European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 12 - 14 December 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a Type II variation for **Equilis StrepE** regarding amendments to the special precautions for use, adverse reactions, amounts to be administered and administration route sections of the summary of product characteristics (SPC) and the associated sections of the package leaflet.

The Committee adopted by consensus a positive opinion for a Type II variation for **Profender** regarding amendments to the adverse reactions section of the summary of product characteristics (SPC) and the associated section of the package leaflet.

Following the request from the applicant for re-examination of the Type II opinion adopted on 11 October 2006 with regard to the information included in section 6.1 of the summary of product characteristics (SPC), the Committee confirmed its previous position for **Previcox Chewable Tablets** for dogs.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the extrapolation of the current MRLs for **dihydrostreptomycin** to rabbits further to a request from a company interested in developing a veterinary medicinal product containing dihydrostreptomycin in rabbits. At this occasion the CVMP also recommended the extrapolation of the existing MRLs for **streptomycin** to rabbits and all ruminants, consistent with the MRLs for dihydrostreptomycin, considering that the chemical structure and biological activity of streptomycin and dihydrostreptomycin are similar and therefore the safety of residues evaluation of the two substances had been carried out together. These recommendations were 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 Monday 18 December 2006 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 **Fevaxyn Pentofel**. The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation. Furthermore, it was agreed that no further renewal would be required.

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Community Referrals

The Committee started a referral under Article 33 of Directive 2001/82/EC for **Enurace 50**. The referral was initiated by the Reference Member State in the Mutual Recognition Procedure, The Netherlands, to resolve disagreement following concerns from France and Italy, regarding the benefit/risk ratio. A rapporteur and co-rapporteur were appointed and a list of questions to be answered by the Marketing Authorisation Holder was agreed.

Scientific advice

The Committee agreed scientific advice regarding quality issues for the development of an anthelmintic product for swine and poultry.

The Committee agreed scientific advice regarding the safety and clinical development of an immunological product for the prevention of a viral infection in cats.

The Committee agreed a scientific advice regarding the establishment of a maximum residue limit (MRL) for an antibiotic substance for use in chickens.

Pharmacovigilance

The Committee adopted by consensus an opinion regarding the procedure initiated by the Netherlands under Article 78(1) of Directive 2001/82/EC in relation to identified veterinary medicinal products containing the **alpha2-adrenoreceptor agonists** romifidine, xylazine, medetomidine or detomidine, for which authorisations have been granted in the Netherlands. The Committee agreed on a set of precautionary measures relating to user safety following exposure to alpha2-adrenoreceptor agonists to be reflected in the product literature of the concerned products. The opinion will be forwarded to the European Commission.

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Dexdomitor** and **Naxcel** and concluded that no further action or changes to the product literature of the products were required. Furthermore, the Committee reviewed a PSUR for **Metacam 0.5 mg/ml and 1.5 mg/ml**, and concluded on a recommendation to include information regarding known off-label use in the product literature. Further to its review of a PSUR for **Profender**, the Committee amended its previous recommendation to vary the marketing authorisation to include new adverse reactions to the product literature recommending now also the incidence and duration to be included and an additional adverse reaction to be added.

The Committee adopted a revision of its published statement on Cox-2 inhibitors in veterinary medicine, reconfirming its prior conclusion that no immediate regulatory actions are required with respect to Cox-2 inhibitors and NSAIDs in relation to possible cardiovascular effects and skin reactions of veterinary medicinal products (EMEA/CVMP/108858/2006-Rev.2).

The document will be available on Monday 18 December 2006 on the EMEA web site: http://www.emea.europa.eu

Guidelines, SOPs and Position Papers

Pharmacovigilance

The Committee gave the mandate to the Pharmacovigilance Working Party to develop a guideline for use of data in EudraVigilance Veterinary following consideration of the comments received during the public consultation on the concept paper on the subject (EMEA/CVMP/PhVWP/68614/2006). The comments received will be taken into an account during the development of the guideline.

