

# Formulating better medicines for children

Meeting the needs of the children

## 9<sup>th</sup> conference of the European Paediatric Formulation Initiative

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

19 to 21 September 2017, Warsaw, Poland · Course No. 6696



### Preconference Workshops

Workshop 1: A 'taster' session on designing taste-masked oral paediatric formulation prototypes and how to plan their palatability assessment

Workshop 2: Biopharmaceutics evaluation of food effects in paediatric medicines development for products co-administered with food

**Soap box sessions – Poster session – Exhibition**

Join us again for another informative and interactive conference on formulating better medicines for children.



International Association for Pharmaceutical Technology

# Formulating better medicines for children

Meeting the needs of the children

Dear Colleagues,

We are pleased to announce that the 9<sup>th</sup> EuPFI annual conference will take place on the 20 - 21 September 2017 in Warsaw, Poland. This conference series is the ideal forum to learn, grow and to be inspired on the development of age appropriate dosage forms.

Marking the 10<sup>th</sup> anniversary of the Paediatric Regulation and foundation of EuPFI consortium, this year's conference will be an opportunity to gather together to reflect back on the past decade of paediatric formulations, to celebrate accomplishments, to welcome new researchers and enriching networking opportunities and to consider how novel and emerging technologies will yield further insights into what the future may bring. Therefore, the programme is devised to include talks on '10 Years of European Paediatric Regulation and Formulation', Scoping the needs for paediatric formulation of old medicine, Lessons learned from acceptability and palatability studies in PIPs and MAA and so on.

The thematic sessions (posters, podium presentations, innovation show cases, etc) range from administration devices, biopharmaceutics, taste masking and taste testing, age appropriateness of formulations to pharmaceutical excipients, without forgetting about the need for developing countries. You will hear about the strategies to successfully taste mask medications: a case example with TB drugs, an overview on system for dosing and dispensing multiparticulate formulations of pediatric drugs, use of colorants in paediatric medicines, lessons learned from paediatric fixed dose combination dispersible tablets for tuberculosis and much more... We encourage you to explore the EuPFI website which contains all the information you need to submit your abstracts.

Take advantage of the pre-conference workshops to advance your knowledge in developing paediatric formulations. The two pre-conference workshops offer highly interactive and focused sessions for participants new to the topic or who want to consolidate their knowledge on 1) Biopharmaceutics evaluation of food effects in paediatric medicines development for products co-administered with food and 2) A 'taster' session on designing taste-masked oral paediatric formulation prototypes and how to plan their palatability assessment. These educational sessions are prelude to main conference and are not included in the conference.

Various refreshments breaks and a social evening will provide plenty of opportunities for networking, making valuable new contacts and reconnecting with old friends. EuPFI's Annual conference is the perfect size to provide you with personal interactions with speakers.

We do hope that you will be able to join us for what promises to be another successful conference. We are looking forward to welcoming you in Warsaw, the amazing city, that survived its tumultuous and complex past, full of contrasts with diverse architecture: restored Gothic, communist concrete, modern glass and steel. A gritty city that knows how to surprise you.

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**Catherine Tuleu, UCL School of Pharmacy, London, United Kingdom**  
**Jörg Breitzkreutz, 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, March 2017



## Programme

### PRECONFERENCE WORKSHOP

**Tuesday, 19 September 2017, 15:30 to 19:00**

**15:30 to 17:00**

**Workshop 1: A 'taster' session on designing taste-masked oral paediatric formulation prototypes and how to plan their palatability assessment**

Joanne Bennett, Pfizer, United Kingdom

Catherine Tuleu, University College London School of Pharmacy, United Kingdom

Jenny Walsh, Jenny Walsh Consulting Ltd., United Kingdom

Anne-Marie Pensé-Lhéritier, Ecole de Biologie Industrielle, France

**Workshop 2: Biopharmaceutics evaluation of food effects in paediatric medicines development for products co-administered with food**

Hannah Batchelor, University of Birmingham, United Kingdom

**17:00 to 17:10 Swap over and settling**

**17:10 to 18:40**

**Workshop 1: A 'taster' session on designing taste-masked oral paediatric formulation prototypes and how to plan their palatability assessment**

Joanne Bennett, Pfizer, United Kingdom

Catherine Tuleu, University College London School of Pharmacy, United Kingdom

Jenny Walsh, Jenny Walsh Consulting Ltd., United Kingdom

Anne-Marie Pensé-Lhéritier, Ecole de Biologie Industrielle, France

**Workshop 2: Biopharmaceutics evaluation of food effects in paediatric medicines development for products co-administered with food**

Hannah Batchelor, University of Birmingham, United Kingdom

**18:40 to 19:00**

**Wrap-up and discussion**

**20:00 Networking dinner**

**Wednesday, 20 September 2017, 08:30 to 18:10**

**08:30 to 09:00**

**Set-up and poster mounting**

**09:00 to 09:15**

**Welcome and Introduction**

Catherine Tuleu, Chair of EuPFI, University College London School of Pharmacy, United Kingdom

