European Medicines Agency
Veterinary Medicines and Inspections

London, 20 June 2008
EMEA/CVMP/276992/2008

PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 17-19 June 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted a positive opinion for **Profender** (*emodepside*, p*raziquantel*), regarding the addition of a new pharmaceutical form (modified release tablets), given by a new route of administration (oral) to a new target species (dogs).

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

The Committee noted that the applicant has requested a re-examination of the CVMP opinion on the marketing authorisation application for **Masivet** (*masitinib*) that was adopted during the May 2008 meeting. The re-examination procedure will be initiated once the applicant has submitted the detailed grounds for the request for re-examination.

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

- **Convenia -** for an additional supplier for the starting material;
- **Poulvac FluFend H5N3 RG** – to broaden the target species for the product from Pekin ducks to all ducks;
- **Dexdomitor** – to add a new rubber stopper and to remove an incompatibility warning from the product literature.

The Committee adopted by majority a negative opinion with regard to a variation application for **Porcilis Porcoli** to remove substances of animal origin from the production media for one of the antigens. The Committee considered that the data presented were insufficient to allow a complete assessment of the variation.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the inclusion of **isoeugenol** in Annex IV of Council Regulation (EC) No 2377/90. The recommendation followed the assessment of an application for the establishment of maximum residue limits for isoeugenol and in particular the results of recently conducted chronic toxicity/carcinogenicity studies in rats and mice by the US National Toxicology Programme (NTP).

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

Referrals

The Committee concluded the assessment of new residue data as a follow-up to the referral for **Suramox 15% LA** (***amoxicillin***), from Virbac S.A., concluding that withdrawal periods for both cattle and pigs can now be established. Therefore, the Committee adopted by consensus an opinion recommending the lifting of the suspension of the marketing authorisations for **Suramox LA 15%** and its associated name **Stabox 15% LA**.

The marketing authorisations for these products were suspended by the Commission Decision of 13 June 2007 further to an opinion of the CVMP on a referral initiated by Belgium under Article 35 of Directive 2001/82/EC. The CVMP had concluded that the data available at the time did not allow the establishment of withdrawal periods for either cattle or pigs.

The background information on the procedure, as well as the scientific conclusions, the summary of the product characteristics (SPC), the package leaflet and the labelling for the product, will be published on the EMEA website once a Commission's Decision is taken on this procedure.

Scientific advice

The Committee agreed scientific advice regarding quality, safety and clinical development aspects of a vaccine for the prevention and control of a bacterial respiratory disease in pigs.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Circovac, Cortavance, Nobilis Influenza H7N1, Suprelorin** and **Ypozane** and concluded that no further action or changes to the product literatures were required.

The Committee endorsed the study methodology developed by IFAH-Europe to investigate the presence of putatively replication competent RD114 retrovirus (xenotropic endogenous feline retrovirus) in cell lines used for the production of veterinary vaccines.

Concept Papers, Guidelines and SOPs

Immunologicals

The Committee adopted a "*Guideline on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue*" (EMEA/CVMP/IWP/220193/2008-CONSULTATION) for release for a 6-month period of public consultation. The guideline follows the publication of a reflection paper in April 2007 and further specifies the data requirements necessary for an authorisation under exceptional circumstances.

Quality

The Committee adopted a Question and Answer document on process validation and other quality data requirements (EMEA/CHMP/CVMP/QWP/139037/2008). This document provides guidance on the data for applications submitted by companies who acquired the rights to the data from another company.

The Committee adopted a Concept Paper on the development of a guideline on setting specifications for related impurities in antibiotics (EMEA/CHMP/CVMP/QWP/136351/2008-CONSULTATION) for release for a 3-month period of public consultation. The development of the guideline intends to provide guidance to industry and regulators on defining acceptance criteria for related impurities in antibiotics produced by fermentation or semi-synthetic processes as currently no such guidance exists for these types of antibiotics.

Safety

The Committee adopted a "*Reflection paper on injection site residues: Considerations for risk assessment and residue surveillance"* (EMEA/CVMP/520190/2007-CONSULTATION) for release for a 3-month period of public consultation. In the document the Committee explores options for risk assessment of injection site residues considering in its review their impact on residue control. This paper is not only for discussion at European level but is intended to be circulated to international organisations for debate.

Environmental risk assessment

The Committee adopted a revised text of the CVMP "*Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH Guidelines GL6 (PHASE I) and GL38 (PHASE II)*" (EMEA/CVMP/ERA/418282/2005-Rev.1-CONSULTATION) for release for a 3-month period of public consultation. The revision of the guideline is a follow-up of a Focus Group meeting with Industry representatives held on 23 January 2008. The objective of the Focus Group meeting was to provide further clarification on the CVMP guideline. The changes made to the guideline are relatively minor and therefore, a shortened public consultation is considered appropriate. The public consultation refers exclusively to the changes made in the revised guideline.

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

International Harmonisation

The Committee endorsed a document prepared by its Safety Working Party discussing the new approach developed by Joint FAO/WHO Expert Committee on Food Additives (JECFA) for exposure and MRL assessment of residues in veterinary medicinal products (EMEA/CVMP/SWP/138366/2008). The EU had raised concerns at the 17th Codex Committee for Residues of Veterinary Drugs in Food (CCRVDF) meeting in May 2007. These comments of the CVMP on the new approach are intended to be submitted to JECFA and to the CCRVDF Working Group on Risk Management Options for considerations.

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

Confidentiality Arrangements EC/EMEA/FDA

On 22 May 2008 the EMEA and the FDA agreed on the specific arrangements for exchange of information relating to veterinary medicinal products in the context of the existing EC/EMEA/FDA confidentiality arrangement. Further detail can be found in the published documents 'Implementation procedures for veterinary medicinal products cluster' and 'General principles for parallel scientific advice meetings'.

The programme of co-operation in the field of veterinary scientific advice will continue from 2008 and parallel scientific advice will take place when specifically requested by the applicant. Prime candidates for parallel scientific advice include products for limited markets, MRLs, innovative medicinal products, products where guidelines do not exist, or if they do, then where there are differences between EMEA and FDA requirements. Details of the procedure can be found at the following link: http://www.emea.europa.eu/htms/vet/press/pus.htm

The next meeting of the CVMP will be held on 15-17 July 2008

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