European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/119411/2005
London, 15 April 2005

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 12 to 14 April 2005

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Equilis Prequenza-Te**, from Intervet International B.V. intended to stimulate active immunity against Equine influenza and tetanus, in horses.

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The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Equilis Te**, from Intervet International B.V. intended to stimulate active immunity against tetanus, in horses.

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

The Committee adopted positive opinions for Type II variations with regard to:

- **Aivlosin** for the modification of the wording of the SPC regarding section 4 on pharmacological properties;
- **Metacam** for the addition of a new presentation (20ml vial);
- **Dexdomitor** for the addition of a new indication on premedication in dogs before induction and maintenance of general anaesthesia;

Renewals of Marketing Authorisations

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

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Porcilis Pesti**. The summary of product characteristics was updated to reference the onset and duration of immunity. 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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Safety

The Committee endorsed a summary of the comments received during the public consultation of the user safety guideline on pharmaceutical veterinary medicinal products (EMEA/CVMP/41180/2005). The final guideline was adopted by the CVMP in January 2005 further to the consideration of the comments received during the public consultation (EMEA/CVMP/543/03-FINAL).

The document will be available on the EMEA web site on Monday 18 April 2005:
http://www.emea.eu.int

Pharmacovigilance

The Committee reviewed the Periodic Safety Update Report (PSUR) for **Gonazon** and concluded that no further action or changes to the product literature of the product was required.

The Committee considered the need for action on the veterinary side regarding Cox-2-inhibitors in the light of recent developments in human medicine and concluded that no action was required in relation to currently authorised veterinary products; a public CVMP statement was adopted, discussing the current situation with regard to veterinary medicines (EMEA/CVMP/108858/2005).

The document will be available on Monday 18 April 2005 on the EMEA web site:
http://www.emea.eu.int

Guidelines, SOPs and Position Papers

Pharmacovigilance

The Committee adopted a guideline on a Strategy for Triggering Investigations preceding Regulatory Actions by EU Competent Authorities, further to the consideration of the comments received during the public consultation (EMEA/CVMP/900/03-FINAL). This guideline is intended to harmonise the approach by Competent Authorities throughout the EU for the investigation of safety issues arising from pharmacovigilance information. This also aids marketing authorisation holders to identify situations which are likely to be investigated by the Competent Authorities.

The Committee adopted for release for a 6-month period of public consultation a Simple Guide to Veterinary Pharmacovigilance in the EU (EMEA/CVMP/PhVWP/110607/2005). This guide is aimed at veterinary practitioners and other veterinary health care professionals, and explains the purpose of veterinary pharmacovigilance, and its importance in veterinary practice in ensuring the safety of medicines once they are authorised.

Quality

The Committee adopted a Revised Guideline on the Active Substance Master File Procedure initially adopted in August 2004. The revision only provides clarification in relation to its applicability to well defined active substances and its non-applicability to biological substances (EMEA/CVMP/134/02-Rev.1).

The Committee adopted a draft Concept Paper on the development of a Guideline on Parametric Release, for release for a 3-month period of public consultation (EMEA/CVMP/QWP/114420/2005-CONSULTATION).

The documents will be available on Monday 18 April 2005 on the EMEA web site:
http://www.emea.eu.int

Scientific Advice

The Committee adopted advice on the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) concerning the clinical development of an oncology product for dogs.

Availability – Minor Uses and Minor Species

Further to several initiatives of the Committee over recent years regarding the availability of veterinary medicines for minor uses and minor species, and in particular the CVMP Position Paper on the availability of products for Minor Uses and Minor Species (MUMS) (EMEA/CVMP/477/03-FINAL) adopted in July 2004, the Committee has now adopted for release for 6-month periods of public consultation, three guidelines concerning data requirements for dossiers for MUMS products (EMEA/CVMP/133672/2005):

- Draft Guideline on the Quality data requirements for veterinary medicinal products intended for Minor Uses or Minor Species (EMEA/CVMP/QWP/128710/2004-CONSULTATION);
- Draft 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-CONSULTATION);
- Draft Guideline on Safety and Residue data requirements for veterinary medicinal products intended for Minor Uses or Minor Species (EMEA/CVMP/66781/2005-CONSULTATION)

The documents will be available on the EMEA web site on Monday 18 April 2005:
http://www.emea.eu.int

Regulatory issues

The Committee endorsed a Procedural Announcement on Request for Eligibility for applications to be submitted after 20th November 2005 under Title III of Regulation (EC) No 726/2004 of the European Parliament and of the Council. The announcement is attached to this Press Release.

The next meeting of the CVMP will be held on 17-19 May 2005

Peter G.H. Jones
Head, Veterinary Medicines Evaluation Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

Attachment

PROCEDURAL ANNOUNCEMENT

Request for Eligibility to the Centralised Procedure in 2005/2006

In accordance with Article 90 of Regulation (EC) 726/2004, access to the Centralised Procedure in relation to the mandatory scope (as defined in Article 3(1) in connection with the Annex to Regulation (EC) No 726/2004) and the optional scope as per Article 3(2) of Regulation (EC) 726/2004, will be applicable as of 20 November 2005.

Until that date, the Annex to Council Regulation (EEC) 2309/93 applies.

Applicants are recommended to submit their requests to confirm the eligibility to the Centralised Procedure at least four to six months in advance of the intended submission date.

Taking into account the above:

- Applicants intending to submit an application before 20 November 2005 should do so in accordance with the Annex to Council Regulation 2309/93.

- Applicants intending to submit an application after 20 November 2005 and requesting confirmation of the eligibility to the Centralised Procedure before that date, should send such a request to the EMEA justifying their eligibility in accordance with the criteria set out in Regulation (EC) 726/2004. Further to the consideration of the justifications for eligibility, the EMEA will inform the applicants on the CVMP opinion as to the access of their application to the Centralised Procedure. After 20 November 2005, this position will need to be officially reconfirmed by the EMEA following the December 2005 CVMP meeting.

In case further clarifications are requested, applicants are advised to contact Jill Ashley-Smith, Head of Sector for Veterinary Marketing Authorisation Procedures at the EMEA.