EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2016
EMA/49414/2018
Human Medicines Research and Development Support Division

EMA/EC multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation

20 March 2018

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom

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Background and objectives

Background

The European Commission (EC) highlighted in its report on 10 years of the EU Paediatric Regulation certain areas for specific actions to better foster the development and availability of medicines for children in Europe.

This workshop is a crucial step for the development of a concrete plan to address the challenges identified.

Main objectives of the workshop:

- To learn from experiences and ideas regarding criteria and methodologies that could be used to identify diseases/conditions of unmet paediatric medical needs
- To exchange ideas on measures to proactively address obstacles to timely completion of paediatric investigation plans (PIPs)
- To identify operational challenges in relation to paediatric procedures and exchange ideas for process improvements
- To inform stakeholders about ongoing and future initiatives of international collaboration of regulators for paediatric medicine development
- To inform stakeholders about planned transparency measures regarding clinical research and new medicines for children

Programme

Time	Topic	Presenter(s)
08:00	Arrival and registration	
09:00	Welcome address	Guido Rasi
09:10	Message from the Commissioner	Vytenis Andriukaitis (video message)
09:15	Message from Member of EU Parliament	Françoise Grossetête (video message)
09:20	Introduction	Enrica Alteri Florian Schmidt
09:25	Workshop objectives	Gunter Egger
09:30	**Topic 1** **Identification of paediatric medical needs – Methodology** 1. Stakeholders' perspective on development of methodology: • *Which ongoing initiatives to identify paediatric medical needs are you working on or aware of?* • *Which criteria and methodology would you suggest to prioritise diseases/conditions of unmet paediatric needs?*	Chair: Enrica Alteri
	1.1. Unmet medical needs – introductory considerations	
	1.2. Academia /health care professionals' perspective	Luca Sangiorgi Tjitske van der Zanden Martina Pitzer Gilles Vassal
	1.3. Industry's perspective	Marie-Yvonne Douste-Blazy
	1.4. Patients' perspective	Anne Goeres Virginie Hivert Hall Skåra
	2. Discussion	All
	3. Summary	Dirk Mentzer

Time	Topic	Presenter(s)
11:45	**Topic 2** **International cooperation of regulators for paediatric medicines**	Chair: Florian Schmidt
	1. Better together – international regulatory cooperation	Sandra Kweder
	2. Discussion	All
12:15	**Lunch**	
13:00	**Topic 3** **Timely completion of paediatric investigation plans (PIPs)** 1. Stakeholders' perspective on measures to improve timely PIP completion: • *Which elements have been experienced as obstacles to a timely completion of the studies of an agreed paediatric development plan?* • *Which measures could be taken to proactively address these obstacles hence leading to increased compliance with the agreed plan?*	Chair: Florian Schmidt
	1.1. Academia / health care professionals' perspective	Mark Turner
	1.2. Industry's perspective	Heidrun Hildebrand
	1.3. Patients' perspective	Begonya Nafria Escalera Elizabeth Vroom
	1.4. Clinical Trial Application perspective	Ann Marie Janson Lang
	2. Discussion	All
	3. Summary	Dirk Mentzer
14:30	**Coffee break**	
14:50	**Topic 4** **Improving the handling of PIP applications** 1. Stakeholders' perspective on overcoming operational challenges in relation to paediatric procedures: • *Which procedural and operational challenges in relation to paediatric processes as described in the PIP guideline (PIP, modification, waiver, compliance check) should be addressed?* • *What are constructive solutions that could facilitate an efficient and robust operational framework (e.g. submission requirements, timelines, outputs and*	Chair: Enrica Alteri

Time	Topic	Presenter(s)
	technical/administrative aspects)?	
	1.1. Industry' perspective	Geneviève Le Visage
	1.2. Academia's perspective	Mark Turner
	2. Discussion	All
	3. Summary	Ralph Bax
15:50	**Topic 5** **Transparency measures**	Chair: Enrica Alteri
	1. Transparency measures regarding paediatric medicine development as planned by European Commission	Fabio D'Atri
	2. Transparency improvements through Clinical Trials Regulation	Fergus Sweeney
	3. Discussion	All
16:20	Conclusions and next steps	Michael Berntgen
16:45	**End of workshop**	

