European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 15-17 January 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a type II variation for **Aivlosin** regarding a reduction in the shelf life of the 42.5mg/g premix for medicated feeding stuff presentations to 1 year.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the inclusion of **lectin extracted from red kidney beans** *(Phaseolus vulgaris)* in Annex II of Council Regulation (EEC) No. 2377/90 for porcine species.

The Committee adopted by consensus an opinion recommending the extrapolation of the current MRLs for **cyfluthrin** for bovine species to include also goats. This recommendation was made in accordance with the review of the risk assessment approach for the establishment of maximum residue limits with the aim of establishing a more pragmatic approach in securing the provision of medicines for treating animals, especially those classed as minor species.

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

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Neocolipor**. The Committee, having re-assessed the benefit-risk balance of the product, concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Community Referrals

The Committee started a referral procedure for all ivermectin injectable veterinary medicinal products which are indicated for use in cattle. The referral has been initiated by the United Kingdom under Article 35 of Council Directive 2001/82/EC, as amended, due to concerns regarding the withdrawal periods established in the EU Member States. A rapporteur and co-rapporteurs were appointed and a list of questions to be answered by the Applicants/Marketing Authorisation Holders was agreed.

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The Committee started a referral procedure for **Compagel** (*heparin sodium, levomenthol, hydroxyethyl salicylate*), gel for horses, from Boehringer Ingelheim Vetmedica GmbH. The matter was referred to the CVMP by Germany, the Reference Member State for the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, as amended, due to concerns raised by France and Sweden regarding the efficacy of the product.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Equilis Prequenza** and **Equilis Prequenza Te** and confirmed the recommendation to include information on new adverse reactions and further detail on the frequency of occurrence of adverse reactions currently detailed in the product literature. The Committee also reviewed the PSUR for **Convenia** and recommended the inclusion of new adverse reactions in the product literature. With regards to the PSURs for **Aivlosin** and **Econor**, the Committee concluded that no further action or changes to the products literature were required.

Concept Papers, Guidelines and SOPs

The Committee adopted a "*Guideline on Dossier Requirements for Anticancer Medicinal Products for Dogs and Cats*" (EMEA/CVMP/28510/2008-CONSULTATION) for release for a 6-months period of public consultation. This guideline outlines the particular information for oncology products in relation to quality, safety, efficacy and environmental impact requirements. The guideline was jointly prepared by the Efficacy, Safety, Quality and Environmental Risk Assessment working parties. In April 2007, a Focus Group Meeting with interested parties was held at the EMEA and discussions at this meeting were taken into account when drafting this guideline.

The Committee adopted a "*Reflection paper on antimicrobials resistance surveillance as post-marketing authorisation commitment*" (EMEA/CVMP/SAGAM/428938/2007-CONSULTATION) for release for a 3-month period of public consultation. This reflection paper addresses post-marketing authorisation measures requested in cases where the documentation provided prior to marketing authorisation could not cover all aspects of importance when assessing the risk for emergence of resistance. The objective of such measures are not to replace or repeat the monitoring of antimicrobial resistance in zoonotic and commensal bacteria currently undertaken by competent authorities of Member States but should comprise aspects not covered or intended to be covered by official monitoring programmes.

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

Regulatory Issues

The Committee adopted a "*Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure*" (EMEA/CVMP/328/98-Rev.3) following the close of the public consultation. This guideline has been revised to take into account the experience gathered since its last update in March 2002, as well as the updates to the corresponding human guideline. It further clarifies specific aspects related to "non-prescription" and "generic/hybrid/similar biological" medicinal products.

The overview of the comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/532811/2007).

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

The Committee adopted a revised "*Reflection Paper on the Implementation of Directive 2001/82/EC, as amended, in respect to the assessment of environmental risk of veterinary medicinal products*" following further legal advice by the European Commission on the previous draft. This paper has been developed following a request from the Commission to reflect further on the practical implementation of the legal provisions under the revised legislation. It addresses all applications, including generic applications, variations, extensions and renewals. The document will be submitted to the European Commission for review with the view to publish it once approved by the Commission.

Organisational Matters

Further to the appointment of 4 co-opted members in November 2007, the Committee appointed Peter Ekström as the fifth co-opted member to complement scientific expertise of the Committee on clinical veterinary practice and efficacy of pharmaceuticals with regard to specific therapeutic areas, such as anaesthesia.

The next meeting of the CVMP will be held on 12-14 February 2008

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http://www.emea.europa.eu