Jörg Breitzkreutz, Heinrich-Heine-University Düsseldorf, Germany

**09:15 to 09:50**

**PLENARY 1: 10 years of European paediatric regulation and formulation: any news?**

Sandrine Chiappini, EMA, United Kingdom

**09:50 to 10:25**

**PLENARY 2: Off patent of the radar? Scoping the needs for paediatric formulation of old medicine**

Catherine Litalien, The Rosalind & Morris Goodman Family Pediatric Formulations Centre of the CHU Ste-Justine, Canada

**10:25 to 11:00**

**Morning break, exhibition and poster presentations**

**Focus Session: Taste masking and taste testing**

Chair: Joanne Bennett, Pfizer, United Kingdom

**11:00 to 11:20**

**TB Alliance and PepsiCo partnership: leveraging shared expertise to help eliminate unpleasant taste of TB medicines**

Rajneesh Taneja, TB Alliance, United States

**11:20 to 11:40**

**Pharmaceutical cocrystals: recent advances, current challenges and unrealised opportunities in paediatric drug formulation**

Dejan-Krešimir Bucar, University College London, United Kingdom

**11:40 to 11:50**

**Discussion**

**11:50 to 12:35**

**Soapbox Session I**

**11:50 to 12:05**

**Tribology as an assessment tool for texture evaluation of pharmaceutical coatings**

Justyna Katarzyna Czarnocka, University of Birmingham, United Kingdom

**12:05 to 12:20**

**Determination of the Bitterness Threshold of Cetirizine Dihydrochloride Minitablets using E-tongue, in-vitro release analysis and Human Taste Panel Assessments**

Stephanie Keser, Glatt GmbH, Germany

**12:20 to 12:35**

**Safe, swallowable and palatable: A novel paediatric mini-tablet formulation for a WHO Model Lists of Essential Medicines for Children compound**

Lisa Freerks, Ernst-Moritz-Arndt University Greifswald, Germany

12:35 to 14:00

Lunch, exhibition and poster presentations

14:00 to 14:30

**PLENARY 3: The birth of PaedForm: a pan-European Paediatric Formulary by EDQM**

Jörg Breitreutz, Heinrich-Heine-University Düsseldorf, Germany

Dirk Leutner, Council of Europe - EDQM & HealthCare, France

**Focus session: Administration devices**

Chair: Jenny Walsh, Jenny Walsh Consulting Ltd., United Kingdom

14:30 to 14:50

**And the winner of the Open Innovation Device Challenge: System for dosing and dispensing multiparticulate formulations of pediatric drugs is...**

Jeremy A. Bartlett, Pfizer, United States

14:50 to 15:10

**Realizing individualized minitabiet administration through efficient dosing spoon design and development**

Andrew Farrington, Merck & Co., Inc., United States

15:10 to 15:20

Discussion

15:20 to 16:00

Afternoon break, exhibition and poster presentations

16:00 to 16:45

Soapbox Session II

16:00 to 16:15

**Extrusion of highly drug-loaded wax-extrudates for paediatric use**

Bastian Hahn, Heinrich Heine University, Germany

16:15 to 16:30

**What makes orodispersible films patient-centric dosage form? Identifying critical acceptability attributes**  
Mariagiovanna Scarpa, University College London School of Pharmacy, United Kingdom

16:30 to 16:45

**User experiences of medicines in the home**

Claire Lewis, University of Nottingham, United Kingdom

**Focus Session: Age appropriateness of formulations**

Chair: Fang Liu, University of Hertfordshire, United Kingdom

16:45 to 17:05

**Success/pitfalls of dispersible tablets in developing countries: lessons learned from PAEDS TB FDC dispersible tablets**

Brenda Waning, Stop TB Partnership, Switzerland

17:05 to 17:25

**Accelerated Development of a Chlorhexidine Gel for the Prevention of Ophthalmitis in Newborns**  
Lee Immins, GlaxoSmithKline, United Kingdom  
Trevor Riley, GlaxoSmithKline, United Kingdom

17:25 to 17:35

Discussion

17:35 to 18:00

**International chapter on paediatric formulations Initiatives for pediatric medicine development in Toyama Prefecture, Japan's top pharmaceutical production base - Unique collaboration between regional government, academia and industries**

Tomonori Shiokawa, Toyama Prefectural Government of Japan, Japan

Hidemasa Nagai, Toyama Prefectural Institute for Pharmaceutical Research of Japan, Japan

18:00 to 18:10

Housekeeping

18:30

Networking dinner and city tour

**Thursday, 21 September 2017, 08:30-15:30**

08:30 to 08:40

Brief introduction Day 2 / Housekeeping

Catherine Tuleu

Jörg Breitreutz

08:40 to 09:15

**PLENARY 4: 3D printing: the future of patient centric manufactured medicine and clinical phase appropriate products?**

Mohamed Albed Alhnan, University of Central Lancashire, United Kingdom

**Focus session: Excipients**

Chair: Smita Salunke, University College London School of Pharmacy, United Kingdom

