European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 6-8 November 2007

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Rheumocam** (meloxicam), from Chanelle Pharmaceuticals Manufacturing Limited intended to alleviate inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs. This is the first opinion for a veterinary medicinal product for a company granted SME status.

The summary opinion is available on the EMEA web site: http://www.emea.europa.eu

Renewals of Marketing Authorisations

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Proteq Flu**, **Proteq Flu-Te**, **Dicural** and **Nobilis OR Inac**. The Committee, having re-assessed the benefit-risk balance of the products, concluded that the quality, safety and efficacy of the products continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

Maximum Residue Limits

The CVMP confirmed that the substances squalane and chocolate flavour, used as adjuvants and excipients, respectively do not fall within the scope of Regulation 2377/90. The list of substances not falling within the scope of Council Regulation 2377/90 was updated accordingly.

The document will be available on the EMEA web site: http://www.emea.europa.eu

Community Referrals

The Committee adopted by consensus an opinion regarding the referral under Article 33 of Directive 2001/82/EC for **Ecomectin** 18.7 mg/g oral paste for horses following a Mutual Recognition Procedure concerning the concerns raised that this veterinary medicinal product may present a potential serious risk to the environment. The Committee agreed that in application of the VICH Guideline on environmental impact assessment (phase I), the assessment can stop at phase I since the product is intended for use in a minor species (horses) that is reared and treated similarly to a major species the same conclusions on the environmental risk as for the major species would be applicable.

The Netherlands notified the EMEA that the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMD(v)) failed to reach an agreement regarding **Equibactin** vet. (333 mg/g + 67 mg/g) Oral Paste for Horses of LeVet BV. Pursuant to Article 33(4) of Council Directive 2001/82/EC, as amended, the matter was referred to the CVMP. The Committee started a referral procedure and sent a list of questions to the company.

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Scientific advice

The Committee agreed scientific advice regarding quality, safety and clinical development of a canine vaccine with a dental indication and also scientific advice regarding safety issues for an antibiotic for use in cattle.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Cortavance**, **Gonazon**, **Profender**, **Draxxin** and **Zubrin** and concluded that no further action or changes to the products literature were required. The Committee also reviewed the PSURs for **Equilis Prequenza** and **Equilis Prequenza Te** and concluded that there was a need to include information on new adverse reactions and further detail on the frequency of occurrence of adverse reactions currently included in the product literature.

Concept Papers, Guidelines and SOPs

Efficacy

The Committee adopted the revision of the "*Guideline for the Testing and Evaluation of the Efficacy of Antiparasitic Substances for the Treatment and Prevention of Tick and Flea Infestation in Dogs and Cats*" (EMEA/CVMP/EWP/005/2000-Rev.2) following the close of the public consultation. The main change to the existing guideline was to extend the scope, which now also addresses products for systemic use and insect-growth regulators (IGRs); in addition, editorial changes, including clarification to the wording of the current guideline, were made. The guideline will be implemented by 1 June 2008. The "Overview of Comments" (EMEA/CVMP/EWP/203830/2007) received during the public consultation of the document is available on the EMEA website.

The document will be available on the EMEA web site: http://www.emea.europa.eu

Antimicrobials

The Committee adopted a revised "Guideline on the SPC for antimicrobial products" (EMEA/CVMP/SAGAM/383441/2005) following the close of the public consultation. This guideline will be implemented by 1 May 2008. The guideline provides updated instructions on the information to be included in the Summary of Product Characteristics of the veterinary medicinal product containing antimicrobial substances. The revision replaces *the guideline on the SPC for antimicrobial products* (EMEA/CVMP/612/01-FINAL) and takes into account the developments during the recent years and the feedback obtained from the users on the previous guideline.

The document will be available on the EMEA web site: http://www.emea.europa.eu

Organisational Issues

The Committee appointed the following co-opted members to complement its expertise:

- Wilhelm Schlumbohm - Quality
- Christian Friis - Residue metabolism and pharmacokinetics
- Boris Kolar - Environmental Risk Assessment
- Rory Breathnach - Expertise in clinical veterinary practice

As no nominations have been received for the fifth area where additional expertise had been sought, the Committee will further consider the need for additional expertise with the aim to appoint the fifth co-opted member shortly.

The next meeting of the CVMP will be held on 11-13 December 2007

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This press release and other documents are available on the Internet at the following address:
http://www.emea.europa.eu