European Medicines Agency
*Veterinary Medicines and Inspections*

London, 15 May 2009
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE**
**SUMMARY OF OPINION***
**MELOVEM**

International Non-proprietary Name (INN):
MELOXICAM

On 13 May 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Melovem 5 mg/ml solution for injection. The Applicant for this veterinary medicinal product is Dopharma Research B.V..

The active substance of Melovem is Meloxicam, a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class (ATCvet code: QM01AC06) which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic and antipyretic properties. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane $B_2$ induced by E. coli endotoxin administration in calves and pigs.

The benefits of Melovem are in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle, in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over 1 week of age and young, non-lactating cattle, and in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation in pigs. The most common side effects are transient swelling at the injection site which was commonly reported in clinical studies following subcutaneous administration in cattle. Such injection site swelling may be painful. Transient swelling at the injection site was observed in clinical studies following intramuscular administration in pigs. In very rare cases, anaphylactoid reactions may occur and should be treated symptomatically.

The approved indication is:

"Cattle: For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle. For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over 1 week of age and young, non-lactating cattle.

Pigs: For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation".

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 Melovem 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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