



Workshop on development of antibacterial medicinal products for paediatric patients

21–22 June 2018

European Medicines Agency
London, United Kingdom



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



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Objectives

To explore - together with relevant stakeholders- development plans that would allow for the timely development of antibacterials for children and discuss EMA, FDA and PMDA data requirements for their approval;

To discuss relevant aspects to antibacterial development in children, including challenges with conducting trials in the paediatric population (including neonates), and extrapolation of safety and efficacy data to optimise the involvement of children in clinical studies;

To gather further feedback on the draft EMA/CHMP [Addendum to the guideline on the evaluation of medicinal products indicated for the treatment of bacterial infections to address paediatric-specific clinical data requirements](#) (EMA/CHMP/187859/2017) (currently on public consultation until end of October 2018).

Programme details

Thursday, 21 June 2018

Order of presentations subject to change

08:30 **Registration**

09:00 **Welcome and introduction**

Marco Cavaleri, EMA; Edward Cox, FDA; Junko Sato, PMDA

15'

09:15 **Session 1: General considerations on regulatory requirements**

Chair: Edward Cox, FDA; Marco Cavaleri, EMA

EMA view: the paediatric Addendum to the antibacterial agents Guideline

Maria Jesús Fernández Cortizo, IDWP

30'

FDA view: ongoing activities and requirements for developing antibacterial agents for children in the US

John Farley, FDA

30'

PMDA perspective: ongoing activities and requirements for developing antibacterial agents for children in Japan

Junko Sato, PMDA

30'

10:45 **Coffee break**

11:00 **Session 2: Challenges with paediatric trials**

Chair: Sumathi Nambiar, FDA; Irmgard Eichler, EMA

Investigator's perspective

John Bradley, University of California, US

30'

Tuuli Metsvaht, University of Tartu, EE

30'

Industry view

TBC

30'

Discussion

30'

13:00 **Lunch break**

14:00 **Session 3: Efficacy Assessment**

Chair: **Irja Lutsar**, PDCO; **Danny Benjamin**, Duke Clinical Research Institute, Durham, USA

Paediatric pharmacokinetics, PK/PD and extrapolation

Joseph Standing, University College London, UK 30'

Clinician's view

Michael Cohen-Wolkowicz, Duke University, Durham, USA 30'

Industry view

TBC 30'

Discussion

30'

16:00 **Coffee break**

16:15 **Session 5: Studying neonates**

Chair: **Ralph Bax**, EMA; **John Bradley**, University of California, US;

Overview

Maria Jesús Fernández Cortizo, IDWP; **Sumathi Nambiar**, FDA 30'

Clinical aspects

Danny Benjamin, Duke Clinical Research Institute, Durham, US 20'

PK aspects

Karel Allegaert, Catholic University Leuven, BE 20'

Developers/industry view

Global Antibiotic Research and Development Partnership (GARDP) 20'

Discussion

30'

18:15 **End of day 1**

Friday, 22 June 2018

Order of presentations subject to change

09:30 **Welcome and introduction**

09:40 **Session 4: Safety Assessment**

Chair: **Dirk Mentzer**, PDCO, **John Farley**, FDA

Clinician's view

Mike Sharland, St George's University of London, UK

15'

John Bradley University of California, US

15'

Industry view

TBC

30'

Discussion

60'

11:40 **Wrap-up**

Chair: **Marco Cavaleri**, EMA; **Edward Cox**, FDA; **Junko Sato**, PMDA

20'

12:00 **End of workshop**

Acronyms

By alphabetic order

EMA – *European Medicines Agency*
FDA - *Food and Drug Administration*
IDWP – *Infectious Disease Working Party*
PDCO - *Paediatric Committee*
PK/PD - *Pharmacokinetic-pharmacodynamic*
PMDA - *Pharmaceuticals and Medical Devices Agency*

Practical information

Venue

The European Medicines Agency can be reached:

- **By Underground**

The nearest stop for Churchill Place is Canary Wharf station on the Jubilee Line. From East exit (NB. This is the closest exit to 30 Churchill Place): exit the station and turn left into Upper Bank Street, turn right at Canada Square and continue straight into Churchill Place.