List of speakers and chairpersons

Surname	Name	Affiliation
Alteri	Enrica	European Medicines Agency (EMA)
Andriukaitis*	Vytenis	Health & Food Safety Commissioner, European Commission (EC)
Bax	Ralph	European Medicines Agency (EMA)
Berntgen	Michael	European Medicines Agency (EMA)
D'Atri	Fabio	European Commission (EC), DG Health and Food Safety
Douste-Blazy	Marie-Yvonne	European Federation of Pharmaceutical Industries and Associations (EFPIA), Servier
Egger	Gunter	European Medicines Agency (EMA)
Goeres	Anne	Fondatioun Kriibskrank Kanner, Luxembourg
Grossetête*	Françoise	Member of the European Parliament (EP), former EP rapporteur for the Paediatric Regulation
Hildebrand	Heidrun	European Biopharmaceutical Enterprises (EBE), Bayer
Hivert	Virginie	Rare Diseases Europe (EURORDIS)
Janson Lang	Ann Marie	Clinical Trials Facilitation Group (CTFG)
Le Visage	Geneviève	European Federation of Pharmaceutical Industries and Associations (EFPIA), Novartis
Kweder	Sandra	U.S. Food and Drug Administration (FDA)
Mentzer	Dirk	Paediatric Committee (EMA)
Nafria Escalera	Begonya	European Young Persons Advisory Groups Network (eYPAGnet)
Pitzer	Martina	Drug Commission of the German Medical Association (DCGMA)
Rasi	Guido	European Medicines Agency (EMA)
Sangiorgi	Luca	European Reference Network on Rare Bone Diseases (BOND ERN)
Schmidt	Florian	European Commission (EC), DG Health and Food Safety
Skåra	Hall	European Pulmonary Hypertension Association (PHA Europe)
Turner	Mark	European Network of Paediatric Research at the EMA (Enpr-EMA)
Van der Zanden	Tjitske	PEDMED-NL (Former Dutch Medicines for Children Research Network)
Sweeney	Fergus	European Medicines Agency (EMA)
Vassal	Gilles	Innovative Therapies for Children with Cancer (ITCC) Consortium
Vroom	Elizabeth	World Duchenne Organization

* Video message

Practical information

Note to attendees

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.

The Agency requires all visitors to provide a valid photo ID on arrival, such as a passport, an identity card or driving licence.

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 45 to 30 minutes before the start of the workshop, to allow you time for registration and settling down.

Meeting room

The plenary meeting will take place in the room 03-A. A seating plan will be provided.

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.

Recording and Photography

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on the European Union. **This workshop will be broadcast live and recorded.** By attending this event you consent to any photographing, recording, broadcast and publication of presentations on the EMA website.

For more information about processing of personal data by EMA, please visit the website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid or contact dataprotection@ema.europa.eu

Travel and Accommodation

Participants must possess valid travel documents and, where relevant, a visa for entry into the United Kingdom. Should you require an official letter of invitation, please contact PMEWorkshops@ema.europa.eu.

