European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 17-18 April 2007

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Prilactone** (spironolactone), from CEVA, intended for use in combination with standard therapy for the treatment of congestive heart failure caused by valvular regurgitation in dogs.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Circovac** (inactivated porcine circovirus type 2), from Mérial, intended for passive immunisation of piglets via the colostrum, after active immunisation of sows and gilts, to reduce lesions in lymphoid tissues associated with PCV2 infection and as an aid to reduce PCV2-linked mortality.

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

The Committee adopted by consensus a positive opinion for a type II variation for **Fevaxyn Pentofel** regarding additional suppliers of bovine serum.

The Committee adopted by consensus a positive opinion for a type II variation for **Metacam** regarding the addition of 2 presentations.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Vaxxitek HVT+ IBD**. The Committee concluded that the risk-benefit balance of the product continued to be favourable and, therefore, recommended the renewal of the marketing authorisation.

Maximum Residue Limits

Further to a request for clarification from a company concerning soybean oil for use as excipient CVMP confirmed that soybean oil does not fall within the scope of Regulation 2377/90. The list of substances not falling within the scope of Council Regulation 2377/90 was updated accordingly.

The document will be available on Monday 23 April 2007 on the EMEA web site: http://www.emea.europa.eu

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

Community Referrals

The Committee concluded the referral procedure for **Bovilis BVD** (inactivated BVDV strain C-86) from Intervet Deutschland. The procedure was referred to the Committee by the Reference Member State in the mutual recognition procedure, Germany, under Article 33(4) of Directive 2001/82/EC due to concerns raised by the Concerned Member State, Denmark, that the testing regime to demonstrate freedom from extraneous agents was insufficient to ensure that the vaccine would not interfere with national eradication campaigns for certain animal diseases and represented a serious potential risk to animal health. The Committee adopted, by majority, an opinion concluding that additional specific extraneous testing requirements was scientifically not justified and that there were no concerns that the product would represent a potential serious risk to animal health. The opinion will be forwarded to the European Commission.

The Committee concluded the referral procedure for **Enurace 50** (ephedrine) from ACE Pharmaceuticals BV. The procedure was referred to the Committee by the Reference Member State in the mutual recognition procedure, The Netherlands, under Article 33(4) of Directive 2001/82/EC due to concerns raised by the Concerned Member States, France and Italy that the risk/benefit analysis was unfavourable and represented a serious potential risk to animal health. The Committee adopted by majority, an opinion concluding that the risk/benefit analysis was favourable and that there were no concerns that the product would represent a potential serious risk to animal health but that advice should be added to Summary of Product Characteristics (SPC) concerning special precautions for use. The opinion will be forwarded to the European Commission.

Scientific advice

The Committee agreed scientific advice regarding quality and safety issues for an Infectious Bovine Rhinotracheitis vaccine and also regarding safety and efficacy issues for a vaccine for rabbits against myxomatosis and rabbit haemorrhagic disease.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **SevoFlo, Nobilis OR inac** and **Oxyglobin** and concluded that no further action or changes to the product literature of the product(s) were required.

Concept Papers, Guidelines and SOPs

Environmental Risk Assessment

The Committee adopted a "*Guideline on Environmental Impact Assessment for VMPs in support of the VICH GL6 and GL38*" (EMEA/CVMP/ERA/418282/2005) for implementation by November 2007 following the close of the public consultation. The purpose of the guideline is to provide additional, more specific technical guidance on environmental impact assessment in areas, where the VICH guidelines are more general or refer to further regional guidance. In the supporting CVMP guideline algorithms, models as well as default values for the different calculations are given for the determination of the concentration in the environment. The guideline is intended to facilitate the preparation of the environmental risk assessment part in marketing authorisation dossiers by applicants and the harmonised interpretation of the VICH guidelines by Member States thus strengthening the predictability and transparency of the outcome of an environmental impact assessment.

The document will be available on Monday 23 April 2007 on the EMEA web site:
http://www.emea.europa.eu

The overview of the comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/CVMP/346335/2006).

Immunologicals

The Committee adopted a "*Guideline on user safety for immunological veterinary medicinal products*" (EMEA/CVMP/IWP/23332/2006) following the close of the public consultation. This guideline provides further guidance on data requirements and assessment methods to be used to identify the risks, or on the measures for risk reduction for user safety related to IVMPs.

The Committee adopted a *"Guideline on data requirements for an authorisation under exceptional circumstances for vaccines in birds against avian influenza"* (EMEA/CVMP/IWP/222624/2006) following the close of the public consultation. This guideline has been developed following the publication of a reflection paper on this topic in February 2006 which resulted from the growing threat of outbreaks of avian influenza within the European Union and the lack of vaccines with marketing authorisations within the Community.

The Committee adopted a *"Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea (BVD) virus"* (EMEA/CVMP/IWP/205351/2006) for release for a 6-month period of public consultation. This guideline outlines the procedure to be followed by the competent authorities when a batch of a vaccine is suspected to be contaminated with Bovine Viral Diarrhoea (BVD) Virus.

The Committee adopted a *"Reflection paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue"* (EMEA/CVMP/IWP/105008/2007). This reflection paper has been developed in response to the growing threat of Bluetongue within the European Union and the lack of vaccines with marketing authorisations within the Community.

The Committee adopted a *"Concept paper on the need for requiring data to demonstrate the influence of maternally derived antibody on the vaccination of very young animals"* (EMEA/CVMP/IWP/501304/2006) for release for a 3-month period of public consultation. The concept paper proposes the development of a guideline to provide better guidance on how to evaluate the safety and efficacy of early life immunisation protocols for target animals.

The Committee adopted a *"Concept paper on requirements for multi-strain dossiers"* (EMEA/CVMP/IWP/90459/2007) for release for a 3-month period of public consultation. The concept paper proposes the development of a guideline on the requirements to be fulfilled for applications for multi-strain dossiers. In this guideline the scientific requirements on quality, safety and efficacy data for such an application will be defined.

The documents will be available on Monday 23 April 2007 on the EMEA web site:
http://www.emea.europa.eu

Quality

The Committee adopted the "*Concept Paper on the revision of the CVMP guideline on stability testing of existing active substances and related finished products*" (EMEA/CVMP/QWP/103377/2007) for release for a 3-month period of public consultation. The aim of this revision is to update provisions in line with some of the requirements of the recently updated VICH guideline on stability.

The document will be available on Monday 23 April 2007 on the EMEA web site:
http://www.emea.europa.eu

Inspections

The Committee adopted an SOP on Coordination of pre-approval GxP Inspections (SOP/INSP/2019). The previous three SOPs for the coordination of GMP inspections (SOP-INSP-2003), GCP (SOP-INSP-2004) and GLP (SOP-INSP-2008) have been extensively modified and integrated in this single SOP. The SOP describes the processes used for inspection coordination in the routine review of applications, preparation and processing of inspection requests, and coordination and reporting of inspections in applications for marketing authorisations under the centralised procedure.

Publication of this document will follow its adoption by the Committee for Medicinal Products for Human Use (CHMP), which is foreseen for its next meeting on 23-26 April 2007.

Availability of Veterinary Medicines

The Committee continued discussions on activities to improve availability of veterinary medicines which addressed in particular criteria for classifying an indication as intended for a "limited market", the scope of Article 79 of Regulation 726/2004 and the procedure for the CVMP to classify veterinary medicinal products as indicated for use in a limited market. It is expected that proposals on these issues can be published in a few months time.

The next meeting of the CVMP will be held on 14-16 May 2007

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