European Medicines Agency

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# QUESTIONS AND ANSWERS ON THE RECOMMENDATION FOR REFUSAL OF A MARKETING AUTHORISATION APPLICATION
# for
# VERAFLOX

International Non-proprietary Name (INN): ***pradofloxacin***

On 17 May 2006 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Veraflox 15 mg, 60 mg & 120 mg Tablets for Cats and Dogs, and Veraflox 25 mg/ml Oral Suspension for Cats. The applicant requested a re-examination of the opinion. After having considered the grounds for this request, the CVMP re-examined the initial opinion, and confirmed the recommendation of the refusal of the marketing authorisation application on 14 September 2006.

The company who applied for a marketing authorisation is Bayer HealthCare AG.

**What is Veraflox?**
Veraflox is an antibiotic. Veraflox Tablets contain 15 mg, 60 mg & 120 mg of the active substance, pradofloxacin. Veraflox Oral Suspension contains 25 mg/ml pradofloxacin.

**What was Veraflox to be used for?**
Pradofloxacin is an antibiotic. In dogs, Veraflox Tablets were to be used for the treatment of skin, urinary tract and gum infections caused by certain specific bacteria. In cats, Veraflox Tablets were to be used for the treatment of acute infections of the upper respiratory tract caused by certain specific bacteria. Veraflox Oral Suspension was to be used for the treatment of cats with acute infections of the upper respiratory tract and also some skin conditions caused by certain specific bacteria.

**How is Veraflox expected to work?**
The active substance in Veraflox, pradofloxacin, belongs to a class of antibiotics called third generation fluoroquinolones. All these fluoroquinolones, including pradofloxacin, kill bacteria by interacting with some of the enzymes in bacteria responsible for major DNA functions. This results in the bacteria dying and so the infection is cured. Like other antibiotics, pradofloxacin is not effective against every type of bacteria.

**What documentation did the Company present to support its application to the CVMP?**
The company presented the results of studies examining the effectiveness of Veraflox against a range of conditions involving bacterial infections in cats and dogs. In dogs, the medicine was studied in some skin, urinary tract and gum infections caused by certain specific bacteria. In cats, the medicine was studied in acute infections of the upper respiratory tract and also some skin conditions caused by certain specific bacteria. In all studies the effectiveness of Veraflox was compared to antibiotics which are commonly used for the treatment of the infection studied.

**Which were the major concerns that lead the CVMP to recommend the refusal of a marketing authorisation?**
The CVMP considered that the company had not been able to identify a dose that was effective whilst at the same time providing an adequate margin of safety. For this reason the Committee concluded that the safety of pradofloxacin had not been conclusively proven. They noted that the genotoxicity data (the potential for the substance to damage genes) showed differences from that for other antibiotics in the same class, and that the reasons for these differences were unclear. The CVMP was therefore of the opinion that Veraflox's benefits had not been shown to be greater than its risks. Hence, the CVMP recommended that Veraflox be refused a marketing authorisation.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

**What are the consequences for animals of the refusal for Veraflox?**
No adverse consequences for animals have been identified by the CVMP, as other medicines exist for all the infections in cats and dogs which Veraflox was intended to treat.