

# Formulating better medicines for children

## Meeting the needs of the children



21<sup>st</sup> to 22<sup>nd</sup> September 2010  
Berlin, Germany

### 2<sup>nd</sup> 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 – your chance to take part  
with a short presentation
- Poster session – present your research results  
with a poster presentation
- Exhibition – present your company with a table top presentation



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## Programme

Tuesday, 21<sup>st</sup> 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

### Lunch, exhibition and poster presentations

### Focus Session: Extemporaneous preparations

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

#### Reflection paper: Extemporaneous dispensing

Prof. Anthony J. Nunn, MD  
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

## 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](mailto:mb@apv-mainz.de))

# edicines for children

Wednesday 22<sup>nd</sup> 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

## Lunch, exhibition and poster presentations

## Formulating medicines for developing countries

Sue Hill, PhD  
WHO headquarter, Geneva, Switzerland

## Focus Session: Excipients

Chair:

Prof. Jörg Breitzkreutz, PhD

### 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

## Chairs:

**Catherine Tuleu, PhD** is a UK-qualified French pharmacist. She graduated from Université Paris V and obtained her PhD with distinction from Université Paris XI. After a postdoctoral period she was appointed as a Lecturer in Chemistry and Pharmaceutical Sciences at Kingston University. In January 2003 she returned to The School of Pharmacy as Pfizer Paediatric Drug Delivery Lecturer for the newly established Centre for Paediatric Pharmacy Research of which she is now deputy director. She was promoted to Senior Lecturer in August 2007.

Catherine is the Chair of the Formulation sub-group of the Department of Health Medicines for Children Research Network (MCRN) Pharmacy and Pharmacology Clinical Studies Group. She leads also a similar European expert network organised through TEDDY (Task-force European Drug Development for the Young), the EU Commissions-funded Network of Excellence in Children Medicines Research (FP6) and an industrial forum on paediatric formulation, the EU Paediatric Formulation Initiative (EuPFI). She was nominated as a UK and European expert for provision of advice relating to formulation of paediatric medicines for the EMEA and MHRA.

**Jörg Breitzkreutz, PhD** studied Pharmacy from 1987 to 1991 at the University of Münster, Germany. He finished his PhD in 1996 at the Institute for Pharmaceutical Technology and Biopharmaceutics in Münster under supervision of Prof. Gröning. From 1996 to 1997 he joined Thiemann Arzneimittel GmbH in Waltrop, Germany, as the head of Product Coordination. From 1997 to 2004 he worked on his habilitation on paediatric drug formulations. In 2004 he became professor for pharmaceutical technology at the Heinrich-Heine-University in Düsseldorf, Germany. Since 2009 he is head of the Pharmacy department. His research focuses on paediatric drug formulations and process analytical technologies.

## Abstract submission:

You are kindly invited to submit abstracts for soap box 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.

**Deadline for abstract submission: 5<sup>th</sup> May 2010**



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



## 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 21<sup>st</sup> Sept. 2010 10:00  
to 22<sup>nd</sup> 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: 31<sup>st</sup> 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 1<sup>st</sup> 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, 21<sup>st</sup> to 22<sup>nd</sup> 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](mailto:apv@apv-mainz.de)

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