12 November 2014
EMA/545429/2014
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Agenda of the workshop on the Guideline on pharmaceutical development of medicines for paediatric use

Monday, 01 December 2014, Time: 08:30-17:30, meeting room 3A

Chairpersons: Diana van Riet-Nales and Piotr Kozarewicz

Background and objectives

The Guideline on pharmaceutical development of medicines for paediatric use (Doc. Ref.: EMA/CHMP/QWP/805880/2012 Rev. 2) has been in force as of February 2014 and is intended to provide additional guidance to pharmaceutical developers on quality aspects related with medicinal products for children between birth and 18 years of age.

As more experience becomes available further work is required to complement the guideline with additional recommendations on pharmaceutical development of paediatric medicines.

The general scope of this workshop is to share among stakeholders (regulators, healthcare professionals, academia and industry) experience gained so far with the use of the guideline and identify gaps in the current knowledge which require further elaboration. This workshop should be considered as a starting point for discussing and work towards finding relevant answers to recognised gaps.

08:00 - 08.30 Registration

08:30 – 08:45 Welcome and introduction by Workshop Chairs

Diana van Riet-Nales, Medicines Evaluation Board (MEB), The Netherlands *15'*

Piotr Kozarewicz, European Medicines Agency (EMA)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

08:45 – 10:00 Session 1: Introduction to the Guideline, Paediatric Regulation and Paediatric Investigation Plans (PIPs)

Paediatric medicines in daily practice ***30'***

Prof Anthony Sinclair, Birmingham Children's Hospital, United Kingdom

Paediatric Regulation and PIP procedure ***30'***

Paolo Tomasi, European Medicines Agency (EMA)

Questions and discussion ***15'***

Diana van Riet-Nales, Medicines Evaluation Board (MEB), The Netherlands

10:00 – 10:30 Coffee break

10:30 - 12:45 Session 2: Pharmaceutical development

Paediatric formulations – principles of development ***30'***

Diana van Riet-Nales, Medicines Evaluation Board (MEB), The Netherlands

Formulation issues – regulators perspective ***30'***

Gary Inwards, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Formulation issues – industry perspective ***30'***

Terry Ernest, GlaxoSmithKline (GSK)

Container closure system, dosing devices and user information ***30'***

Mirza Ćatibušić, Health Products Regulatory Authority (HPRA), Ireland

Questions and discussion ***15'***

Piotr Kozarewicz, European Medicines Agency (EMA)

12:45 – 13:30 Lunch break

13:30 – 15:15 Session 3: Experience and challenges

Industry experience from working with the guideline ***30'***

Alecia Barry, AstraZeneca

Academia and Paediatric research ***30'***

Prof Joerg Breitkreutz, Heinrich-Heine-University Duesseldorf, Germany

Excipients and paediatric medicines ***30'***

Jean-Marc Vidal, European Medicines Agency (EMA)

Questions and discussion ***15'***

Diana van Riet-Nales, Medicines Evaluation Board (MEB), The Netherlands

15:15 – 15:45 Coffee break

15:45 – 16:45 Session 4: Next steps

Open session – gap analysis ***30'***

All participants

Next steps ***30'***

Piotr Kozarewicz, European Medicines Agency (EMA)

Questions and discussion ***15'***

Piotr Kozarewicz, European Medicines Agency (EMA)

17:00 Closing remarks

Diana van Riet-Nales*, Medicines Evaluation Board (MEB,)* The Netherlands

List of speakers and moderators

Alecia Barry	AstraZeneca
Joerg Breitkreutz	Institute of Pharmaceutics and Biopharmaceutics, Heinrich-Heine-University Duesseldorf, Germany
Mirza Ćatibušić	Health Products Regulatory Authority (HPRA), Ireland
Terry Ernest	GlaxoSmithKline
Gary Inwards	Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
Piotr Kozarewicz	European Medicines Agency (EMA)
Diana van Riet-Nales	Medicines Evaluation Board (MEB), The Netherlands
Anthony Sinclair	Birmingham Children's Hospital, United Kingdom
Paolo Tomasi	European Medicines Agency (EMA)
Jean-Marc Vidal	European Medicines Agency (EMA)

