European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 15-17 July 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by majority a positive opinion for **Trocoxil** (*mavacoxib*), chewable tablets for dogs, intended for the treatment of pain and inflammation associated with degenerative joint disease in dogs.

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

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

- **Circovac -** additional site for the manufacture of the active substance
- **Nobivac Bb for cats -** addition of an alternative manufacture site
- **Nobivac Bb for cats -** change of concentration method for the *Bordetella bronchiseptica* component and to update the detailed description of the production process

The Committee adopted by consensus a negative opinion for a type II variation application for **Porcilis Pesti** concerning an urgent safety restriction to reduce the shelf life. The need for regulatory measures to deal with an observed reduction in shelf life will be reconsidered when additional data expected from the marketing authorisation holder in October, is received. The Committee considered that the current restrictions on release at national level should be maintained until this reconsideration has taken place.

Maximum Residue Limits

The Committee adopted a revised summary report for penicillins. The summary report was updated primarily to reflect data indicating that results of residue depletion studies are dependent on whether residues are quantified using liquid chromatography-mass spectrometry or fluorescence detection.

The Committee adopted an European Public MRL Assessment Report (EPMAR) on clorsulon concerning review of the ADI for the substance. The ADI was revised following the acknowledgment that the study on which the original ADI was based, had used a related substance rather than clorsulon itself.

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

Renewals of Marketing Authorisations

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

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Referrals

The Committee concluded the referral procedure for all authorised veterinary medicinal products containing **toltrazuril** intended for use in poultry species. The procedure was referred to the Committee by Germany under Article 35 of Directive 2001/82/EC, due to concerns on a potential serious risk to the environment. The Committee adopted by consensus an opinion concluding that the assessment of the risk presented by toltrazuril and its major metabolite toltrazuril sulfone to terrestrial plants and to groundwater demonstrated that use of products containing toltrazuril is acceptable and the marketing authorisations can be maintained without special warnings in point 5.3 (Environmental properties) of the SPC provided that the product is used under the conditions agreed, i.e. a dose of 7 mg/kg bw on two consecutive days for the treatment of coccidiosis in chickens and turkeys. Considering that there are differences in the indications, species and posology in the SPCs of the authorised products, changes would need to be introduced in order to bring these in line with the indications and dosing regimens on which the environmental risk assessment was based. These changes will include removing reference to repeat treatment after 5 days, prevention and control of coccidiosis and use in pigeons from the SPCs.

The Committee concluded the referral procedure for oral soluble powders containing **sodium salicylate**, for calves and pigs. The matter was referred to the CVMP by Ireland under Article 35 of Directive 2001/82/EC, as amended, due to concerns raised in relation to possible lack of efficacy for this group of products. The Committee adopted by majority an opinion concluding that efficacy had been shown for calves as supportive therapy in acute respiratory disease and for pigs in respiratory disease and inflammation in combination with concurrent antibiotic therapy. The Committee therefore recommended to vary the marketing authorisations accordingly. The opinion would be forwarded to the European Commission.

The Committee started a referral procedure for **Pulmotil** 40/100/200 VET Premix (*tilmicosin*) and associated names, from Eli Lily. The matter was referred to the CVMP by Belgium, under Article 34 of Directive 2001/82 due to divergent decisions taken by Member States on the dosage and withdrawal period.

Pharmacovigilance

Further to request from the European Commission following the CVMP opinion adopted on 13 December 2006 regarding the procedure initiated by the Netherlands under Article 78(1) of Directive 2001/82/EC in relation to identified veterinary medicinal products containing the **alpha2-adrenoreceptor agonists** romifidine, xylazine, medetomidine or detomidine and for which authorisations had been granted in the Netherlands, the Committee agreed to revise its opinion in order to include the marketing authorisations for these concerned products in all countries of the European Union. The procedure will review and update the previously agreed set of precautionary measures relating to user safety following exposure to alpha2-adrenoreceptor agonists to be reflected in the product literature of the concerned products to take into account any additional observations from Marketing Authorisation Holders.