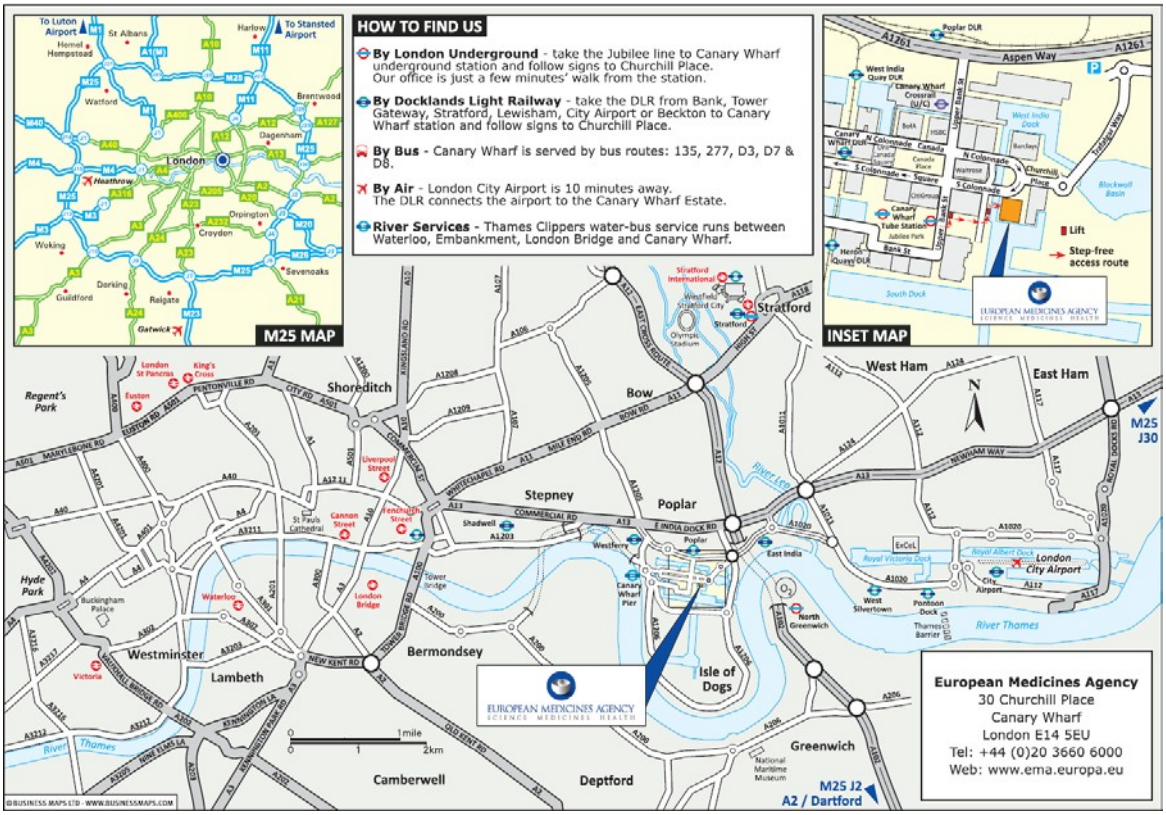
Conference venue

European Medicines Agency

30 Churchill Place, Canary Wharf London E14 5EU, United Kingdom

Telephone +44 (0)20 3660 6936 | Facsimile +44 (0)20 3660 5550

Directions to European Medicines Agency and map of the area



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/

By Bus

Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.

River services

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 DLR City Airport to Canary Wharf (journey time is around 20 minutes).

From Gatwick Airport

Take a mainline train to London Bridge, then the Jubilee Line to Canary Wharf (journey time around 50 minutes).

From Heathrow Airport

Take the London underground Piccadilly Line to Green Park, change to the Jubilee Line to Canary Wharf (journey time around 1hr 20 minutes).

Alternatively, take the Heathrow Express train to Paddington. From Paddington you can take the Circle or Bakerloo line to Baker Street, then the Jubilee Line to Canary Wharf (journey time around 1hr 20 minutes).

Alternatively, you can take the Heathrow Express train to Paddington, then the District or Circle Line to Tower Hill then the Docklands Light Railway (DLR) to Canary Wharf (journey time around 1hr 30 minutes).

From Stansted Airport

Take the Stansted Express to London Liverpool Street then the Circle Line to Tower Hill and change onto the DLR to Canary Wharf (journey time around 70 minutes).

From Luton Airport

Take a first Capital Connect train to London Bridge then the Jubilee Line to Canary Wharf (journey time around 60 minutes).

From St Pancras International train station

Take the Northern Line to London Bridge then the Jubilee Line to Canary Wharf (journey time around 45 minutes).

Contact

Should you have any questions, please contact PMEWorkshops@ema.europa.eu