

The EFGCP Children's Medicines Working Party
4th Annual Conference

*EU & US Paediatric Legislation: What is
Changing in Practice in Paediatric Drug
Treatment, Research & Development?*

26 November 2008 - Management Centre Europe, Brussels, Belgium

organised by the

Children's Medicines Working Party

European Forum for Good Clinical Practice



'where science & ethics meet'

Conference Rationale and Objectives

The EU Paediatric Regulation has now been in force for 1½ years. Regulatory authorities, clinical organisations and pharmaceutical companies have made their first experiences with preparing, submitting and discussing Paediatric Investigation Plans (PIPs). This conference will on a high level compare the experiences and lessons learned in the European regulatory authorities, pharmaceutical companies and evolving paediatric research networks and will continue the dialogue how to further improve child health and paediatric research in Europe. Furthermore, this conference will also address the WHO initiative 'make medicines child size' and will reflect its place within the US and EU paediatric legislation.

Conference Participants

The conference audience will include representatives and participants from regulatory authorities, academic paediatric research, health professionals, pharmaceutical & biotech companies, and patient and parents' organisations.

Conference Language

The language of the conference is English.

Conference Dinner

As this conference will take place back-to-back with the Paediatric Oncology conference, a common working dinner will be organized the evening between the two conferences on Tuesday 25 November 2008.

Steering Committee

Deborah Alvarez- Van Lanschot	PRIOMEDCHILD; ZonMw, The Netherlands
Sophie Fornairon	Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), France
Tricia Fowler	Independent Consultant, United Kingdom
Angelika Joos	Associate Director, Regulatory Affairs Europe, Merck Sharp & Dohme, Belgium
José Ramet	European Academy of Paediatrics (EAP-CESP), Universitair Ziekenhuis Antwerpen & ZNA Koningin Paola Kinderziekenhuis, Antwerp, Belgium
Klaus Rose	EFGCP Children's Medicines Working Party; Roche, Switzerland
Agnes Saint-Raymond	Scientific Advice and Orphan Drugs, European Medicines Agency (EMA)
Thomas Severin	Novartis Pharma, Switzerland

Faculty

Deborah Alvarez- Van Lanschot	PRIOMEDCHILD; ZonMw, The Netherlands
Sophie Fornairon	Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), France
Tricia Fowler	Independent Consultant, United Kingdom
Agnès Gyurasics	National Institute of Pharmacy, Hungary

**The EFGCP Children's Medicines Working Party 4th Annual Conference on EU & US Paediatric
Legislation: What is Changing in Practice in Paediatric Drug Treatment, Research & Development?
26 November 2008, Management Centre Europe, Brussels, Belgium**

Sue Hill	World Health Organisation (WHO), Switzerland
Kalle Hoppu	International Pediatric Association (IPA) & International Union of Pharmacology (IUPHAR); Helsinki University Central Hospital, Poison Information Centre, Finland
Angelika Joos	Associate Director, Regulatory Affairs Europe, Merck Sharp & Dohme, Belgium
Birka Lehmann	Federal Institute for Drugs and Medical Devices (BfArM), Germany
Dirk Matthys	Ethics Committee, University Hospital Ghent, Belgium (invited)
José Ramet	European Academy of Paediatrics (EAP-CESP), Universitair Ziekenhuis Antwerpen & ZNA Koningin Paola Kinderziekenhuis, Antwerp, Belgium
Klaus Rose	EFGCP Children's Medicines Working Party; Roche, Switzerland
Agnes Saint-Raymond	Scientific Advice and Orphan Drugs, European Medicines Agency (EMA)
Thomas Severin	Novartis Pharma, Switzerland
Hans Stötter	Swissmedic, Switzerland
Ivo Timmermans	Dutch Medicines for Children Research Network (MCRN); Academic Medical Center, The Netherlands
Maria Virkki	National Agency for Medicines, Finland
Lothar-Bernd Zimmerhackl	University of Innsbruck, Austria

