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Media and Public Relations

Press release

Public hearing on 13 June 2018

Citizens to be consulted on quinolone and fluoroquinolone antibiotics

The European Medicines Agency (EMA) has opened registration for its next public hearing which will take place on 13 June 2018 at EMA's premises. The public hearing will give a voice to patients, doctors, nurses, pharmacists, researchers and everyone else who wants to share experience with quinolones and fluoroquinolones[1], a class of antibiotics widely prescribed in the European Union (EU).

The public hearing is part of a review being carried out by EMA's safety committee, the Pharmacovigilance Risk Assessment Committee (or PRAC), that is investigating reports of serious persistent side effects mainly affecting muscles, joints and the nervous system. Some of these side effects have been reported in patients with infections that were not severe and could have been treated with other antibiotics.

The PRAC would like to hear from the public what it thinks about the risks associated with these antibiotics. It also wants to explore whether further measures could ensure that these antibiotics are used as safely as possible.

"The public hearing provides citizens with the opportunity to contribute to this review. Their experiences and views will complement the available scientific evidence and enrich PRAC's deliberations," said Guido Rasi, EMA's Executive Director. "Public hearings underline our commitment to include patients and healthcare professionals in our decision-making."

Those interested in participating in the public hearing, either as a speaker or an observer should submit an application form to EMA no later than 30 April 2018.

To ensure that the public interventions are as useful as possible, the PRAC has put forward three questions to be addressed by the speakers:

1. What is your view on the role of quinolones and fluoroquinolones in the treatment of infections?
2. What is your view of the risks associated with quinolone and fluoroquinolone use?

[1] INN/active substances: cinoxacin, ciprofloxacin, enoxacin, flumequin levofloxacin, lomefloxacin, moxifloxacin, nalidixic acid, norfloxacin, ofloxacin, pefloxacin, pipemidic acid, prulifloxacin and rufloxacin.

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3. In your opinion, what further measures could be taken to optimise the safe use of quinolones and fluoroquinolones?

EMA will review the applications. Speakers will need to address the questions from the PRAC and will be selected based on their experience with quinolones and fluoroquinolones (a short description on how they plan to address the questions needs to be provided in the application form). The Agency also seeks to achieve a wide representation of all groups of stakeholders across the EU.

EMA will try to accommodate as many people as possible. For those who cannot attend in person, the hearing will be broadcast live on EMA's website.

Practical information on EMA's public hearings is available in a video and Guidance for public participants, which explain what to expect from a public hearing, how to register and how EMA selects 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
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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