The European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 8 to 10 November 2005

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an extension application for **Aivlosin** premix for medicated feedingstuff from ECO Animal Health concerning a new strength (8.5 mg/g).

The Committee also adopted by majority a positive opinion on an extension application for **Aivlosin** concerning a new pharmaceutical form (oral powder).

The Committee adopted by consensus a positive opinion for a type II variation for **Zubrin** regarding an extension of the indication and the duration of treatment to allow treatment of dogs with chronic conditions.

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

Establishment of Maximum Residue Limits

The Committee adopted a revised list of substances considered as not falling within the scope of Council Regulation (EEC) No 2377/90 (EMEA/CVMP/046/00-Rev. 7) in order to include **oxygen** in the list.

The document will be available on Monday 14 November 2005 on the EMEA web site: http://www.emea.eu.int

Community Referrals

The Committee adopted by majority a revised opinion with regard to the referral concerning the Marketing Authorisations existing in several EU Member States for Micotil 300 (tilmicosin). The referral had been initiated by France following the receipt of a second report in April 2004 of a fatal accidental injection associated with Micotil in a human being in the USA. The Committee adopted an initial opinion in December 2004 concluding that the benefits of Micotil under appropriate use outweigh the potential risk to the user and recommended specific measures such as restriction of use by veterinarians, amended safety warnings and better guidance on advisable courses of treatment should accidental administration occur. Further to receipt of new information regarding the options of treatment following accidental administration, the European Commission requested the Committee to review its previous opinion taking into account the new information made available. The Committee amended its previous opinion providing expanded guidance on advisable treatment in the case of accidental human injection.

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Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Porcilis AR-T DF**. 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.

Scientific Advice

The Committee adopted scientific advice on the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) concerning safety issues for a product for the treatment of sheep parasites.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Gonazon**, **Metacam** and **Novem** and concluded that no further action or changes to the product literature of the products were required.

The Committee updated the public statement released in April with regard to Cox-2-inhibitors in the light of recent developments in human medicine. Following the investigation from the CVMP Pharmacovigilance Working Party who looked at the available safety data in relation to NSAIDs in the different Member States it was concluded that suspected symptoms of cardiotoxicity and skin toxicity are rarely reported and that no action was required in relation to currently authorised veterinary products (EMEA/CVMP/108858/2005-Rev.1).

The document will be available on Monday 14 November 2005 on the EMEA web site:
http://www.emea.eu.int

Concept Papers, Guidelines and SOPs

Safety

The Committee adopted a concept paper on Guidance on the approach on how to demonstrate whether a substance is capable of pharmacological action or not (EMEA/CVMP/SWP/139646/2005-CONSULTATION) for release for a 3-month period of public consultation. According to the EU legislation maximum residue limits need to be established for pharmacologically active substances prior to the marketing authorisation, and this requirement applies also for excipients, if they are pharmacologically active. Unless an excipient is included in Annex I, II or III of Regulation 2377/90, proof of the absence of pharmacological activity is to be provided at the stage of the marketing authorisation application. The objective of the intended guideline is to provide guidance on how to demonstrate whether a substance is capable of pharmacological action or not.

The Committee also agreed a document clarifying the approaches on how to consider the excipients in the context of Council Regulation 2377/90 (EMEA/CVMP/223005/2005).

These documents will be available soon on the EMEA web site:
http://www.emea.eu.int

Immunologicals

The Committee adopted a revised Guideline on requirements and controls applied to bovine serum used in the production of immunological veterinary medicinal products (EMEA/CVMP/743/00-Rev.2). The only change affected by this revision was a clarification to Section 3 (Legal Basis) of the document that this guideline concerns the application of Title II of Annex I to Directive 2001/82/EC as amended to address the data requirements that need to be fulfilled for each new batch of bovine serum used in the manufacture of immunological veterinary medicinal products. The guideline will be effective from 1 January 2006.

The document will be available on Monday 14 November 2005 on the EMEA web site: http://www.emea.eu.int

International Harmonisation

Following endorsement by the VICH Steering Committee at its 17th meeting on 1 and 2 November 2005 in Kyoto, Japan, the CVMP adopted four VICH guidelines.

The Committee adopted the VICH Quality guidelines as new EU guidelines following the close of the public consultation:

- GL 39 on Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances (EMEA/CVMP/VICH/810/04);
- GL 40 on Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products (EMEA/CVMP/VICH/811/04).

The guidelines will be implemented by November 2006.

The Committee adopted two draft VICH pharmacovigilance guidelines for public consultation for a reduced period of 3 months.

- Revised Draft GL 24: Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AERs) (EMEA/CVMP/VICH/547/00-CONSULTATION);
- Draft GL 42: Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports (EMEA/CVMP/VICH/355996/2005-CONSULTATION).

A public consultation of draft guideline GL 24 had been held previously. During the subsequent discussions section V of draft GL 24 was turned into a separate guideline (GL 42). Considering the important changes made to these documents since the first consultation, the VICH Steering Committee decided to hold a second public consultation.

The documents will be available on Monday 14 November 2005 on the EMEA web site: http://www.emea.eu.int

Further to the request from the Commission the Committee agreed comments on the proposal from Codex Alimentarius for the future organisation of the Codex work on antimicrobial resistance work on antimicrobial resistance (Circular Letter CL 2005/33-CAC of the Codex Alimentarius Commission).

The Committee also agreed on comments on Maximum Residue Limits for Veterinary Drugs for consideration by the 16th Session of the Codex Committee on Residues of Veterinary Drugs In Foods (CCRVDF) to be held on 8-12 May 2006. The MRLs concern the substances flumequine, pirlimycin, cypermethrin, alpha-cypermethrin and doramectin, at step 6 of the Codex procedure.

These comments will be submitted to the Commission for the preparation of EU comments.

Regulatory Issues

The Committee reviewed certain aspects of the implementation of the new legislation for the authorisation of veterinary medicinal products and agreed on a draft guideline for the processing of renewals in the centralised procedure. The draft guideline will be reviewed by the European Commission before release for consultation.

In the context of the implementation of the new legislation the Committee also agreed on transitional measures for submission of Periodic Safety Update Reports (PSURs) for centrally authorised products further to the consideration of comments received from the European Commission. The document will be published on the EMEA website further to the endorsement of the CHMP.

The next meeting of the CVMP will be held on 6-8 December 2005

CVMP Secretariat
Veterinary Medicines and Inspections Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int