European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/323417/2006

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 12 to 14 September 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Yarvitan** intended for the treatment of overweight and obesity in dogs.

Following the request for a re-examination of the negative opinion adopted on 17 May 2006, the Committee confirmed its previous position and adopted by majority an opinion recommending not to grant a marketing authorisation 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 opinions are available on the EMEA web site: http://www.emea.europa.eu

Maximum Residue Limits

The Committee adopted by consensus a negative opinion concerning the modification of the acceptable daily intake (ADI) for **amoxicillin** and the establishment of a maximum residue limit in eggs.

The Committee adopted by consensus an opinion recommending the inclusion of **ginseng, standardised extracts and preparations thereof** in Annex II of Council Regulation 2377/90 for all food producing species.

The Summary opinions will be available on Monday 18 September 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 **Virbagen Omega**. 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.

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Referrals

Following a request for the re-examination of the opinion adopted on 17 May 2006, the Committee confirmed its previous position and adopted by consensus an opinion recommending the suspension of the marketing authorisations for **Suramox 15% LA** (amoxicillin) and the associated invented name, **Stabox 15% LA** 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 referral was initiated by Belgium under Article 35 of Directive 2001/82/EC. The CVMP will review the grounds for the suspension should new data on the establishment of withdrawal periods be submitted for evaluation.

The Committee considered the notification for a referral under Article 34 of Directive 2001/82/EC for **Methaxasol T** from Germany, due to different decisions on granting the marketing authorisation taken by Member States. The referral was submitted to the Committee due to concerns that the efficacy of the product has not been adequately justified. A Rapporteur and a Co-Rapporteur were appointed and a list of questions to be responded to by the Marketing Authorisation Holder was agreed.

Scientific advice

The Committee agreed two separate scientific advice procedures regarding the clinical development of a product for the treatment of atopic dermatitis in dogs and also advice regarding the pharmacological activity of an excipient (metacresol). Regarding the latter the Committee concluded that metacresol, does not fall within the scope of Council Regulation 2377/90 at the dose at which it is intended to be administered to the target animals. The CVMP list of substances considered as not falling within the scope of Regulation 2377/90 has been updated accordingly (EMEA/CVMP/046/00-Rev.9).

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

Pharmacovigilance

Further to the notification from the Netherlands the Committee initiated a procedure in accordance with Article 78 of Directive 2001/82/EC to consider the need for additional precautionary measures concerning user safety in relation to identified veterinary medicinal products containing the **alpha2-agonists** romifidine, xylazine, medetomidine or detomidine, for which authorisations have been granted in the Netherlands.

The Committee reviewed the Periodic Safety Update Report (PSUR) for **ProteqFlu-Te** and concluded that no regulatory action or change to the product literature of the product is required.

Concept Papers, Guidelines and SOPs

Pharmacovigilance

The Committee adopted the Summary of amendments of VEDDRA terminology (animal & human) 2006 and the following standard lists used for electronic reporting of suspected adverse reactions*:*

- VEDDRA list of clinical terms for adverse reactions in animals
- VEDDRA list of clinical terms for adverse reactions in humans
- List of species and breeds
- List on additional controlled terminology

The date for implementation of these lists will be decided by the Joint Implementation Group in October 2006 and their publication on the EMEA website will follow.

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This press release and other documents are available on the Internet at the following address:
http://www.emea.europa.eu