The European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 14 to 16 February 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a Type II variation for **Porcilis Pesti** regarding a new manufacturing site for the antigen.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of provisional MRLs for **lasalocid** in **poultry eggs**. Lasalocid already has final MRLs established for poultry tissues.

The Committee adopted by consensus an opinion recommending the extrapolation of the current MRLs for **flubendazole** to poultry further to a request from the applicant. This recommendation was made in accordance with the review of the risk assessment approach for the establishment of maximum residue limits with the aim of establishing a more pragmatic approach in securing the provision of medicines for treating animals, especially those classed as minor species.

Renewals of Marketing Authorisations

The Committee adopted, by consensus, a positive opinion for the renewal of the marketing authorisation for **Eurican Herpes 205**. 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 the clinical development of a veterinary medicinal product for the treatment of congestive heart failure in dogs.

Pharmacovigilance

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

The Committee endorsed the public bulletin on veterinary pharmacovigilance for 2005 summarising the EMEA activities regarding pharmacovigilance for veterinary medicinal products during the passed year. Annual public bulletins on veterinary pharmacovigilance are being produced by the EMEA with the intention to improve communication to all stakeholders, but particularly to veterinary health professionals, on the surveillance of the safety of veterinary medicines in the EU.

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The bulletin includes descriptive statistics on suspected adverse reactions reports and safety updates, and provides an overview of the activities and issues addressed during 2005.

The document will be available on Monday 20 February 2006 on the EMEA web site: http://www.emea.eu.int

Concept Papers, Guidelines and SOPs

Avian Influenza

At the request of the European Commission, the Committee considered the minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against H5 and/or H7 highly pathogenic avian influenza virus.

The Committee is therefore publishing the Reflection paper (EMEA/CVMP/46853/2006) on such minimum data requirements in order to assist applicants in submitting applications and to provide information on the current status of discussions on this topic which could form the basis of future guidance.

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

Regulatory Issues

The Committee adopted a Guideline on the procedure for accelerated assessment pursuant to Article 39(8) of Regulation (EC) No 726/2004 for release for a one month period of public consultation (EMEA/CVMP/32995/2006-CONSULTATION). It is foreseen that this guideline will be of particular relevance to any forthcoming centralised avian influenza vaccine applications.

The document will be available on Monday 20 February 2006 on the EMEA web site: http://www.emea.eu.int

The next meeting of the CVMP will be held on 14-16 March 2006

CVMP Secretariat
Veterinary Medicines and Inspections Unit
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http://www.emea.eu.int