European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/58270/2007

QUESTIONS AND ANSWERS ON THE WITHDRAWAL OF THE APPLICATION TO CHANGE THE MARKETING AUTHORISATION APPLICATION for DRAXXIN

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

On 17 January 2007 Pfizer Ltd officially notified the Committee for Medicinal Products for Veterinary Use (CVMP) that it wishes to withdraw its application for a new indication for the treatment of bovine interdigital necrobacillosis associated with *Bacteroides melaninogenicus, Bacteroides nodosus* and *Fusobacterium necrophorum*.

What is Draxxin?

Draxxin is an antibiotic. It is a solution for injection and is packaged in 20, 50, 100, 250 and 500 ml bottles. Draxxin contains the active substance tulathromycin 100 mg/ml.

What is Draxxin used for?

Draxxin is used in cattle to treat and prevent bovine respiratory disease (BRD). The presence of the disease in the herd should be established before preventative treatment. Draxxin is also used for the treatment of swine respiratory disease (SRD).

What was Draxxin expected to be used for?

The new indication was expected for the treatment of bovine interdigital necrobacillosis (commonly often referred to as foot rot) associated with the bacteria *Bacteroides melaninogenicus, Bacteroides nodosus* and *Fusobacterium necrophorum*.

How does Draxxin work?

Draxxin contains tulathromycin, which belongs to a class of antibiotic medicines called macrolides. Draxxin binds to bacterial RNA and kills the bacterial cells. Draxxin is effective against the bacteria that most commonly cause bovine and swine respiratory disease.

What documentation did the Company present to support its application to the CVMP?

The company presented an MIC (Minimum Inhibitory Concentration: This is the lowest concentration of an antimicrobial that will inhibit the visible growth of a microorganism after overnight incubation) study on the relevant target pathogens isolated in Europe, and a challenge model study in calves performed in the U.S.

How far into the evaluation was the application when it was withdrawn?

The application was at day 147 when the company withdrew.
After the CVMP had assessed the responses given by the company to a list of questions, the CVMP still had some concerns.

What were the main concerns of the CVMP?

The main concern of the CVMP was that no controlled clinical field study was provided in order to confirm the efficacy of tulathromycin, shown in the infection model study, under field conditions. The MIC data basis for the claimed pathogens was also considered insufficient.

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

The predictability of the infection model study was also questioned: Tulathromycin proved to be efficacious in resolving clinical signs associated with interdigital necrobacillosis, induced by *F. necrophorum* and *B. melaninogenicus*, but the susceptible strain of *B. melaninogenicus*, used for inoculation, is considered not representative of the European isolates, and the study did not fully reflect the clinical disease process under field conditions and target population.

In conclusion, based on the limited microbiological data basis for the claimed pathogens and the infection model study, only, the administration of Draxxin for the treatment of bovine interdigital necrobacillosis was not sufficiently justified.

Therefore, at the time of the withdrawal, the CVMPs view was that a benefit of this new indication for Draxxin had not been sufficiently demonstrated and any benefits did not outweigh the identified risks.

What were the reasons given by the company to withdraw the application?

The company stated that insufficient field data had been generated to enable CVMP to make a true assessment of the benefit risk balance of this indication.

The letter from the company notifiying the EMEA of the withdrawal of the application is available here.

What are the consequences for animals of the withdrawal of this new indication for Draxxin?

No adverse consequences for animals have been identified by the CVMP as other medicines exist for interdigital necrobacillosis in cattle which Draxxin was intended to treat.