Formulating better medicines for children

Meeting the needs of the children

9th 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 9th 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 10th 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.

Catherine Tuleu, UCL School of Pharmacy, London, United Kingdom Jörg Breitkreutz, 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 tastemasked 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 King-

17:00 to 17:10 Swap over and settling

17:10 to 18:40

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Workshop 1: A 'taster' session on designing tastemasked 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 Breitkreutz, Heinrich-Heine-University Düsseldorf, Germany

09:15 to 09:50 PLENARY 1: 10 years of European paediatric regulati-

on 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, invitro 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 Breitkreutz, Heinrich-Heine-University Düsseldorf, Germany Dirk Leutner, Council of Europe - EDQM & HealthCare,

Focus session: Administration devices Chair: Jenny Walsh, Jenny Walsh Consulting Ltd., United Kingdom

14:30 to 14:50

France

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 minitablet 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 learn 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 Omphalitis 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 Breitkreutz

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/

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



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

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)

Workshop prices additional to registration fee:

Do you want to participate in the Workshops: yes

Non-Member + Member EuPFI (non academic, non governmental)

Formulating better medicines for children

Non-Member + Member of EuPFI (academic, governmental)

Non-Member (academic, governmental)

Students (please enclose evidence)

Students (please enclose evidence)

Course no. 6696

Member of EuPFI (academic, governmental)

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 conference 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 conference 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

Full fee
1325 EUR
1195 EUR
575 EUR
510 EUR
270 EUR
380 EUR
205 EUR
115 EUR

Registration

Valid until: CVC code:

in Warsaw, Poland, 1	7 All correspondence regarding the conference should be addressed to:	
Title, First Name, Name	APV Kurfuerstenstraße 59	
Company/institution name		55118 Mainz/Germany Phone: +49 6131 9769-0 Fax: +49 6131 9769-69
Company/institution address		e-mail: apv@apv-mainz.de www.apv-mainz.de
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