European Medicines Agency
Veterinary Medicines and Inspections

London, 18 September 2009
EMEA/CVMP/560974/2009

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 15-17 September 2009

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus positive opinions for type II variation applications to change the detailed description of the pharmacovigilance system with regard to the qualified person for Pharmacovigilance for **Circovac**, **BVTPUR Alsap 8**, **Equioxx**, **Zactran**, **Loxicom** and **Masivet**.

The Committee also adopted a positive opinion for a type II variation for **Fevaxyn Pentofel** to change the materials used for the tips and plunger stoppers of the syringes to latex-free substances.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisations for **Halocur**. The Committee, having re-assessed the benefit-risk balance of the product, concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated, therefore, recommended the indefinite renewal of the marketing authorisation.

Community Referrals

The Committee considered the grounds for re-examination of the CVMP opinion for **Clavobay Lactating Cow** (*amoxicillin and clavulanic acid*) and associated names adopted on 13 May 2009 in the context of an arbitration procedure initiated under Article 33 of Directive 2001/82/EC. The Committee concluded that the previous scientific conclusions of the Committee should stand as the application does not satisfy the criteria for authorisation in respect to efficacy. The European Commission has clarified that no Commission Decision will be adopted in this case as there is no legal basis for arbitration by CVMP in cases where there is a negative assessment by the reference Member State at the end of a decentralised procedure.

The Committee noted a request for re-examination of the CVMP opinion adopted during the July 2009 meeting concerning the referral procedure under Article 33 of Directive 2001/82/EC, for **Tildren 500mg** (*tiludronic acid*), from CEVA Animal Health Limited. The procedure will be initiated once the grounds for re-examination are submitted.

The Committee noted a request for re-examination of the CVMP opinion adopted during the July 2009 meeting concerning the referral procedure under Article 33 of Directive 2001/82/EC, for **APPM Respipharm** (*strains of Actinobacillus pleuropneumoniae* (serotypes 2, 9 and 11), *Pasteurella multocida* serotype A) from Pharmagal Bio, s.r.o.. The grounds for re-examination were submitted and procedure started.

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

Maximum Residue Limits

The Committee adopted a new document listing the substances considered as not falling within the scope of the MRL Regulation (EMEA/CVMP/519714/2009). This document supersedes the *List of Substances considered as not falling within the scope of Council Regulation (EEC) No 2377/90* (EMEA/CVMP/046/00-Rev.16), and was adapted to take account of the new legal references relevant to the new MRL Regulation (EC) No 470/2009. In addition, the following additional substances have been included in the list, for use as excipients: diethylaminoethyl (DEAE)-dextran (at concentrations up to 150 mg/ml) and fatty acid methyl esters (for topical administration).

The document is available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/mrls/background.htm

Scientific Advice

The Committee agreed scientific advice for two separate veterinary medicinal products regarding bioequivalence requirements.

MUMS/Limited markets

The Committee endorsed the first request for classification under the new MUMS/limited markets policy announced in July 2009 for a veterinary medicinal product for hypertension in cats.

An EMEA MUMS Information Day will be held at the EMEA on 20 October 2009. The agenda and full details may be found on the EMEA website.

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

Pharmacovigilance

The Committee reviewed the PSURs for **Aivlosin**, **Dexdomitor**, **Flexicam**, **Nobilis Influenza H5N2**, **Nobilis Inluenza H7N1**, **Nobivac Piro, Purevax RCP**, **Purevax RCP FeLV**, **Purevax RCPCh**, **Purevax RCPCh FeLV**, **Rabigen SAG2** and **Trocoxil** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Environmental Risk Assessment

The Committee adopted a revised Question & Answer document on the implementation 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/172074/2008-Rev.1). This document has been revised to take into account the experience from assessors and also from queries received on the above-mentioned guidance.

The Committee adopted a "*Concept paper on higher tier testing of antiparasitics to dung organisms* " for a 2-month period of public consultation (EMEA/CVMP/ERA/12254/2009-CONSULTATION). This concept paper has been prepared with a view to receiving comments on the development of a guideline on how to proceed if the initial environmental Tier A risk assessment indicates a risk to dung flies or beetles.

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/vetguidelines/safety.htm

General

The CVMP adopted a draft "*Guideline on the change in classification of veterinary medicinal products authorised by the Community*" for a 6-month period of public consultation (EMEA/CVMP/430509/2009-CONSULTATION). The guideline has been developed to describe the procedure for changing classification from prescription only to non-prescription medicine.

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/genguidance/genreg.htm

Implementation of new MRL Regulation

The Committee adopted a proposal for an extension of the list of essential substances for horses. The new MRL Regulation (EC) No 470/2009 includes provisions for the amendment of Article 10(3) of Directive 2001/82/EC by introducing new criteria for the derogation from the provisions of Article 11 of Directive 2001/82/EC regarding the treatment of Equidae and the establishment of a list of essential substances for horses. The list shall now contain not only substances that are essential for the treatment but also those which bring added clinical benefit compared to other treatment options available for Equidae. The proposal for an extension of the existing list will be submitted to the European Commission for consideration in preparing a legislation amending the current list of essential substances. Once adopted, the substances in that list can be used by veterinarians in the horse under the conditions of the "cascade", providing a minimal withdrawal period of 6 months is applied.

Organisational Issues

The Committee adopted a revised document on *Appointment and responsibilities of rapporteur and co-rapporteur for procedures regarding veterinary medicinal products* (EMEA/CVMP/468877/2009) that supersedes the previous version (EMEA/CVMP/928/02-Revision FINAL). This document describes the appointment of rapporteurs and co-rapporteurs and their respective responsibilities in the evaluation processes with regard to community procedures for veterinary medicinal products. The document now expands on the principles to be applied for appointment of rapporteurs and co-rapporteurs for referral procedures, and takes into account the new MRL Regulation.

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/genguidance/genreg.htm

The Committee also adopted a revised *Procedural advice on the re-examination of CVMP opinions* (EMEA/CVMP/2128/2007-Rev.1-CONSULTATION) for release for a 2-month period of public consultation. The document has been revised in order to extend the scope of the guideline to the re-examination of referral opinions. The opportunity was also taken to update it to take into account the new Variations Regulation (Commission Regulation (EC) No 1234/2008).

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/general/direct/legislation/legislationvet.htm

The next meeting of the CVMP will be held on 13-15 October 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