The Committee reviewed the PSUR for **Cerenia** and recommended to the marketing authorisation holder to include information on a new adverse reaction in the product literature. The Committee also reviewed Periodic Safety Update Reports (PSURs) for **Dexdomitor, Nobilis Influenza H5N2, Poulvac Flufend H5N3 RG, Purevax RC, Purevax RCCh, Purevax RCP, Purevax RCP FeLV, Purevax RCPCh, Purevax RCPCh FeLV** and **Vaxxitek HVT+IBD** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Pharmacovigilance

The Committee adopted the following standard lists used for electronic reporting of suspected adverse reactions following the yearly review and update*:*

- *VEDDRA* list of clinical terms for adverse reactions in animals (EMEA/CVMP/413/99-Rev.5);
- *VEDDRA* list of clinical terms for adverse reactions in humans (EMEA/CVMP/891/04-Rev.3);
- List of species and breeds (EMEA/CVMP/553/03-Rev.3).

The Committee adopted a Revised Call for Comments on Standard Lists for EudraVigilance Veterinary (EMEA/123353/2004-Rev.3).

These lists and the call for comments will be published on the EMEA website in due course and the implementation of these lists in EudraVigilance Veterinary is scheduled for 14 October 2008.

The Committee also adopted Guidance Notes on the Use of VeDDRA Terminology for Reporting Suspected Adverse Reactions in Animals EMEA/CVMP/PhVWP/288284/2007) to be published alongside the 2008 standard lists, to make the information immediately available. The content of the Guidance Notes would be included in the concept paper for revision of the causality assessment guideline in due course.

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

Immunologicals

The Committee adopted an update to the "*Guideline on data requirements for IVMPs intended for minor use or minor species/limited markets*" (EMEA/CVMP/IWP/123243/2006-Rev.1) for release for a 3-month period of public consultation. The update involved the addition of *M. synoviae* in turkeys to the list of indications listed in table 2: Minor uses/limited markets for IVMPs of the guideline.

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

The Committee adopted a change to the SPC interactions statement further to comments from International Federation for Animal Health-Europe to the Federation of Veterinarians of Europe indicating ambiguity in the text concerning the compatibility of the product with other veterinary medicinal products (EMEA/CVMP/IWP/345850/2008). The new statements will be incorporated in the relevant QRD templates and the guideline on Summary of Product Characteristics for immunological veterinary medicinal products.

Quality

The Committee adopted a revised "*Guideline on Stability Testing: Stability testing of existing active substances and related finished products*" (EMEA/CVMP/QWP/846/99-Rev.1). The aim of this revision is to update provisions in line with the recently updated VICH guideline on stability (GL3).

The overview of the comments received during the public consultation of this guideline would be published on the EMEA website (EMEA/CVMP/QWP/360143/2008).

The Committee adopted Question and Answer documents on:

- Glycerol (glycerin) contamination (EMEA/CHMP/CVMP/QWP/321287/2008). These two new questions and answers provide further guidance on testing glycerol to ensure the absence of contamination with diethylene glycol.
- The harmonised Ph.Eur. General chapter: Uniformity of dosage units (2.9.40) (EMEA/CHMP/CVMP/QWP/321422/2008). These two questions and answers are intended to clarify the application of this new harmonised General Chapter.
- The calculation of expiry dates (EMEA/CHMP/CVMP/QWP/321388/2008). This document aims to clarify how expiry dates should be calculated by providing examples.

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

Organisational Issues

The Committee held a question and answer session with representatives invited from the Community Reference Laboratory for Bluetongue Virus (BTV) and the Disease Control Sector of DG SANCO to discuss the current situation with regard to BTV in the EU and the role of vaccination in Community control policy.

The Committee agreed to organise a Focus Group meeting on PK/PD modelling to take place at the EMEA in the afternoon of 24 September 2008. The objective of the meeting is to explore the reasons why this methodology is not currently more widely used when developing veterinary medicines and if (and how) training could be provided to achieve a better understanding of this methodology by regulatory authorities and / or the pharmaceutical industry. Participants from academia, regulatory agencies and pharmaceutical industry / consultants are invited to attend. Interested participants should contact the secretariat of the Efficacy Working Party (vet@emea.europa.eu).

For the agenda of the focus group meeting click here.

The next meeting of the CVMP will be held on 16-18 September 2008

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This press release and other documents are available on the Internet at the following address:
http://www.emea.europa.eu