- **By Docklands Light Railway (DLR)**

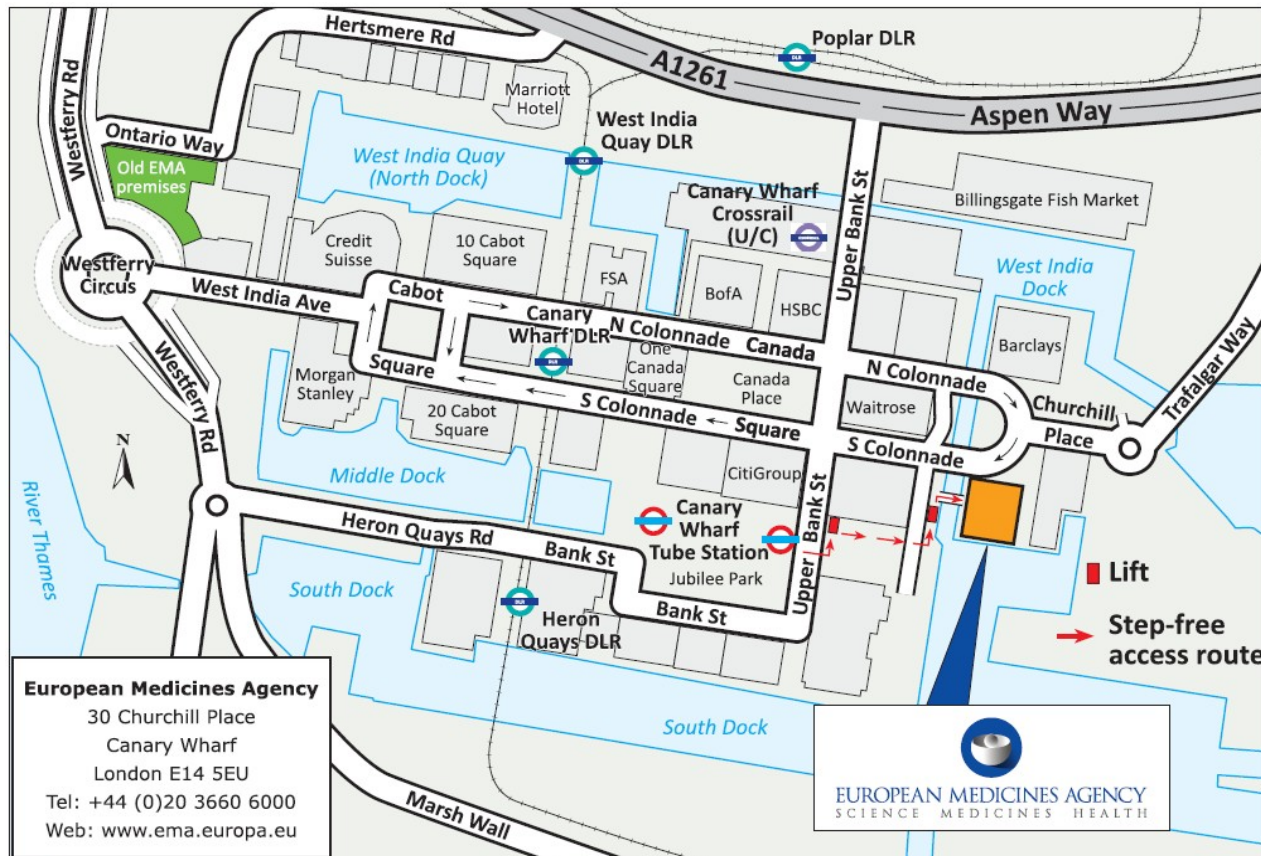
The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

- **By car**

There are no parking facilities at 30 Churchill Place and it is recommended that you take public transport. However, four nearby public car parks are operated by Canary Wharf. Rates and further information can be found on the Canary Wharf website:

<http://www.canarywharf.com/aboutus/The-Estate/Travel-/Roads--Parking/>

Map



Arrival at the Agency

On arriving for your meeting at 30 Churchill Place, please report to reception where you will be issued with an access pass. This pass will allow you to access our industry lounge, which you are welcome to utilise during your visit. The industry lounge is located through the sliding doors to the right of the reception desk past the security turnstiles. Your EMA contact point will meet you here.

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

Upon arrival each day, please find your allocated seat in the meeting room. Speakers will be able to navigate through their presentation slides from their seats with a pointer, mouse or keyboard.

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:

<http://www.ema.europa.eu/ema/>

Wi-Fi access & Laptop computers

Wi-Fi is available throughout the EMA. Login details can be found on the back of your EMA access pass.

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http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid

or contact

dataprotection@ema.europa.eu

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Conference venue and secretariat

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For any questions prior to the workshop in relation to the content and participation, please write to Paediatric.antibacterial.agents.workshop@ema.europa.eu