Agenda

Wednesday, 26 November 2008

08:00 Registration and Welcome Coffee

08:45 Welcome

Klaus Rose, Chairman, Children's Medicines Working Party, European Forum for Good Clinical Practice (EFGCP); Head, Paediatrics, Roche, Switzerland

Session 1

First Assessment of EU Paediatric Regulation & the Evolving Worldwide Campaign

09:00 EU Regulation: Learnings from EMEA & PDCO

Agnes Saint-Raymond, Head of Sector, Scientific Advice and Orphan Drugs, European Medicines Agency (EMA)

09:30 EU Regulation: Learnings from Industry

Angelika Joos, Associate Director, Regulatory Affairs Europe, Merck Sharp & Dohme, Belgium

Klaus Rose, Chairman, Children's Medicines Working Party, European Forum for Good Clinical Practice (EFGCP); Head, Paediatrics, Roche, Switzerland

10:00 Coffee Break

10:30 Breakout Session: 'Focus on Specific Issues'

Working Group 1:

'Promises & limitations of existing paediatric data'

Chair: *Birka Lehmann, Head, Licensing Division 3, Federal Institute for Drugs and Medical Devices (BfArM), Germany*

Introduction: *Agnes Saint-Raymond, Head of Sector, Scientific Advice and Orphan Drugs, European Medicines Agency (EMA)*

Rapporteur: *Dirk Matthys, Ethics Committee, University Hospital Ghent, Belgium (invited)*

Working Group 2:

'Early consideration of children in the drug development process'

Chair: *José Ramet, European Academy of Paediatrics (EAP-CESP), Universitair Ziekenhuis Antwerpen & ZNA Koningin Paola Kinderziekenhuis, Antwerp, Belgium*

Introduction 1: *Angelika Joos, Associate Director, Regulatory Affairs Europe, Merck Sharp & Dohme, Belgium*

Introduction 2: *Hans Stötter, Clinical Reviewer, SwissMedic, Switzerland*

Rapporteur: *Agnès Gyurasics, Head, Medicine & Biology Department, National Institute of Pharmacy, Hungary*

Working Group 3:

'WHO campaign & Child Health in the Developing World'

Chair: *Sue Hill, Scientist, Medicines, Access and Rational Use, Essential Medicines and Pharmaceutical Policies, World Health Organisation (WHO), Switzerland*

Introduction 1: *Kalle Hoppu, International Pediatric Association (IPA) & International Union of Pharmacology (IUPHAR); Helsinki University Central Hospital, Poison Information Centre, Finland*

Introduction 2: *Klaus Rose, Chairman, Children's Medicines Working Party, European Forum for Good Clinical Practice (EFGCP); Head, Paediatrics, Roche, Switzerland*

Rapporteur: *Sophie Fornairon, Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), France*

12:30 Lunch

Session 2

Strategic Thoughts & Educational Essentials

13:45 Report from Working Groups
Chair: *Maria Virkki, Head of Section, Specialist of Paediatrics and Ped. Inf. Diseases Clinical Trials, National Agency for Medicines, Finland*
Working Groups Rapporteurs

14:45 The multitude of paediatric professional organisations
José Ramet, European Academy of Paediatrics (EAP-CESP), Universitair Ziekenhuis Antwerpen & ZNA Koningin Paola Kinderziekenhuis, Antwerp, Belgium
Lothar-Bernd Zimmerhackl, Director, Department for Kinder- und Jugendheilkunde-Pädiatrie I, Medical University of Innsbruck, Austria
Thomas Severin, Head, Paediatrics External Affairs, Novartis Pharma, Switzerland

15:15 National, European and Global Paediatric Research Networks
Deborah Alfarez- Van Lanschot, PRIOMEDCHILD; ZonMw, The Netherlands
Ivo Timmermans, Dutch Medicines for Children Research Network (MCRN); Academic Medical Center, The Netherlands

15:45 Coffee Break

16:00 Panel Discussion & General Discussion
Chair: *Hans Stötter, Swissmedic, Switzerland*

16:50 Conclusions

17:00 End of Meeting