

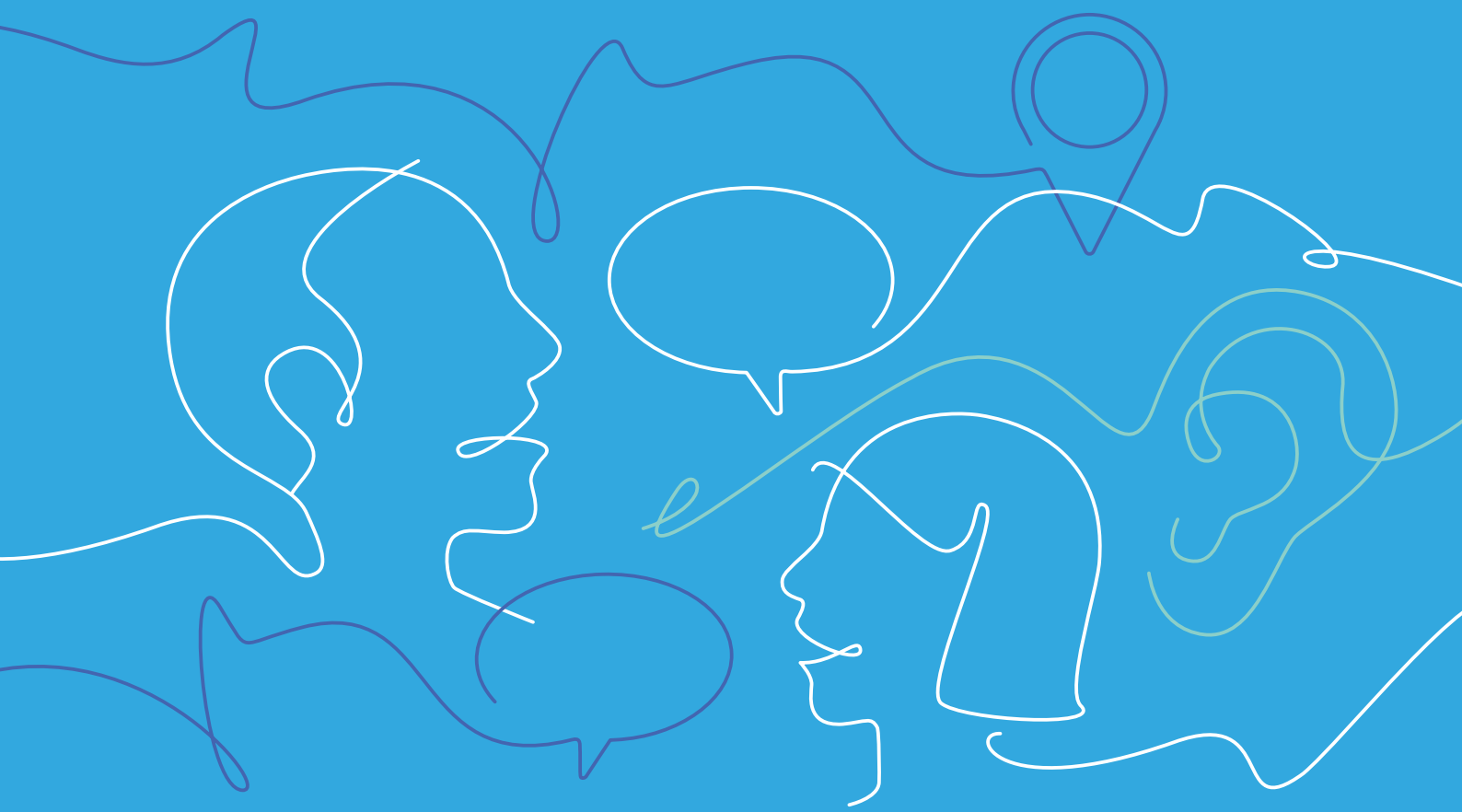


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Hearing: quinolone and fluoroquinolone medicines

Wednesday, 13 June 2018

Pharmacovigilance Risk Assessment Committee (PRAC)



Agenda

Chair: June Raine (PRAC chair)

