European Medicines Agency
Veterinary Medicines and Inspections

London, 19 September 2008
EMEA/CVMP/473629/2008

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 16-18 September 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for **Easotic** (*combined hydrocortisone aceponate, miconazole nitrate, gentamicin sulphate*), ear drops suspension for dogs, intended for the treatment of acute otitis externa, and acute exacerbation of recurrent otitis externa associated with bacteria susceptible to gentamicin and fungi susceptible to miconazole in particular *Malassezia pachydermatis*.

The Committee adopted by consensus a positive opinion for **Duvaxyn WNV** (*inactivated West Nile virus strain VM-2*), intended for the active immunisation of horses of 6 months of age or older against West Nile Virus disease by reducing the number of viraemic horses.

Following the request for a re-examination of the opinion adopted on 14 May 2008, the Committee adopted by majority a revised opinion recommending to grant a marketing authorisation for **Masivet** (*masitinib*) for use in dogs with non-resectable Grade 2 or 3 mast cell tumours which express the mutant c-KIT tyrosine kinase receptor.

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

The Committee was informed of the formal notification from Elanco Animal Health of their decision to withdraw the application for **Kexxtone** (avilamycin) premix for rabbits. More information about Kexxtone and the state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report. The document, together with the withdrawal letter from the company will be published on the EMEA website in due course.

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

Previcox - additional indication to include relief of post-operative pain and inflammation associated with orthopaedic surgery in dogs and updated the product information with new renal/hepatic warnings based on pharmacovigilance reports received;

Aivlosin - several changes to the quality part of the dossier including a new packaging material for the finished product and change in shelf-life;

Convenia - an increase in the shelf-life of the finished product;

Prac-Tic - update in the detailed description of the pharmacovigilance system (change of a qualified person for pharmacovigilance;

Purevax FeLV - tightening of release specifications for the feline leukaemia component;

Purevax RCPCh FeLV - an increase of the target formulation titre for the feline rhinotracheitis component and tightening of release specifications for the feline rhinotracheitis, calicivirus and feline leukaemia components;

Purevax RCPCh - an increase of the target formulation titre for the feline rhinotracheitis component and tightening of release specifications for the feline rhinotracheitis and calicivirus components;

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Purevax RCP FeLV - an increase of the target formulation titre for the feline rhinotracheitis component and tightening of release specifications for the feline rhinotracheitis and feline leukaemia components;

Purevax RCP - an increase of the target formulation titre and tightening of release specifications for the feline rhinotracheitis component;

Purevax RC- an increase of the target formulation titre and tightening of release specifications for the feline rhinotracheitis component;

Purevax RCCh - an increase of the target formulation titre for the feline rhinotracheitis component and tightening of release specifications for the feline rhinotracheitis and calicivirus components;

Vaxxitek HVT + IBD - addition of an alternative site for the manufacture of the vaccine.

Maximum Residue Limits

The Committee adopted a revised list of substances not falling within the scope of the Council Regulation (EEC) No 2377/90, in order to include **triethanolamine** after concluding that the substance is not pharmacologically active at doses of up to 0.25 mg/kg bw.

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

Annual Reassessments

The Committee adopted by consensus a positive opinion on the annual re-assessment for **Nobilis Influenza H5N2** (inactivated whole influenza virus H5N2), from Intervet International BV, a vaccine intended for active immunisation of chickens against avian influenza type A, subtype H5. The CVMP having reviewed the evidence of compliance with the specific obligations submitted by the marketing authorisation holder and having re-assessed the benefit/risk profile of the medicinal product, recommended that the Community marketing authorisation under exceptional circumstances be continued and updated.

The Committee adopted by consensus a positive opinion on the annual re-assessment for **Poulvac FluFend H5N3 RG** (recombinant inactivated avian influenza virus), from Fort Dodge Animal Health, a vaccine intended for active immunisation of chickens and ducks against avian influenza type A, subtype H5. The CVMP having reviewed the evidence of compliance with the specific obligations submitted by the marketing authorisation holder and having re-assessed the benefit/risk profile of the medicinal product, recommended that the Community marketing authorisation under exceptional circumstances be continued.

