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Press release

Public hearing on quinolones and fluoroquinolones: 23 speakers from 11 EU countries to share experience

Agenda and list of speakers for 13 June hearing available

The European Medicines Agency (EMA) has published today the agenda and the list of speakers for its public hearing taking place on 13 June 2018 at the Agency's offices. EMA is organising this hearing to give European citizens the opportunity to share their experience with quinolones and fluoroquinolones, a class of antibiotics widely prescribed in the European Union (EU).

The hearing will be broadcast live on EMA's website (accessible through the 'Public hearing' tab) from 13:00 to 18:00 UK time on 13 June 2018.

The public hearing is part of a review being carried out by EMA's safety committee, the Pharmacovigilance Risk Assessment Committee (PRAC), which is investigating the persistence of serious side effects with quinolones and fluoroquinolones mainly affecting muscles, joints and the nervous system. These side effects are of particular importance when the medicines are used for less severe infections.

The Agency received 115 applications to attend, with 55 requests to speak from various citizens with experience with quinolones and fluoroquinolones: patients, doctors, nurses, pharmacists, academics, representatives of EU associations. 60 registrants expressed their interest to participate as observers. 23 speakers from 11 EU Member States were selected to share their views directly with the PRAC. Individuals who requested to speak but who could not be allocated a slot due to time restrictions will have their written contributions equally transmitted to the scientific committee, taken into account and published on the EMA website. Contributions are grouped into 21 speaker slots, as highlighted in the agenda of the event. To make sure all speakers have the chance to share their views, each contribution should not exceed five minutes.

For its final decision, the PRAC will take into account all views and experiences shared during the public hearing. Giving EU citizens a voice in the evaluation of medicines will enrich the available scientific evidence and add value to the PRAC assessment.

Public hearings complement EMA's existing channels for engaging with patients and healthcare professionals in the assessment of medicines, such as written consultations and participation in EMA's expert meetings during safety reviews.

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Practical information on EMA's public hearings is available in a video and the guidance for participants, which explains what to expect from such an event, how to register and how EMA selected the speakers.

If additional information is needed, interested citizens can send an email to publichearings@ema.europa.eu.

Notes

1. The review of quinolone and fluoroquinolone antibiotics was initiated on 9 February 2017 at the request of the German medicines authority (BfArM), under Article 31 of Directive 2001/83/EC.
2. The review is carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will issue recommendations. PRAC's recommendations will then be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for medicines for human use, which will adopt the Agency's opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.
3. The public hearing follows the adoption of rules of procedure on the organisation and conduct of public hearings.

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