European Medicines Agency
*Veterinary Medicines and Inspections*

London, 16 May 2008
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE**
**SUMMARY OF OPINION***
**ZACTRAN**

International Non-proprietary Name (INN):
Gamithromycin

On 14 May 2008 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Zactran, 150 mg/ml, solution for injection, intended for the therapeutic and preventive treatment of bovine respiratory disease (BRD) in cattle associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*. The Applicant for this veterinary medicinal product is Merial S.A.S.

The active substance of Zactran is Gamithromycin, a semi-synthetic macrolide medicinal product, (ATC vet code: QJ01FA95). Gamithromycin has both bacteriostatic and bactericidal action, mediated through the disruption of bacterial protein synthesis. The broad spectrum of the antimicrobial activity of Gamithromycin includes *Mannheimia haemolytica, Pasteurella multocida and Histophilus somni,* the bacterial pathogens most commonly associated with Bovine Respiratory Disease.

The benefits of Zactran are the efficacy of a single dose of 1 ml/25 kg for the treatment and prevention of bovine respiratory disease, demonstrated by the improvement of the clinical signs of the disease. Also, the efficacy of gamithromycin was demonstrated comparable to that of an already approved veterinary medicinal product containing tulathromycin. The most common side effect is a transient local swelling at the injection site consistent with the macrolide class of antimicrobials

The approved indication is: Therapeutic and preventive treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*.

The presence of the disease in the herd should be established before preventive treatment

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Zactran and therefore recommends the granting of the marketing authorisation.

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* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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