Referrals

The Committee started a referral procedure for **Clavobay Lactating Cow** (a*moxicillin and clavulanic acid)*, from Bayer PLC. The matter was referred to the CVMP by the United Kingdom, as the reference Member State in a decentralised procedure, under Article 33 of Directive 2001/82/EC, due to disagreement among the Concerned Member States on the granting of a marketing authorisation following the decentralised procedure. The main area of disagreement relates to the efficacy and dosage of the product.

The Committee started a referral procedure for **Shotaflor** (*florfenicol)*, from Virbac S.A.. The procedure was referred to the Committee by the United Kingdom, as the reference Member State in the mutual recognition procedure, under Article 33 of Directive 2001/82/EC, due to concerns raised by Germany and The Netherlands regarding the environmental risk assessment.

The Committee started a referral procedure for **Fenflor** (*florfenicol)*, from Gosmore Ltd. The procedure was referred to the Committee by the United Kingdom, as the reference Member State in the mutual recognition procedure, under Article 33 of Directive 2001/82/EC, due to concerns raised by Germany and The Netherlands regarding the environmental risk assessment.

The Committee started a referral procedure for **Pulmotil AC** (*tilmicosin)*, from Lily Deutschland GmbH. The matter was referred to the CVMP by Germany, under Article 34 of Directive 2001/82/EC, due to different decisions taken by Member States on the use in target species turkeys.

Scientific advice

The Committee agreed scientific advice regarding safety issues for an anti-inflammatory product for use in horses.

Pharmacovigilance

The Committee reviewed the PSURs for **Equilis Prequenza, Equilis Prequenza Te** and **Previcox** and recommended to the marketing authorisation holders to include in the product literature information on new adverse reactions. The Committee also reviewed Periodic Safety Update Reports (PSURs) for **Aivlosin, Equilis StrepE, Flexicam, Meloxivet, Nobivac Piro, Poulvac Flufend H5N3 RG** and **Rabigen SAG2** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Safety

The Committee adopted a "*Reflection paper on assessment of bioavailability of bound residues in food commodities of animal origin*" (EMEA/CVMP/SWP/95682/2007) following the close of the public consultation. This reflection paper has been updated to take account of comments received during the public consultation.

The overview of the comments received during the public consultation of this reflection paper will be published on the EMEA website (EMEA/CVMP/SWP/213492/2008).

The Committee adopted an introductory note to its "*Reflection paper on the new approach developed by JECFA for exposure and MRL assessment of residues of VMP*" (EMEA/CVMP/SWP/138366/2008) to clarify its understanding of how JECFA intends to use the EDI. The introductory note will be incorporated into the reflection paper and published on the EMEA website (EMEA/CVMP/SWP/138366/2008-Rev 1).

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

Immunology

The Committee adopted a clarification note on the requirements for starting materials of biological origin in order to progress the current discussions on ensuring adequate traceability of relevant materials used in immunological veterinary medicinal products authorised at national and centralised level.

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

International Harmonisation

The Committee adopted the following VICH guidelines following sign-off by the VICH Steering Committee at its 21st meeting on 8-9 July 2008:

- *GL43 on Target Animal Safety for Pharmaceuticals*" (EMEA/CVMP/VICH/393388/2006). After implementation this guideline replaces the current "Guideline on the evaluation of the safety of veterinary medicinal products for target animals".

- "*GL44 on Target Animal Safety for Veterinary Live and Inactivated Vaccines*" (EMEA/CVMP/VICH/359665/2005). This guideline establishes agreed criteria and recommendations for the conduct of studies that evaluate the safety of final formulation of veterinary live and inactivated vaccines.

The implementation date for these guidelines is July 2009.

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

Regulatory Issues

The Committee recommended the suspension of the marketing authorisation for Porcilis Pesti, a marker vaccine against classical swine fever. The recommendation will now be forwarded to the European Commission who will consider the need to request the Committee for a formal opinion on suspension.

The Committee adopted the Volume 9B of the Rules Governing Medicinal Products in the European Union - Pharmacovigilance for Veterinary Medicinal products (EMEA/CVMP/PhVWP/430286/2007). This document was developed further to the request from the European Commission in May 2007 for the CVMP and its Pharmacovigilance Working Party to provide input on revised guidance on pharmacovigilance for veterinary medicinal products. The document includes guidance for marketing authorisation holders and the competent authorities on roles, responsibilities and procedures in relation to pharmacovigilance systems and reporting of adverse events.

The document will be submitted to the European Commission for review.

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