European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends restricting the use of oral moxifloxacin-containing medicines

Finalising a review of the safety of moxifloxacin-containing medicines for oral use, the European Medicines Agency (EMEA) has concluded that these medicines should only be prescribed in the treatment of acute bacterial sinusitis, acute exacerbation of chronic bronchitis and community-acquired pneumonia when other antibiotics cannot be used or have failed. The Agency also recommended strengthening the warnings for oral moxifloxacin medicines.

Moxifloxacin is a fluoroquinolone antibiotic. Oral formulations of medicines containing moxifloxacin are authorised at the level of the Member States in the European Union (EU) under several trade names for the treatment of acute exacerbation of chronic bronchitis, community-acquired pneumonia, acute bacterial sinusitis and, in some Member States, for mild to moderate pelvic inflammatory disease.

The EMEA's Committee for Medicinal Products for Human Use (CHMP) has reviewed all available information on the safety of moxifloxacin-containing medicines for oral use, following concerns over their liver safety when used for acute bacterial sinusitis, acute exacerbation of chronic bronchitis and community-acquired pneumonia.

At its July 2008 meeting, the CHMP concluded that the benefits of oral moxifloxacin medicines continue to outweigh its risks. However, due to safety concerns, mainly related to an increased risk of adverse hepatic reactions, the CHMP recommended restricting their use in these indications. For acute bacterial sinusitis and acute exacerbations of chronic bronchitis, they should only be prescribed when other antibiotics cannot be used or have failed. For community acquired pneumonia, they should only be given when treatment with other antibiotics cannot be used.

The CHMP also recommended that the warnings of oral moxifloxacin-containing medicines should be strengthened concerning the risk of diarrhoea, heart failure in women and older patients, severe skin reactions and fatal liver injury.

Doctors are advised to prescribe oral moxifloxacin-containing medicines according to the updated product information and to consider the official guidance on the appropriate use of the antibiotics and the local prevalence of resistance. Patients should speak to their doctor or pharmacist if they have any questions.

The CHMP opinion will now be forwarded to the European Commission for the adoption of a decision applicable to all oral moxifloxacin-contain medicines authorised in the EU.

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Notes:
1. More information is available in a question-and-answer document.
2. Medicines containing moxifloxacin include Actimax, Actira, Avelox, Havelox, Infekt, Izilox, Moxifloxacin, Octegra and Proflox.
3. The procedure was initiated by United Kingdom under an Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing

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authorisation of a nationally authorised medicinal product as result of the evaluation of safety data. It provides for a harmonised European approach because the CHMP is asked to prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.

4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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