European Medicines Agency
Press office

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PRESS RELEASE
Menarini International Operations Luxembourg withdraws its marketing authorisation application for Factive (gemifloxacin)

The European Medicines Agency has been formally notified by Menarini International Operations Luxembourg S.A. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Factive (gemifloxacin), 320 mg film-coated tablets.

Factive was expected to be used for the treatment of bacterial infections causing mild to moderate community-acquired pneumonia and acute exacerbation of chronic bronchitis.

The application for the marketing authorisation for Factive was submitted to the Agency on 26 March 2008. 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 the application was based on the CHMP's view that the data provided did not allow the Committee to conclude on a positive benefit-risk balance for Factive at that time.

More information about Factive 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 Agency's website after the next CHMP meeting of 22-25 June 2009.

-- 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 Agency, can be found on the Agency's website: www.emea.europa.eu.

Media enquiries only to:
Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu