Course No. 6330 Formulating better medicines for children in Berlin, Germany, 21st to 22nd September 2010

Title, First Name, Name

Company/institution name

Company/institution address

Phone

Fax

e-mail

Position in Company/institution

Department

APV member

Non-member

Date

Signature

Registration

All correspondence regarding the conference should be addressed to:

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz / Germany
Phone: ++49/6131/9769-0
Fax: ++49/6131/9769-69
e-mail: apv@apv-mainz.de

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