European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 13-15 January 2009

CVMP Opinions on Veterinary Medicinal Products

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

Promeris Duo – addition of new therapeutic indication, new information on activity against ticks, addition of local signs of possible adverse reactions and change of application site and the amendment of the SPC and Product Literature with inclusion of additional precautionary measures concerning respiratory reactions in humans;
Purevax RCPCh FeLV – addition of an alternative site for the production of inactivated feline calicivirus antigens and update of the product information to include an additional warning in section 4.6 of the SPC and section 6 of the package leaflet;

Purevax RCPCh – addition of an alternative site for the production of inactivated feline calicivirus antigens and update of the product information to include an additional warning in section 4.6 of the SPC and section 6 of the package leaflet;
Purevax RCP FeLV – addition of an alternative site for the production of inactivated feline calicivirus antigens;

Purevax RCP – addition of an alternative site for the production of inactivated feline calicivirus antigens;
Purevax RC – addition of an alternative site for the production of inactivated feline calicivirus antigens;
Purevax RCCh – addition of an alternative site for the production of inactivated feline calicivirus antigens and update of the product information to include an additional warning in section 4.6 of the SPC and section 6 of the package leaflet.

Renewals of Marketing Authorisations

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

Maximum Residue Limits

The Committee adopted by majority a positive opinion recommending the inclusion of gamithromycin in Annex I of Council Regulation (EEC) No. 2377/90 for bovine species further to establishment of provisional maximum residue limits (MRLs). Gamithromycin is currently included in Annex III with provisional MRLs established for bovine species expiring on 1 July 2009.

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

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.europa.eu http://www.emea.europa.eu

The CVMP considered that the substance **isopropyl myristate** is not pharmacologically active when used as excipient at doses up to 5 mg/kg bw and therefore at these doses does not fall within the scope of Regulation 2377/90. The list of substances not falling within the scope of Council Regulation 2377/90 was updated accordingly (EMEA/CVMP/046/00).

The document is available on the EMEA web site: http://www.emea.europa.eu

Community Referrals

The Committee concluded the referral procedure for **Enro-K 10% Oral Solution** (e*nrofloxacin)*, for chickens and turkeys. The matter was referred to the CVMP by Ireland, the reference Member State for the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns relating to the environmental risk assessment raised by Germany, as concerned Member State. The Committee adopted by consensus an opinion concluding that the use of the product as recommended does not constitute a risk for the environment and therefore the objections raised by Germany should not prevent the granting of a marketing authorisation.

The Committee concluded the referral procedure for **Unisol (Aviflox) 10% Oral Solution** (e*nrofloxacin)*, for chickens and turkeys. The matter was referred to the CVMP by Ireland, the reference Member State for the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, due to concerns relating to the environmental risk assessment raised by Germany, as concerned Member State. The Committee adopted by consensus an opinion concluding that the use of the product as recommended does not constitute a risk for the environment and therefore the objections raised by Germany should not prevent the granting of a marketing authorisation.

The Committee were unable to accept a referral procedure for **Uniferon 200 mg/ml solution for injection**, an iron dextran injection for piglets from Pharmacosmos A/S. The matter was referred to the CVMP by Denmark as the reference Member State in the mutual recognition procedure, under Article 33 of Directive 2001/82/EC, due to concerns related to quality raised by Germany. Further to advice received from the European Commission indicating that the scientific basis for the issues raised was not open to deliberation by the Committee in view of the over-riding obligation to meet particular legal requirements, the Committee did not initiate the procedure.

The Committee noted that the Marketing Authorisation Holder has requested a re-examination of the CVMP opinion on the referral procedure concerning **Pharmasin 100% w/w water soluble granules** that was adopted during the December 2008 meeting. The re-examination procedure will be initiated once the company has submitted the grounds for the request.

Pharmacovigilance

The Committee reviewed the PSURs for **Ingelvac CircoFLEX**, **Poulvac Flufend H5N3 RG**, **Profender** and **Vaxxitek HVT+IBD** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Quality

The Committee adopted a revised "*Guideline on the quality aspects of single-dose veterinary spot-on products*" (EMEA/CVMP/QWP/544461/2007) following the close of public consultation. The guideline provides recommendations on certain quality-related issues for single-dose spot-on products and has been updated to take account of some of the comments received during the public consultation. The guideline will come into effect on 1 February 2010.

The overview of comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/CVMP/QWP/25621/2009).

The Committee adopted a Question and Answer document on Plastic Immediate Packaging Materials (EMEA/CHMP/CVMP/QWP/663093/2008). This short document aims to clarify the acceptability of plastics complying with the relevant EU food legislation (for plastics and articles intended to come into contact with foodstuffs) for use as immediate packaging for solid oral dosage forms and active substances for medicinal products for veterinary or human use.

The Committee endorsed the Standard Operating Procedure (SOP) on Management of pharmacovigilance Rapid Alerts (RAs) and Non Urgent Information (NUI) for medicinal products for veterinary use. This SOP standardises the related communication and actions within the Agency, including the Committee and its Pharmacovigilance Working Party, and relates to other procedures on pharmacovigilance issues.

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

Organisational Matters

The Committee adopted the following documents prepared by the Pharmacovigilance Inspectors Working Group:

- Procedure for the preparation of a risk-based programme for routine PhV Inspections of MAHs connected with Veterinary Centrally Authorised Products (CAPs) (EMEA/INS/GCP/390778/2008);
- Procedure for coordination of pharmacovigilance inspections requests by the CVMP (EMEA/INS/GCP/85059/2008).

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

The Committee agreed the programme for the EMEA/IFAH Europe Info Day to be held on 12-13 March 2009 at the EMEA, which will focus on the latest developments in scientific reviews, legislation and marketing authorisation procedures.

The next meeting of the CVMP will be held on 10-12 February 2009

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.europa.eu