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 July 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Cerenia** intended for the treatment and prevention of emesis in dogs.

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

The Committee adopted by consensus a positive opinion for a type II variation for **Naxcel,** solution for injection for pigs, adding a new 50 ml pack size.

The Committee adopted by consensus a positive opinion for a type II variation for **Vaxxitek HVT+IBD** regarding an extension of shelf-life.

The Committee adopted by consensus two positive opinions for type II variations for **Metacam** and **Novem** relating to the container closures.

Avian Influenza

The Committee adopted a positive opinion for **Nobilis Influenza H5N2,** from Intervet International BV for intramuscular or subcutaneous administration to chickens to reduce clinical signs and virus excretion of avian influenza.

The Committee adopted a positive opinion for **Poulvac FluFend H5N3 RG,** from Fort Dodge Animal Health BV for intramuscular or subcutaneous administration to chickens and Pekin ducks to reduce clinical signs and virus excretion of avian influenza.

Taking into account the epidemiological situation within the EU, the assessment of the vaccines was carried out under an accelerated procedure and the opinions were adopted in 79 days.

The recommendations of the Committee with regard to both vaccines were made according to Article 39(7) of Regulation No (EC) 726/2004 for authorisations under exceptional circumstances and subject to specific obligations and follow-up measures by the marketing authorisation holders, including enhanced pharmacovigilance measures to ensure the safe use of the product. The use of these products will be restricted to administration as part of disease control campaigns implemented by national competent authorities.

A separate press release and a question and answer document have been published and can be found on the EMEA website. To access the press release click here, to access the question and answer document click here.

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

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Maximum Residue Limits

Further to an appeal from the applicant, the Committee confirmed by majority the opinion recommending the modification of the ADI (acceptable daily intake) and established new MRLs for **doramectin** for all mammalian food producing species, which were initially adopted at the April 2006 meeting.

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

Referrals

The Committee concluded the evaluation of the referral initiated following a type II variation under the Mutual Recognition Procedure for **Cobactan DC** concerning the reduction of the withdrawal period. The procedure was referred to the Committee by the Marketing Authorisation Holder under Article 6(13) of Commission Regulation (EC) no 1084/2003 due to disagreement over the outcome of the procedure. The Committee adopted by consensus an opinion concluding that on the basis of the available data, the withdrawal period for Cobactan DC and associated names should be as follows:

- 1 day after calving when dry period is more than 5 weeks
- 36 days after treatment when dry period is 5 weeks or less

The opinion will be forwarded to the Commission.

The company concerned may submit a request for re-examination of this opinion within the deadlines provided by legislation.

The Committee considered the notification for two referrals under Article 40 of Directive 2001/82/EC for **Suvaxyn Parvo/E** and **Suvaxyn Ery** from France, following mutual recognition variation procedures. The referrals were submitted to the Committee due to concerns that the equivalence could not be confirmed between the reference batch validated in the original dossier and the two new reference batches introduced for each product.

A Rapporteur and a Co-Rapporteur were appointed and a list of questions to be responded by Marketing Authorisation Holders was agreed.

Pharmacovigilance

The Committee reviewed the Periodic Safety Update Reports (PSUR) for **Aivlosin and ProteqFlu** and concluded that no regulatory action or change to the product literature of the products is required. The Committee also reviewed the PSUR for **Nobivac Piro** which is not yet marketed within the EU, and agreed with the Marketing Authorisation Holder that there is a need to amend the Summary of Product Characteristics (SPC) to include the possible observation of certain systemic reactions seen after the use of the product in a Non-EU country.

Concept Papers, Guidelines and SOPs

Immunologicals

The Committee adopted the "*Guideline on requirements for an authorisation under exceptional circumstances for vaccines for use in birds against avian influenza*" (EMEA/CVMP/IWP/222624/2006-CONSULTATION) for release for a 2-month period of public consultation. This guideline has been developed in response to the growing threat of outbreaks of avian influenza within the European Union and the lack of authorised vaccines within the Community. The scope of this guideline is restricted to applications for an authorisation under exceptional

circumstances according to Article 39 (7) of Regulation (EC) No 726/2004 for vaccines in birds against highly pathogenic avian influenza virus infections. In view of the urgency of the issue a reduced consultation period is foreseen.

