European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 11-13 November 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for **Loxicom** (*meloxicam*), oral suspension for dogs and solution for injection for dogs and cats, intended for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs (oral suspension and solution for injection) and in the case of the solution for injection reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery in dogs, and reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery in cats.

The Committee adopted by consensus a positive opinion for **Porcilis PCV** (vaccine containing *Porcine circovirus type 2 ORF2 subunit antigen*), an emulsion for injection, intended for the active immunisation of pigs to reduce the virus load in blood and lymphoid tissues and to reduce weight loss associated with Porcine circovirus (PCV) type 2 infection occurring during the fattening period.

Summary of opinions are available on the EMEA web site: http://www.emea.europa.eu

The Committee adopted by consensus positive opinions for type II variation applications for:

Equilis StrepE - the addition of an alternative site for production of the solvent;

Equilis StrepE - the replacement of the stabiliser and amendment of the production process and quality control method;

Equilis StrepE - the replacement of the applicator of Equilis StrepE.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Novem**. 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.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the inclusion of **monepantel** in Annex I of Council Regulation (EC) No 2377/90 for sheep and the establishment of provisional maximum residue limits for goats.

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Further to the recommendation of the CVMP to include oxytetracycline for honey bees in Annex I of Regulation 2377/90, the European Commission requested the Committee to reconsider its opinion in view of the fact that the theoretical maximum daily intake of residues, calculated with the existing MRLs, exceeds the ADI. Following the European Commission's request the CVMP revisited the issue and agreed to revise its opinion and recommended the establishment of a provisional maximum residue limit for oxytetracycline in honey. The CVMP noted the relevance of ongoing international debate on the topic of how consumer exposure should be modelled and the make up of the standard food basket, and considered that the outcome of this debate should be awaited before a final decision is made on MRLs for oxytetracycline in honey.

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

Referrals

The Committee started a referral procedure for **Tildren 500mg** (*tiludronic acid*), from CEVA Animal Health Limited. The matter was referred to the CVMP by the United Kingdom as the reference Member State in a decentralised procedure, under Article 33 of Directive 2001/82/EC, due to concerns relating to the efficacy of the product.

Scientific advice

The Committee agreed scientific advice regarding safety aspects of a vaccine for swine.

Pharmacovigilance

The Committee adopted by consensus a revised opinion regarding the procedure 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 EU. The Committee confirmed its previous conclusions agreeing 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 the PSURs for **Cerenia**, **Cortavance**, **Draxxin**, **Equilis Prequenza**, **Equilis Prequenza Te**, **Medicinal Oxygen Air Liquide Santé**, **Meloxidyl**, **Porcilis Porcoli**, **Prac-Tic, Suprelorin** and **Ypozane** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Immunologicals

The Committee adopted a "*Guideline on requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue*" (EMEA/CVMP/IWP/220193/2008) following the close of the public consultation. This guideline has been developed in response to the growing threat of outbreaks of Bluetongue within the northern part of Europe and the lack of vaccines with Marketing Authorisations within the Community. This guideline aims to provide guidance to applicants on the minimum data requirements for authorisation of bluetongue vaccines for emergency use under Article 26 of Directive 2001/82/EC, as amended, and Article 39(7) of Regulation 726/2004. Additional guidance on measures to facilitate the rapid inclusion of new or different virus serotypes in authorised vaccines and advice on requirements for vaccines intended for use in particular epidemiological situations will be the subject of a future revision.

The overview of the comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/CVMP/IWP/521211/2008).

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

Environmental Risk Assessment

The Committee adopted a revised "*Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)*" (EMEA/CVMP/ERA/418282/2005-Rev.1) following the close of the public consultation. This guideline has been updated to provide further clarification to the application of the guideline following its initial publication in April 2007.

The overview of the comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/CVMP/ERAWP/571947/2008) together with the minutes of the Focus Group meeting held on 23 January 2008 to discuss the above mentioned guideline (EMEA/CVMP/ERA/106566/2008) and also a Question and Answer document (EMEA/CVMP/ERA/172074/2008). This Question and Answer document will be updated as needed according to the questions received on the guideline.

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

The next meeting of the CVMP will be held on 9-11 December 2008

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http://www.emea.europa.eu