European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/165988/2006
London, 19 May 2006

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 16 to 18 May 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted a negative opinion on an initial marketing authorisation application for **Veraflox** (containing pradofloxacin) intended for oral administration to cats and dogs for the treatment of specific skin and soft-tissue infections, and specific acute infections of the upper respiratory tract and the urinary tract.

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

The Committee adopted by consensus a positive opinion for a type II variation for **Porcilis Porcoli** regarding an extension of the shelf-life of the product and other quality changes.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **fenvalerate** in Annex I of Council Regulation (EEC) No. 2377/90 in cattle further to the establishment of provisional MRLs expiring on 1 July 2007.

The Committee adopted by consensus an opinion recommending the inclusion of **thiamphenicol** in Annex I of Council Regulation (EEC) No. 2377/90 for all food producing species. This recommendation was made as MRLs had previously been established in cattle and chicken and the CVMP could agree at this meeting also to recommend final MRLs in pigs further to the previous establishment of provisional MRLs. Thus, this enabled the extrapolation of the MRLs set in these three species to all food producing species, as the criteria of the CVMP guidance on the extrapolation of MRLs (CVMP Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in food of animal origin) were met.

The Committee adopted by consensus an opinion recommending the extrapolation of the current MRLs for **meloxicam** to rabbits and goats further to a request from a company. Meloxicam is currently included in Annex I of Council Regulation 2377/90 with MRLs established for cattle, pigs and horses and this recommendation was made in accordance with the above mentioned CVMP guidance on MRL extrapolations.

The summary opinions will be available on Monday 22 May 2006 on the EMEA web site: http://www.emea.eu.int

Scientific Advice

Following the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) the Committee adopted scientific advice concerning the safety and clinical development of a new canine vaccine for the treatment of leptospirosis.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int

Pharmacovigilance

The Committee reviewed the Periodic Safety Update Reports (PSUR) for **Dexdomitor** and **SevoFlo** and concluded that no regulatory action or change to the product literature of the products is required.

Referrals

The Committee concluded the evaluation of the referral initiated following disagreement within the Mutual Recognition Procedure for **Cobactan IV 4.5%** (cefquinome). The procedure was referred to the Committee by the Reference Member State under Article 33 of Directive 2001/82/EC due to concerns raised by one Concerned Member State, United Kingdom, regarding the safety of the starting material 2,3-cyclohexenopyridine which is also an impurity of cefquinome. The Committee adopted by consensus an opinion concluding that there were no concerns that 2,3-cyclohexenopyridine would represent a potential serious risk to animals or users of the product. The opinion will be forwarded to the Commission.

The Committee concluded the evaluation of the referral initiated by Belgium under Article 35 of Directive 2001/82/EC for **Suramox 15% LA** (amoxicillin) and the associated invented name, **Stabox 15% LA.** The referral was initiated due to divergent opinions from Concerned Member States during the Mutual Recognition Procedure with regard to the withdrawal period established for cattle and pigs. The Committee adopted by consensus an opinion recommending the suspension of the marketing authorisations for Suramox 15% LA and the associated invented name Stabox 15% LA, for cattle and pigs. The reasons being the following:

- it was not possible to establish a withdrawal period for cattle and pigs based on the data available;
- the currently established withdrawal periods for cattle and pigs are inadequate to ensure that residues do not exceed the MRLs;
- the currently authorised withdrawal periods are inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer.

The grounds for the suspension will be reviewed as soon as new data are submitted for evaluation.

Appeals against these opinions may be launched by the companies concerned within the deadlines provided by legislation.

The Committee also started a referral procedure for **Equimectin 12mg/g** oral gel for horses from Le Vet B.V.. The product is indicated for the treatment of endo-and ectoparasitic infections in horses, particularly gastrointestinal nematodes, dermal nematodes, lung nematodes and bots. The matter was referred to the CVMP by the Netherlands under Article 33(4) of Directive 2001/82/EC, as amended following a Mutual Recognition Procedure initiated due to concerns regarding the demonstration of efficacy of the product.

Immunologicals

The Committee adopted a public statement regarding the need for sterility testing at the end of the proposed shelf-life for Immunological Veterinary Medicinal Products (EMEA/CVMP/168467/2006). In this statement the CVMP clarifies that for variations affecting the extension of the shelf-life for antigen stocks in immunological veterinary medicinal products sterility testing should not be required at the end of the proposed shelf-life.

The statement is available on the EMEA web site: http://www.emea.eu.int

Regulatory Issues

The Committee adopted a revised 'Guideline on the Procedure for Accelerated Assessment Pursuant to Article 39(8) of Regulation (EC) No 726/2004' following a 1-month period of public consultation (EMEA/CVMP/32995/2006-Rev.1). The guideline has been updated to take into account comments received from IFAH-Europe and AVC as well as the updated human guideline and is now being published with immediate effect.

The document will be available on Monday 22 May 2006 on the EMEA web site: http://www.emea.eu.int

The next meeting of the CVMP will be held on 20-22 June 2006

David Mackay
Head, 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