23 March 2018
EMA/166405/2018

Public hearing on quinolones and fluoroquinolones

Summary of safety concerns and list of questions

Background and summary of safety concerns

Quinolones and fluoroquinolones[1] are a class of antibiotics which are widely prescribed in the European Union (EU) and are important for treating serious, life threatening bacterial infections.

The European Medicines Agency (EMA) is reviewing these medicines due to 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 review was started after the German medicines authority (BfArM) notified EMA of reports of long-lasting side effects in their national safety database and the published literature.

The review of quinolones and fluoroquinolones is being carried out by EMA's Safety Committee – the Pharmacovigilance Risk Assessment Committee (PRAC).

At its March 2018 meeting, the PRAC decided that it would be of benefit to engage the wider EU public in this review. In particular, the PRAC would like to hear the public's view on acceptability of risks associated with quinolones and fluoroquinolones in both mild and severe infections, and to explore what further measures could be taken to ensure that these antibiotics are used as safely as possible.

The public hearing will be held on **13 June 2018** at the EMA offices in London and it will focus on the questions outlined below. Information about public hearings, including full details on how this hearing will be conducted and how interested individuals can participate, is available on EMA's webpage for public hearings.

After the public hearing, the PRAC will continue its review according to the published timetable. Once the assessment is finalised, the PRAC will publish a report on the safety of quinolones and fluoroquinolones which will set out its conclusions and will clearly explain how the information gathered during the public hearing has informed the Committee's recommendations.

[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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Questions for the public

Within the scope of this review and based on your experience with quinolone and fluoroquinolone treatment:

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