12:00 *Registration opens*

12:45 *Participants escorted to meeting room 3M*

13:00 **Welcome and introduction**

- ▶ **Melanie Carr** (EMA Head of Stakeholders and Communication)
- ▶ **June Raine** (PRAC chair)

13:10 **Public hearing rules and background information**

- ▶ **Juan García Burgos** (EMA Head of Public Engagement)
- ▶ **Eva Jirsová** (PRAC rapporteur)

13:20 **Speakers interventions** (*5 minutes per intervention*)

General public (patient representatives, carers, families)

Speaker 1:

- ▶ **Elizabeth Carmouche**, Belgium

Speaker 2:

- ▶ **Manex Bettan Arguinzoniz**, Spain

Speaker 3:

- ▶ **Richard Cooknell**, UK

Speaker 4:

- ▶ **Markus Hamedinger**, Austria

Speaker 5:

- ▶ **Miriam Knight**¹, Quinolone Toxicity Support UK
Raymond Miller, Quinolone Toxicity Support UK
Geoffrey Robinson, Fluoroquinolone Toxicity Victims in Europe

Speaker 6:

- ▶ **Julie Le Normand**, France

Speaker 7:

- ▶ **Elsa Leitão**, Germany

Speaker 8:

- ▶ **Jaroslaw Linka**, Poland

Speaker 9:

- ▶ **Andrea Noya**, Italy

Speaker 10:

- ▶ **Joshua Sutton**, UK

¹For grouped interventions, the name in **bold** is the speaker

Speaker 11:

- ▶ **Miriam van Staveren**, The Netherlands

Speaker 12 (joining via teleconference):

- ▶ **John Crowley**, Luxembourg

Speaker 13 (joining via teleconference):

- ▶ **Enikő Pongrácz**, Hungary

15:30 **Coffee break**

16:00 **Speakers interventions** (*5 minutes per intervention*)

Pharmaceutical companies

Speaker 14:

- ▶ **Leo Plouffe**, Bayer AG

Healthcare professionals and academia

Speaker 15:

- ▶ **Jamie Wilkinson**, Pharmaceutical Group of the European Union (PGEU)

Speaker 16:

- ▶ **Graham Bothamley**, European Respiratory Society (ERS)

Speaker 17:

- ▶ **Mary McCarthy**, European Union of General Practitioners (UEMO)

Speaker 18:

- ▶ **Neal L Millar**, Institute of Infection, Immunity and Inflammation, University of Glasgow, UK

Speaker 19:

- ▶ **Ber Oomen**, European Specialist Nurses Organisations (ESNO)

Speaker 20:

- ▶ **Paul Tulkens**, Louvain Drug Research Institute, Belgium

Speaker 21:

- ▶ **Florian Wagenlehner**, European Association of Urology (EAU)

17:30 **Wrap up, summary of interventions and next steps**

- ▶ **June Raine** (PRAC chair)

18:00 *End of public hearing*

List of Speakers

Note: Some speakers have been grouped together

General public (patient representatives, carers, families)

Markus Hamedinger	Austria
Elizabeth Carmouche	Belgium
Julie Le Normand	France
Elsa Leitão	Germany
Enikő Pongrácz	Hungary
Andrea Noya	Italy
John Crowley	Luxembourg
Miriam van Staveren	The Netherlands
Jaroslaw Linka	Poland
Manex Bettan Arguinzoniz	Spain
Miriam Knight / Raymond Miller	Quinolone Toxicity Support UK
Geoffrey Robinson	Fluoroquinolone Toxicity Victims in Europe
Joshua Sutton	UK
Richard Cooknell	UK

Pharmaceutical companies

Leo Plouffe	Bayer, AG
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Healthcare professionals and academia

Jamie Wilkinson	Pharmaceutical Group of the European Union (PGEU)
Florian Wagenlehner	European Association of Urology (EAU)
Graham Bothamley	European Respiratory Society (ERS)
Mary McCarthy	European Union of General Practitioners (UEMO)
Ber Oomen	European Specialist Nurses Organisations (ESNO)
Paul Tulkens	Louvain Drug Research Institute, Belgium
Neal L Millar	Institute of Infection, Immunity and Inflammation, University of Glasgow, UK

Speakers declaration of interests (where applicable)

Florian Wagenlehner

European Association
of Urology (EAU)

