



MENARINI

International Operations Luxembourg, S.A.

Date: 17 June 2009

Dr Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Dear Dr Abadie,

Subject: Withdrawal of FACTIVE, (gemifloxacin), 320mg film-coated tablet - EMEA/H/C/000995

We would like to inform you that, at this point of time, Menarini International Operations Luxembourg S.A. (MIOL) has taken the decision to withdraw the application for Marketing Authorisation of FACTIVE (gemifloxacin), 320mg film-coated tablet, which was intended to be used for Community Acquired Pneumonia of mild to moderate severity, and for Acute Exacerbation of Chronic Bronchitis.

This withdrawal is based on the following reason:

- MIOL has taken this decision based on the CHMP's view that the data provided do not allow the Committee to conclude on a positive benefit-risk balance for FACTIVE at this time.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

We agree for this letter to be published on the EMEA website.

Yours sincerely,
Menarini International Operations Luxembourg S.A.