10 May 2016
EMA/251741/2016
Human Medicines Evaluation Division

Targeted consultation on development of new medicinal products for the treatment of rheumatoid arthritis

Programme

7 June 2016

European Medicines Agency, London, United Kingdom

Meeting room 2A

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

Objectives of the meeting

- To provide interested stakeholders the opportunity to discuss the most up-to-date scientific views relevant to the development of medicinal products in RA with leading experts in this area
- To provide a forum of discussion on suitable study designs and possible label for new substances

List of speakers

Jan Mueller-Berghaus	Paul-Ehrlich-Institute (PEI), Germany Rheumatology Immunology Working Party (RIWP) Committee for Medicinal Products for Human Use (CHMP)
Arantxa Sancho-Lopez	Spanish Agency of Medicines and Medical Devices (AEMPS), Spain Rheumatology Immunology Working Party (RIWP) Committee for Medicinal Products for Human Use (CHMP)
Elisabeth Johanne Rook	Medicines Evaluation Board (CBG-MEB), Netherlands Rheumatology Immunology Working Party (RIWP)
Enrica Alteri	European Medicines Agency (EMA)
Richard Vesely	European Medicines Agency (EMA)
Andreas Kouroumalis	European Medicines Agency (EMA)

Programme details

9:00	**Registration**

Registration and badge collection at the reception on the ground floor.

The meeting room 2A is on the second floor.

10:00	**Welcome and opening**
	Enrica Alteri
	Richard Vesely
10:15	**Introduction**
	Jan Mueller-Berghaus
20'	***The development of the guideline for development of new medicinal products for the treatment of rheumatoid arthritis***
	Jan Mueller-Berghaus
	Elisabeth Rook
10:40	**Session 1: From clinical trials to regulatory approval**
20'	***Defining and selecting populations to be studied in rheumatoid arthritis*** ***Extrapolation of clinical benefit between different populations in rheumatoid arthritis***
	Jan Mueller-Berghaus
60'	**Discussion**
12:00-13:00	**Lunch break**
13:00	**Session 2: Endpoints in clinical trials**
20'	***Disease activity criteria vs. relative response*** ***Feasibility and need to demonstrate prevention of structural damage***
	Arantxa Sancho-Lopez
60'	**Discussion**
14:20-14:40	**Coffee break**
14:40	**Session 3: Clinical trial designs**
20'	***Placebo vs. active control: when and for how long*** ***Inclusion of treatment irresponsive patients in trials***
	Andreas Kouroumalis

60’	**Discussion**
16:00	**Conclusions and next steps**

Jan Mueller-Berghaus
Richard Vesely

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 RIWPsecretariat@ema.europa.eu

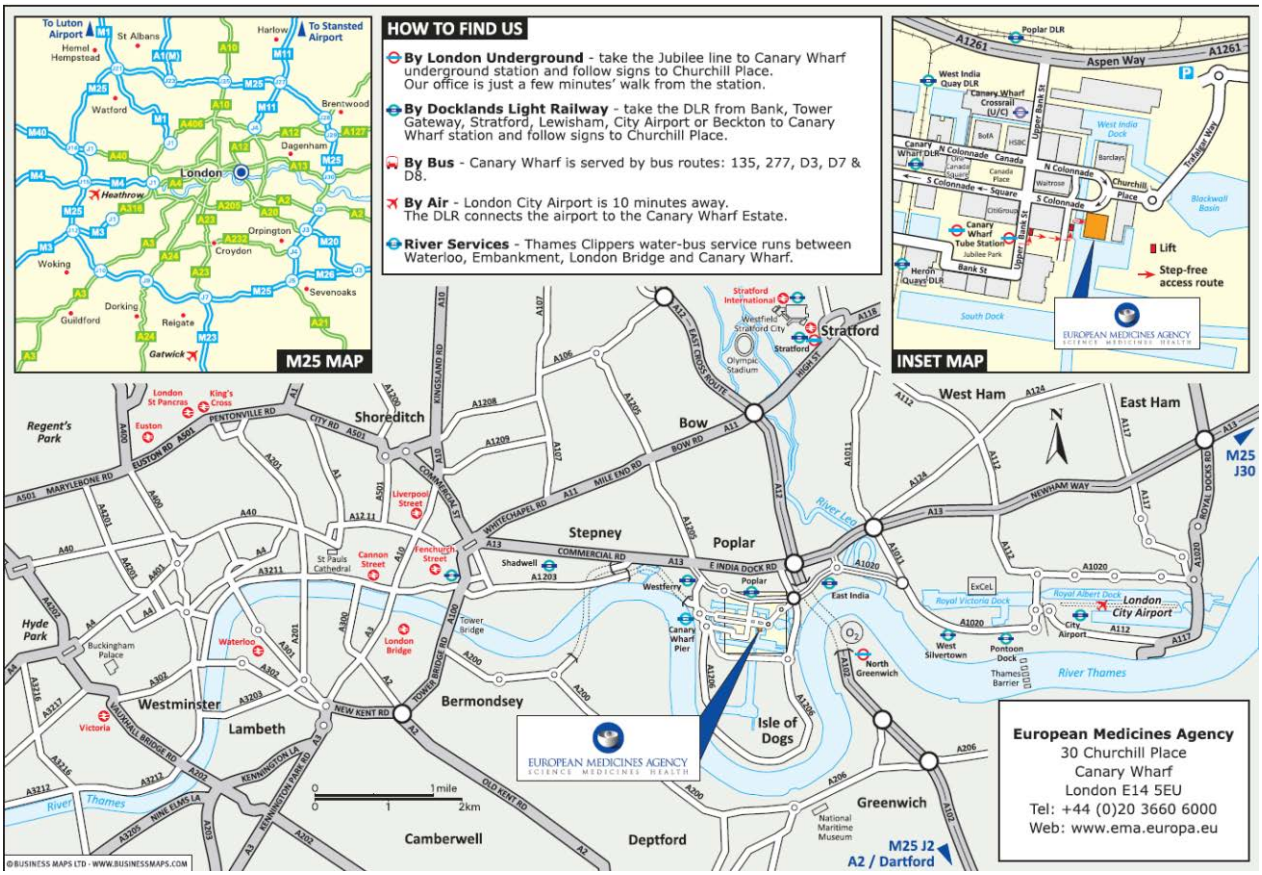
Recording and Photography

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. The conference will be recorded. By attending these events you consent to any photographing, recording, broadcast and publication of presentations on the EMA website.

Contact

Should you have any questions, please contact Monica Simeoni or Andreas Kouroumalis via RIWPsecretariat@ema.europa.eu

Directions to European Medicines Agency and map of the area



By Docklands Light Railway (DLR)

Both venues are a short walk from Canary Wharf or Heron Quays station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.

By Underground

The nearest stop for both venues is Canary Wharf station on the Jubilee Line.

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 a taxi to Canary Wharf, or catch the DLR to Westferry station then change to the DLR to Canary Wharf.

Useful links

http://www.tfl.gov.uk/

National Rail

Gatwick Express

Heathorw Express

Stansted Express

Eurostar

Heathrow airport

Gatwick airport

London City

London Stansted

Hillgate travel