I am involved in a phase 2 study developing a new fluoroquinolone with MerLion Pharmaceuticals Pte Ltd

Paul Tulkens

Louvain Drug Research
Institute, Belgium

I have the following links with pharmaceutical companies who developed and/or who market quinolone and fluoroquinolone medicines:

1. Bayer: consulting, speaker's bureau, and research grants (moxifloxacin)
2. Sanofi-Aventis: expert's report (levofloxacin)
3. Melinta/Menarini: research grants and speaker's bureau (delafloxacin [approved in USA only])
4. Ferrer: member of the safety assessment committee during clinical development (ozenoxacin)

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)

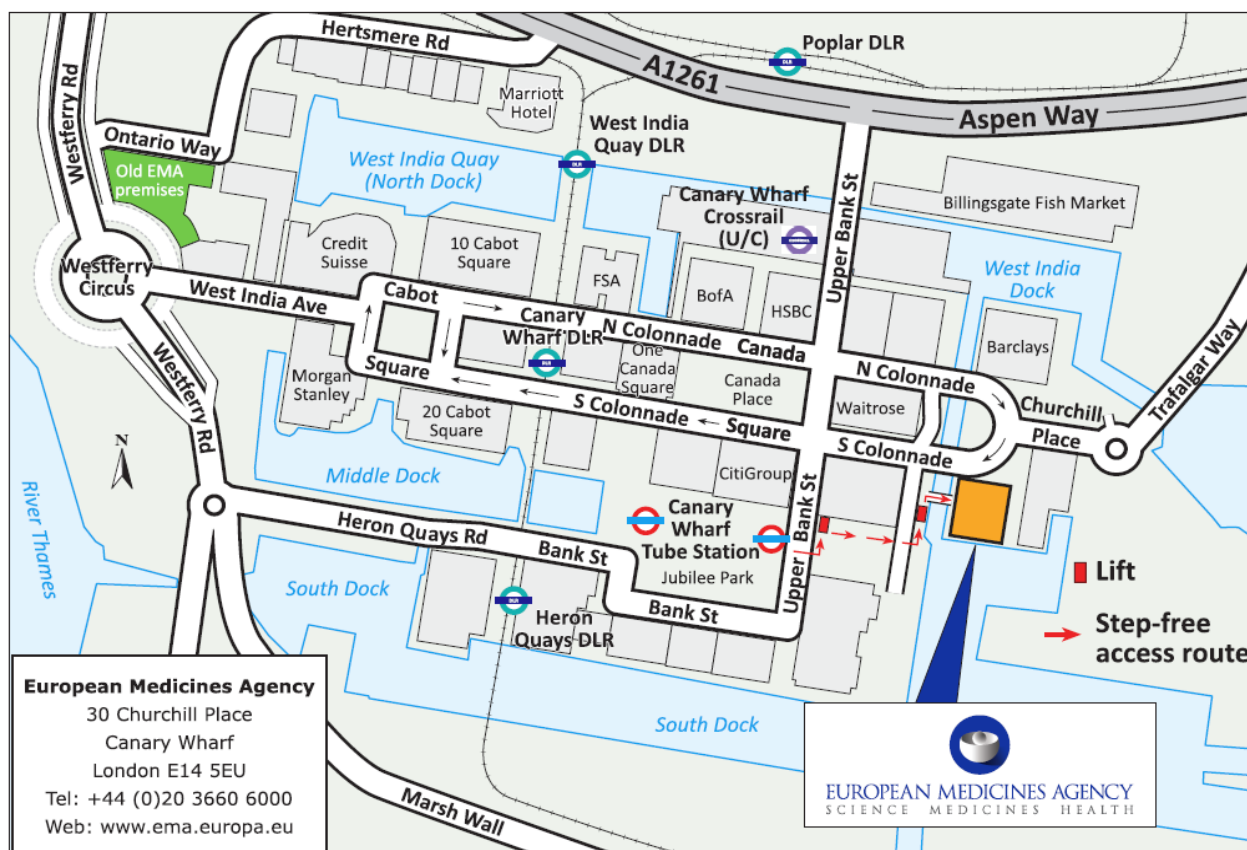
The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

► 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://canarywharf.com/getting-here/parking/>

Map



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