European Medicines Agency
Press office

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PRESS RELEASE
Schering-Plough Europe withdraws its marketing authorisation application for Garenoxacin mesylate

The European Medicines Agency (EMEA) has been formally notified by Schering-Plough Europe of its decision to withdraw the application for a centralised marketing authorisation for the medicinal product Garenoxacin mesylate 400 mg and 600 mg film-coated tablets and 2 mg/ml solution for infusion.

Garenoxacin mesylate was expected to be used for the treatment of the following infections in adults, when due to garenoxacin-susceptible pathogens:

- acute bacterial exacerbation of chronic bronchitis,
- acute bacterial sinusitis,
- community-acquired pneumonia,
- uncomplicated skin and skin structure infections,
- complicated skin and skin structure infections, including diabetic foot infections,
- complicated intra-abdominal infections, including post-surgical infections and acute pelvic infections.

The application for marketing authorisation for Garenoxacin mesylate was submitted to the EMEA on 5 May 2006. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of Garenoxacin mesylate was based on the CHMP's request for additional information, to which the company was unable to respond within the permitted timeframe.

More information about Garenoxacin mesylate and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website in due course.

-- ENDS --

Notes:
1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. 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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