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EMA to review persistenceofside effects known to occur with quinolone and fluoroquinolone antibiotics

Review to focus on long-lasting effectsmainlyaffecting musculoskeletal and nervous systems

The European Medicines Agency (EMA) is reviewing systemic and inhaled quinolone and fluoroquinolone antibioticsto evaluate the persistence of serious side effects mainlyaffecting muscles, joints andthe nervous system.These side effects are of particularimportancewhen the medicines are used forless severe infections.

The review is at the request of the German medicines authority (BfArM) following reports of long-lasting side effects in the national safety database and the published literature. There has been no previous EU-wide review specifically focusing on the persistence of the side effects,butthe side effects themselves are known and covered in the EU prescribing information for these medicines.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will now evaluateall availabledataand determinewhetherthere is a need to introduce new measures to minimise these risksormodify how the medicines are used.

Quinolonesand fluoroquinolonesare widelyprescribedin the EUand are important options for treating serious, life-threatening bacterial infections.Healthcare professionals using these medicinesshould continue to follow the official prescribing information.

Patients who have any questions about their treatment should speak to their doctor.

More about the medicines

Quinolones and fluoroquinolones are a class of broad spectrum antibiotics that are active against so-called Gram-negative and Gram-positive bacteria.

The review covers the following medicines: cinoxacin, ciprofloxacin,enoxacin,flumequine, levofloxacin,lomefloxacin,moxifloxacin,nalidixic acid, norfloxacin,ofloxacin,pefloxacin,pipemidic acid, prulifloxacin and rufloxacin.

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The review concerns only inhaled medicines and medicines given systemically (by mouth or injection). Topical medicines, such as those applied directly to the skin, eyes or ears, are not included.

More about the procedure

The review of quinolone and fluoroquinoloneantibioticswas initiated on 9 February 2017 at the request of German medicines authority (BfArM), under Article 31 of Directive 2001/83/EC.

The review will be carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which willissue recommendations. The PRAC recommendations will then be sentto the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning 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.

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