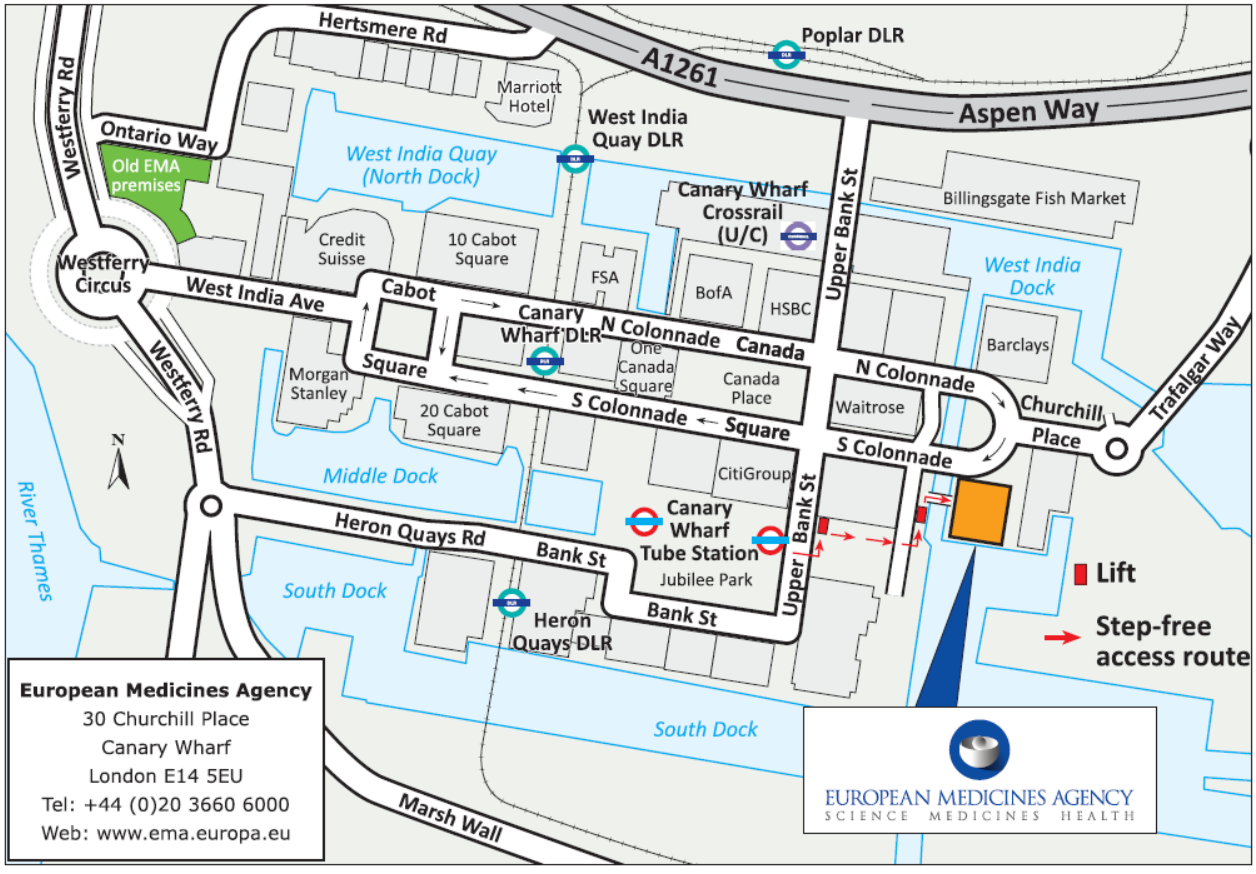
Practical information

Venue

The European Medicines Agency can be reached:

- **By Docklands Light Railway (DLR)**
  The European Medicines Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.
- **By Underground**
  The nearest stop for the European Medicines Agency Westferry Circus is Canary Wharf station on the Jubilee Line.
- **By bus**
  Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.
- **By boat**
  River services run between Embankment, London Bridge and Canary Wharf throughout the day. Canary Wharf pier is roughly a 15-minute walk from the European Medicines Agency.
- **From London City Airport**
  Take a taxi to Canary Wharf, or catch the DLR to Westferry station then change to the DLR to Canary Wharf.

Map



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Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We strongly advise you to arrive up to 30 minutes before the start of the workshop, to allow you time for registration and settling down.

Meeting room

You will be able to sit wherever you wish; note that the only reserved seats are for the speakers, panellists and organisers of the workshop.

Presentations

We will not circulate printouts of speakers' presentations. However, you will be able to download them from the Agency's website approximately two weeks after the end of the workshop.

Laptop computers

For those of you travelling from the continent and wishing to use your laptop, may we remind you to bring with you an appropriate UK power adapter.

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Conference venue and secretariat

30 Churchill Place, Canary Wharf
London E14 5EU, United Kingdom
Tel.: +44 (0)20 3660 6000
Fax: +44 (0)20 3660 5555
E-mail Marta.Jakimiuk@ema.europa.eu/ Simona.Keckesova@ema.europa.eu
Website www.ema.europa.eu