The European Medicines Agency
Veterinary Medicines and Inspections

London, 16 October 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

SUMMARY OF OPINION[*]
EQUIOXX (EMEA/V/C/142/X/001)

International Non-proprietary Name (INN):
Firocoxib

On 14 October 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[**] recommending the extension of the marketing authorisation for the veterinary medicinal product EQUIOXX. The Applicant for this veterinary medicinal product is Merial.

EQUIOXX is currently authorised as an oral paste for horses. The extension concerns the addition of a new pharmaceutical form, solution for injection.

The active substance of EQUIOXX is firocoxib, an anti-inflammatory and anti-rheumatic product, non-steroid ATCvet code: QM01AH90

The new presentations will be available as 20 mg/ml solution for injection and are to be administered as intravenous injection at a dosage of 0.09 mg firocoxib/kg bodyweight once daily. EQUIOXX 8.2 mg/g Oral Paste may be used for continuation of treatment at a dosage of 0.1 mg firocoxib/kg bodyweight once daily. The overall duration of treatment should not exceed 14 days.

The most common side effects are mild swelling at the injection site and lesions of the skin around the mouth have occasionally been observed.

The approved indication is: “Alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses”.

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 extension to 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 EQUIOXX and therefore recommends the granting of the extension of the marketing authorisation.

[*] 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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