Efficacy

The Committee adopted a concept paper for a revision of the Guideline for the conduct of Bioequivalence studies for veterinary medicinal products (EMEA/CVMP/EWP/295306/2006-CONSULTATION) for release for a 3-month period of public consultation. The revision was considered necessary due to the increase in generic applications and a number of queries regarding the interpretation of the guideline.

The document will be available on Monday 18 December 2006 on the EMEA web site:
http://www.emea.europa.eu

Efficacy and Safety

The Committee adopted a Guideline on pharmaceutical fixed combination products (EMEA/CVMP/83804/2005) for implementation by July 2007 following the close of the public consultation. The guideline and an overview of the comments received during the public consultation of this guideline will be published on the EMEA website.

The documents will be available on Monday 18 December 2006 on the EMEA web site:
http://www.emea.europa.eu

Quality

The Committee adopted a concept paper for the development of a Guideline on the quality aspects of single-dose veterinary spot-on product (EMEA/CVMP/QWP/434665/2006-CONSULTATION) for release for a 3-month period of public consultation.

The document will be available on Monday 18 December 2006 on the EMEA web site:
http://www.emea.europa.eu

Regulatory Issues

The Committee adopted a questions and answers document regarding application of the so-called 'sunset clause' to centrally authorised veterinary medicinal products (EMEA/CVMP/120559/2006-CONSULTATION) for a 2-month period of consultation. This document addresses questions that the Marketing Authorisation Holder may have on this topic and gives practical information on how EMEA will monitor any centrally authorised veterinary medicinal product never marketed within the EEA after granting of the marketing authorisation and any complete cessation of marketing for a three consecutive year-period.

The Committee also adopted the following guidelines and reflection papers for release for a 2-month period of pubic consultation:

- Guideline on procedures for re-examination of CVMP opinions (EMEA/CVMP/482393/2006-CONSULTATION);
- Withdrawals of marketing authorisation applications in the centralised procedure (EMEA/CVMP/425558/2006-CONSULTATION);
- Refusals of marketing authorisation applications in the centralised procedure (EMEA/CVMP/459912/2006-CONSULTATION).

The documents have been based on the recently published EMEA guidance for products for human use as similar legislative provisions exist. The guidance on re-examinations describes the procedure and gives guidance for the re-examination of different types of CVMP opinions, on the timetable for applicants/MAH's involvement and assessment by CVMP, rapporteurs, and Scientific Advisory Groups/Ad Hoc Expert Groups (SAG/AHEGs) if deemed necessary, and on the documentation to be supplied. The reflection paper on "Withdrawals" defines the scope, content and format of the documents to be published by EMEA in connection with the withdrawal of an application for a centralised veterinary product by the MAH/Applicant, taking into account commercially confidential data and the different stages of the evaluation procedure. Similarly, the reflection paper on "Refusals" defines the scope, content and format of the documents on negative opinions and refusals to be published, also taking into account commercially confidential information and the different stages of the evaluation procedure.

The Committee adopted a concept paper on How to evaluate the risk/ benefit balance of veterinary medicinal products (EMEA/CVMP/377102/2006-CONSULTATION) for release for a 3-month period of public consultation. Whilst Risk/Benefit considerations have long been part of the decisions on marketing authorisations, the new legislation places an increased emphasis on the Risk/Benefit balance when granting a marketing authorisation as well as of any re-evaluation of the product when pharmacovigilance data are provided or at renewal. The future guideline on Risk/Benefit analysis evaluation is aimed at improving the methodology for Risk/Benefit analyses to provide for a more systematic approach, hence improving the consistency of decisions taking at the CVMP level.

The document will be available on Monday 18 December 2006 on the EMEA web site: http://www.emea.europa.eu

The Committee adopted a reflection paper on the assessment of environmental risk of veterinary medicinal products considering generic applications, variations, extensions and renewals, attempting to review the interpretation of the new provisions regarding environmental risk assessment under Directive 2001/82/EC, as amended by Directive 2004/28/EC, as to their scientific requirements and practical applicability. This reflection paper has been developed following a request from the Commission to reflect further on the practical implementation of these new legal provisions. The document will be submitted to the European Commission for review.

The next meeting of the CVMP will be held on 16-18 January 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