European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 18 to 20 April 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Convenia** (containing cefovecin) for administration by subcutaneous injection to cats and dogs for the treatment of specific skin, soft tissue and urinary tract infections.

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

The Committee adopted by majority positive opinions for two separate Type II variations for **Aivlosin** regarding the addition of new indications for swine dysentery and porcine proliferative enteropahty (ileitis).

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the modification (increase) of existing maximum residue limits (MRLs) for **doramectin** in bovine, porcine and ovine species and deer including reindeer. This recommendation was possible in view of new safety information allowing to modify the acceptable daily intake value (ADI) and new residue data made available. The MRLs are now recommended for all mammalian species in line with the CVMP policy on extrapolation on MRLs and the values harmonised in the target tissues muscle, fat, liver and kidney.

The Committee adopted by consensus an opinion recommending the establishment of MRLs for **oxytetracycline** in honey. Oxytetracycline has already MRLs established for all food producing species in tissues, milk and eggs.

The Committee adopted by consensus a positive opinion recommending the inclusion of **peforelin** in Annex II of Council Regulation (EEC) No. 2377/90 for pigs.

The Committee adopted by consensus a positive opinion recommending the inclusion of **sodium nitrite** in Annex II of Council Regulation (EEC) No. 2377/90 for cattle.

The Committee adopted by consensus a positive opinion recommending the inclusion of **fluazuron** in Annex I of Council Regulation (EEC) No. 2377/90 for bovine species. Fluazuron had already provisional MRLs established, which will expire on 1 January 2007.

The Committee confirmed that the substance **mannit oleate** is covered by the assessment and Annex II entry for montanide, as mannit oleate is a major constituent of montanide. Therefore, a specific entry into Annex II of Council Regulation 2377/90 for mannit oleate is not required.

The summary opinions will be available on Monday 24 April 2006 on the EMEA web site: http://www.emea.eu.int

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Scientific Advice

Following the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) the Committee adopted scientific advice concerning follow-up advice on the clinical development of a veterinary medicinal product for the treatment of canine atopic dermatitis.

Pharmacovigilance

The Committee reviewed the Periodic Safety Update Reports (PSUR) for **Draxxin, Gonazon, Naxcel** and **Nobilis OR inac** and concluded that no regulatory action or change to the product literature of the products is required.

Referrals

The Committee started a referral procedure for **Cobactan DC** (cefquinome) from Intervet International BV. The product is used in the treatment and prevention of mastitis during the dry period in cows. The matter was referred to the CVMP by the marketing authorisation holder under article 6(13) of Commission Regulation (EC) No 1084/2003 following a Mutual Recognition Procedure for a type II variation. The Committee is requested to consider whether or not the proposed reduction of the withdrawal period should be granted.

Concept Papers, Guidelines and SOPs

Immunologicals

The Committee adopted a concept paper on *Concurrent administration of immunological veterinary medicinal products (IVMPs) in view of determining day X to be 14 days and consequent revision of the summary o product characteristics (SPC) guideline for immunologicals* for release for a 3-month period of public consultation (EMEA/CVMP/123846/2006-CONSULTATION). The aim is to clarify the terms “concurrent administration” and “simultaneous administration” as well as to revise other guidelines dealing with these terms accordingly.

The Committee also adopted a concept paper on *Requirements for Vaccines for Use in Birds Against Avian Influenza Virus* for release for a one-month period of public consultation (EMEA/CVMP/86063/2006-CONSULTATION). The aim is to provide comprehensive guidance in relation to avian influenza vaccines and to ensure that the guideline is relevant not only to the emergency situation of the time of its development but also to a range of foreseeable future epidemiological situations.

The documents will be available on Monday 24 April 2006 on the EMEA web site:
http://www.emea.eu.int

Quality

The Committee adopted a revised guideline on the ‘Active Substance Master File’ procedure for release for a 4-month period of public consultation (EMEA/CVMP/QWP/134/02-Rev.2-CONSULTATION). This guideline was revised solely to include a specific reference to herbal substances/preparations.

The document will be available on Monday 24 April 2006 on the EMEA web site:
http://www.emea.eu.int

General

Following the close of their consultation periods the Committee adopted two revised Guidelines on the Summary of Product Characteristics for:

- pharmaceutical veterinary medicinal products (EMEA/CVMP/064/05)
- immunological veterinary medicinal products (EMEA/CVMP/065/05)

The guidelines have been revised in view of changes in the legislation and to provide further clarification to some sections. Publication of these two guidelines will follow their adoption by the Notice to Applicants group (foreseen for June 2006).

International harmonisation

The Committee agreed on comments on draft MRLs for consideration by the 16th session of the Codex Committee on Residues of Veterinary Drugs In Foods (CCRVDF) to be held on 8-12 May 2006 as proposed in Codex document CX/RVDF/06/16/07. The MRLs concern the substances colistin, erythromycin, flumequine, melengestrol acetate, ractopamine and triclabendazole.

These comments will be submitted to the Commission for the preparation of EU comments.

The next meeting of the CVMP will be held on 16-18 May 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