Public Hearing: quinolone and fluorquinolone 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 Arquizoniz, 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

¹ For 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 Practioners (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)

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<thead>
<tr>
<th>Name</th>
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<td>Markus Hamedinger</td>
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## Pharmaceutical companies

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<td>Leo Plouffe</td>
<td>Bayer, AG</td>
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## Healthcare professionals and academia

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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 (ozonoxacin)
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