09:15 to 09:35

**Safety assessment of excipients –an industry view**

Jim Ridings, GlaxoSmithKline, United Kingdom

09:35 to 09:55

**The Use of colours in medicines**

Gary Inwards, MHRA, United Kingdom

09:55 to 10:05

Discussion

10:05 to 10:35

Innovation Show Cases

10:05 to 10:20

**ODF (Oral Disintegrating Film) as a delivery system for (case studies)**

Carmen Popescu, Roquette America Inc, Switzerland

10:20 to 10:35

**"Dial the Dose" – a precision liquid dispenser**

Corinna Fischer, Balda Medical GmbH & Co. KG, Germany

10:35 to 11:15

Morning break, exhibition and poster presentations

11:15 to 12:00

Soapbox Session III

11:15 to 11:30

Child-driven design of milk micelles for drug delivery  
Tânia Fernandes, Universidade de Lisboa, Portugal

11:30 to 11:45

Standardize 4 Safety: A U.S. Project Going Global  
Deborah a. Pasko, Center on Medication Safety and Quality  
ASHP, United States

11:45 to 12:00

Dissolution and compatibility of hydrocortisone granules following exposure to common paediatric administration fluids and food matrices  
Erik Wollmer, Ernst-Moritz-Arndt University Greifswald, Germany

12:00 to 12:50

Case Studies

12:00 to 12:25

Acceptability and palatability studies in PIPs and MAA  
Nasir Hussain, MHRA, United Kingdom

12:25 to 12:50

Infacort®: A PUMA application success story  
Martin Whitaker, The University of Sheffield, United Kingdom

12:50 – 13:00

Announcement of PCCA winners

13:00 to 14:30

Lunch, exhibition and poster presentations

Focus Session: Biopharm

Chair: Hannah Batchelor, University of Birmingham, United Kingdom

14:30 to 14:50

The gastrointestinal environment in paediatrics: what do we (not) know?  
Jens Van Den Abeele, University of Leuven, Belgium

14:50 to 15:10

Biopharmaceutics evaluation of solid dispersion-based paediatric dosage forms – The new frontier  
Henry Yunhui Wu, Merck, United States

15:10 to 15:20

Discussion

15:20 to 15:30

Conference Wrap-up and discussion

Programme is subject to change



## 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/](http://www.apv-mainz.de/en/seminare/sponsoring-exhibition/)

As an exhibitor you will be also invited to attend the sessions and 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 15 July 2017, to take advantage of the early bird fee!).

## Exhibitors



Please contact Antonia Herbert

Phone +49 6131 9769-90

e-mail ah@apv-mainz.de

## Date

Course no. 6696

from 19 September 2017 15:30  
to 21 September 2017 15:30

Registration times for workshop participants:  
19 September 2017 15:00

Registration times for conference participants:  
20 September 2017 08:00

Set up and poster mounting times:  
20 September 2017 08:30

## Location

BIOLOGICAL and CHEMICAL RESEARCH CENTRE  
UNIVERSITY of WARSAW

st. Żwirki i Wigury 101  
02-089 Warsaw  
www.cnbch.uw.edu.pl

Mainz, March 2017

## Hotel reservation

Sound Garden Hotel

Żwirki i Wigury 18  
02-092 Warszawa  
Phone: +48 22 279 14 00  
www.soundgardenhotel.pl/en

Special rate: Single room incl. breakfast buffet from  
95,00 EUR per night. Deadline for special confe-  
rence rate: 18 August 2017.

DoubleTree by Hilton Hotel & Conference Centre  
Warsaw

Skalnicowa Street 21  
04-797 Warsaw  
Phone: +48 22 27 800 00  
www.doubletreewarsaw.pl

Special rate: Single room incl. breakfast buffet from  
110,00 EUR per night. Deadline for special confe-  
rence rate: 7 August 2017.

## Conference Secretariat

For organisational questions

International Association for  
Pharmaceutical Technology (APV)  
Kurfuerstenstraße 59  
55118 Mainz, Germany  
Phone: +49 6131 9769-0  
Fax: +49 6131 9769-69  
e-mail: apv@apv-mainz.de  
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  
e-mail: admin@eupfi.org  
www.eupfi.org

Register by 15 July 2017 to take advantage of the early bird fee

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

### Workshop prices additional to registration fee:

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

Do you want to participate in the Workshops: yes  no

Course no. 6696

## Formulating better medicines for children in Warsaw, Poland, 19 to 21 September 2017

Title, First Name, Name

Company/institution name

Company/institution address

Phone

Fax

e-mail address participant

Order no.

Position in Company/institution

Department

EuPFI member

Non-member

Date

Signature

## Full fee

1325 EUR

1195 EUR

575 EUR

510 EUR

270 EUR

380 EUR

205 EUR

115 EUR

## Registration

All correspondence regarding the  
conference should be addressed to:

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

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

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Card holder: \_\_\_\_\_

Card no.: \_\_\_\_\_

Valid until: \_\_\_\_\_

CVC code: \_\_\_\_\_