European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 20 to 22 June 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a type II variation for **Rabigen SAG2** regarding the replacement of an excipient.

The Committee adopted by consensus a positive opinion for a type II variation for **Eurican Herpes 205** regarding the transfer of part of the manufacturing process.

The Committee noted that the applicant has requested a re-examination of the CVMP opinion on the marketing authorisation application for **Veraflox** that was adopted during the May 2006 meeting. The re-examination procedure will be initiated once the company has submitted the grounds for the request.

Scientific Advice

Following the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) the Committee agreed scientific advice regarding the clinical development of a product with a proposed indication for a metabolic disorder in cattle.

Referrals

The Committee started a referral procedure for **Doxyprex 100 mg/g premix**. The product is indicated for the treatment of swine respiratory disease caused by susceptible *Pasteurella multocida, Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae* to doxycycline. The matter was referred to the CVMP by Spain under Article 33(4) of Directive 2001/82/EC, as amended, following a Mutual Recognition Procedure. The referral was initiated due to concerns regarding the demonstration of the product's efficacy.

The Committee noted that the Marketing Authorisation Holder has requested a re-examination of the CVMP opinion on the referral procedure concerning **Suramox 15% LA** that was adopted during the May 2006 meeting. The re-examination procedure will be initiated once the company has submitted the grounds for the request.

Pharmacovigilance

The Committee reviewed the Periodic Safety Update Reports (PSUR) for **Draxxin, Naxcel, Nobivac Bb, Purevax RC, Purevax RCCh, Purevax RCP, Purevax RCP FeLV, Purevax RCPCh** and **Purevax RCPCh FeLV,** and concluded that no regulatory action or change to the product literature of the products is required.

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The Committee also reviewed the PSUR for **Equilis StrepE** and recommended that the SPC is updated to reflect new information concerning points 5.4 "Undesirable effects," by adding new adverse reactions, and 5.12 "Special precautions to be taken by the person administering the medicinal product to animals" by adding instructions for appropriate administration to the user and advice to the physician in case of accidental exposure in man leading to reactions.

The Committee also reviewed the PSUR for **Profender** and recommended that the SPC is updated concerning point 5.4 "Undesirable effects" by adding new adverse reactions.

Concept Papers, Guidelines and SOPs

Quality

The Committee adopted the "*Guideline on the declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC*" for release for a 6-month period of public consultation (EMEA/HMPC/287539/2005-CONSULTATION). The guideline was developed in order to clarify how herbal medicinal products should be described in the SPC, in particular their qualitative and quantitative composition.

The Committee adopted a concept paper for the development of a guideline on the quality of combination herbal medicinal products/traditional herbal medicinal products for release for a 3-month period of public consultation (EMEA/HMPC/58222/2006-CONSULTATION). The concept paper follows the new legislation on traditional herbal medicines (for human use), which highlighted the lack of guidance and the need for clarification on aspects of combination herbal products. Although Council Directive 2004/24/EC is applicable only to human herbal products, the same regulatory principles would apply to veterinary combination herbal products.

The Committee adopted a concept paper on the revision of the *"Guideline on the use of near-infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations"* for release for a 3-month period of public consultation (EMEA/CHMP/QWP/173698/2006-CONSULTATION). The concept paper is a result of identification of the need to update the guideline for this new technology in the light of regulatory experience, technical developments, and feedback from both regulators and the pharmaceutical industry.

Efficacy

The Committee adopted the "*Guideline on the SPC for anthelmintics*" for release for a 6-month period of public consultation (EMEA/CVMP/EWP/170208/2005-CONSULTATION). The guideline was developed due to concerns about the increase in anthelmintic resistance against products used in ruminants and horses. It recommends adding standard warnings to the SPC and product literature of anthelmintics authorised for these species, if appropriate. During the development of the guideline, a focus group meeting with interested parties took place in February 2006 and conclusions made at this meeting have been taken into account in the preparation of this guideline.

Pharmacovigilance

The Committee adopted a concept paper for a guideline on use of data in EudraVigilance veterinary for release for a 4-month period of public consultation (EMEA/CVMP/68614/2006-CONSULTATION). The concept paper points out the issues to be further considered in the foreseen guideline, including the purpose of using the data, parties to be involved in the use, signal detection and transformation of the knowledge into regulatory measures and information to the public.

The documents will be available on Monday 26 June 2006 on the EMEA web site:
http://www.emea.eu.int

The Committee adopted the "*Simple guide to veterinary pharmacovigilance in the EU*" (EMEA/CVMP/PhVWP/110607/2005). The guide is aimed at veterinarians and other health professionals. It explains the concept and importance of pharmacovigilance, the reporting system for suspected adverse reactions, and the use of the reported data. The English version of the guide will be published on the EMEA website. The guide will then be published in the near future by Member States in their national language(s).

The document will be available on Monday 26 June 2006 on the EMEA web site:
http://www.emea.eu.int

Organisational matters

The Committee agreed to the organisation of an EMEA/IFAH Europe Info day to be held on 9-10 November 2006. The Info day is intended to be a forum for information and discussion of topics of interest to the Committee and Interested Parties.

The Committee confirmed the organisation of a meeting with Interested Parties to be held on 19 July 2006. The meeting will address topics to be proposed by the Interested Parties.

The next meeting of the CVMP will be held on 18-20 July 2006

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