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**Dr. E. Abadie**
**Chairman of the CHMP**
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Brussels, 25 July 2007

Subject: **Withdrawal of Garenoxacin mesylate Film-coated tablets 400 and 600 mg and Solution for infusion 2 mg/ml - intravenous bags 200 ml (400 mg), and 300 ml (600 mg) - EMEA/H/C/747**

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Schering-Plough Europe has taken the decision to withdraw the application for Marketing Authorisation of Garenoxacin mesylate Film-coated tablets 400 and 600 mg and Solution for infusion 2 mg/ml - intravenous bags 200 ml (400 mg), and 300 ml (600 mg), which was initially intended 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.

This withdrawal is based on the CHMP's request for additional information, to which the company is unable to respond within the permitted timeframe.
All EU clinical trials are closed to patient enrolment and no compassionate use programmes are active.

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

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

Sincerely yours,

Schering-Plough Europe