The Committee adopted two concept papers for release for a 3-month period of public consultation for the development of guidelines concerning:

- New master seeds to replace established master seeds already used in authorised immunological veterinary medicinal products (IVMPs) (EMEA/CVMP/IWP/205712/2006-CONSULTATION). The concept paper describes the need for a guideline that defines the data concerning quality, safety and efficacy, which have to be provided for a replacement of the Master Seed in order to ensure that the replacement does not change the final product.
- Data requirements to support in-use stability claims for IVMPs (EMEA/CVMP/IWP/219089/2006-CONSULTATION). The concept paper describes the need for a guideline in order to overcome the subjectivity often involved in the allocation of the in-use shelf-life. Furthermore, this guideline is intended to inform applicants of the studies required to support the proposed in-use shelf-life and additionally complement the existing guidance which currently only includes brief references to this issue.

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

Availability – Minor Uses and Minor Species

The Committee adopted four guidelines concerning data requirements for dossiers for minor uses and minor species. Three of the guidelines were adopted for implementation by February 2007 following the close of the public consultation:

- "*Guideline on the **quality** data requirements for veterinary medicinal products intended for minor uses or minor species*" (EMEA/CVMP/QWP/128710/2004);
- "*Guideline on **safety and residue** data requirements for veterinary medicinal products intended for minor uses or minor species*" (EMEA/CVMP/66781/2005).
- "*Guideline on **efficacy and target animal** safety data requirements for veterinary medicinal products intended for minor uses or minor species*" (EMEA/CVMP/EWP/117899/2004);

The overview of the comments received during the public consultation of these guidelines will be published on the EMEA website.

The fourth guideline, "*Guideline on data requirements for **immunological veterinary medicinal products** intended for minor use or minor species*" (EMEA/CVMP/IWP/123243/2006-CONSULTATION) was adopted for release for a 6-month period of public consultation.

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

International Harmonisation

Following sign-off by the VICH Steering Committee at its 18th meeting on 30 May – 1 June 2006, the Committee adopted the following VICH guidelines:

- VICH GL29 on Pharmacovigilance of veterinary medicinal products – management of periodic summary update reports (EMEA/CVMP/VICH/646/01). This guideline describes the principles and requirements for periodic pharmacovigilance summary reporting for veterinary medicinal products. The guideline will be implemented by June 2007;

- VICH GL30 on Pharmacovigilance of veterinary medicinal products – controlled list of terms (EMEA/CVMP/VICH/647/01-Rev.1-CONSULTATION) for release for a second 6-month period of public consultation. The purpose of this guideline is to establish harmonised and controlled lists of terms used in veterinary pharmacovigilance reporting, in particular for electronic reporting. The use of harmonised and controlled terms is important in order to assure consistency, as well as to allow comparison between products and across product classes.

The documents will be available on Monday 24 July 2006 on the EMEA web site:
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Regulatory Issues

The Committee adopted a questions and answers document regarding application of the so-called 'sunset clause' to centrally authorised veterinary medicinal products (EMEA/CVMP/120559/2006). This guidance document gives advice on how the EMEA will monitor any centrally authorised veterinary medicinal product never marketed within the European Economic Area (EEA) after granting of the marketing authorisation and any complete cessation of marketing where a three consecutive year period has elapsed leading to the invalidity of the marketing authorisation. The monitoring of the 'sunset clause' provision will be based on the data related to the marketing status of the medicinal product reported by the Marketing Authorisation Holder. The document will be reviewed by the European Commission before release for consultation

Organisational matters

Informal CVMP meeting

The Committee discussed the preparation of the informal CVMP meeting to be held in Helsinki on 4-5 September 2006 at the initiative of Finland under the activities of the presidency of the European Union. The Committee agreed that the meeting would consider the following items:

- CVMP experience on referrals;
- How to deal effectively with referrals;
- Risk-benefit analysis;
- Follow-up of CVMP audits;
- Improvement of procedure for appointment of rapporteurs;
- Improvement of communication of EMEA/CVMP activities and their role in the international forums

In a Joint session with the Co-ordination Group for Mutual Recognition and Decentralised Procedures the Committee will discuss implementation of the new legislation, improvement of communication between the two committees, authorisation of diluents for veterinary immunological products and the European Surveillance Scheme (ESS).

Interested Parties

The Committee agreed the programme for the EMEA/IFAH Europe Info Day to be held on 9-10 November 2006 at the EMEA, which will focus on managing the risk and seeing the benefits of veterinary medicines.

The Committee held a meeting with the interested parties on 19 July 2006. The topics discussed concerned the CVMP work programme for 2007, update on minor uses minor species (MUMS) initiatives within CVMP, on referrals and on development of Eudrapharm. The meeting also discussed issues of specific interest to the different interested parties attending in particular antimicrobial resistance, availability of medicines and establishment of MRLs for honey.

The next meeting of the CVMP will be held on 12 - 14 September 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