European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 14-16 July 2009

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on **ZOLVIX** (*monepantel*), from Novartis Healthcare A/S, intended as a broad spectrum anthelmintic for the treatment and control of gastro-intestinal nematodes and associated diseases in sheep of all age groups including lambs, hoggets, breeding rams and ewes.

The Committee adopted by consensus a positive opinion on an extension application for **Naxcel** (*ceftiofur*), from Pfizer Ltd., to add a new target species (cattle).

The Committee adopted by consensus a positive opinion on an extension application for **Rheumocam** (*meloxicam*), from Chanelle Pharmaceuticals Manufacturing Limited, to add a new pharmaceutical form (chewable tablets) for dogs.

The Committee adopted by consensus a positive opinion on an extension application for **MELOXIDYL** (*meloxicam*), from CEVA Santé Animale, to add a new pharmaceutical form (solution for injection) for dogs and cats.

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

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

Posatex – change in the formulation to improve the stability of the finished product;

Cerenia – addition of a new indication (nausea induced by chemotherapy);

Locatim – to remove the target animal batch safety test from the finished product testing;

Circovac – related to the number of passages between the Master Seed Virus (MSV) and the Working Seed Virus (WSV).

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisations for **Oxyglobin** and **Stronghold**. The Committee, having re-assessed the benefit-risk balance of the products, concluded that the quality, safety and efficacy of the products continued to be appropriately demonstrated, therefore, recommended the renewal of the marketing authorisations.

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Annual Reassessment of Marketing Authorisations

The Committee adopted an opinion on the annual reassessment for **Poulvac FluFend H5N3 RG**, further to the evaluation of the data submitted by Fort Dodge Animal Health. The Committee recommended the continuation of the Community Marketing Authorisation under exceptional circumstances for the veterinary medicinal product.

Community Referrals

The Committee concluded the referral procedure for **APPM Respipharm** (*strains of Actinobacillus pleuropneumoniae* (serotypes 2, 9 and 11), *Pasteurella multocida* serotype A) from Pharmagal Bio, s.r.o.. The matter was referred to the CVMP by Slovakia, as the Reference Member State in a mutual recognition procedure, under Article 33 of Directive 2001/82/EC, due to concerns raised by Spain regarding quality and efficacy of the product. The Committee adopted by consensus an opinion concluding that the application did not satisfy the criteria for authorisation with regard to efficacy and therefore recommended the refusal of the granting of the marketing authorisations. Furthermore, the CVMP recommended that the existing marketing authorisation should be suspended.

The Committee concluded the referral procedure for **Tildren 500mg** (*tiludronic acid*), from CEVA Animal Health Limited. The matter was referred to the CVMP by the United Kingdom, as the Reference Member State in a mutual recognition procedure, under Article 33 of Directive 2001/82/EC, due to concerns raised by Belgium and Sweden regarding the efficacy of the product. The Committee adopted by majority an opinion concluding that the application did not satisfy the criteria for authorisation with regard to efficacy and therefore recommended the refusal of the granting of the marketing authorisations. Furthermore, the CVMP recommended that the existing marketing authorisation should be suspended.

The Committee started a referral for **Vasotop P** (1.25, 2.5 and 0.625 mg) (*ramipril*), from Intervet International B.V., with regard to a line extension to cats. The matter was referred to the Committee by Belgium as a Concerned Member State in the mutual recognition procedure, under Article 6(12) of Commission Regulation (EC) No 1084/2003, due to concerns regarding the efficacy of the product.

The Committee started a referral for **Poulvac Bursa Plus** (*live Infectious Bursal DiseaseVirus, strain V877*), from Fort Dodge Animal Health Ltd., The matter was referred to the Committee by the UK as Reference Member State in the mutual recognition procedure, under Article 33 of Directive 2001/82/EC due to concerns raised by Belgium relating to the efficacy of the product.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of provisional maximum residue limits for **methylprednisolone** in milk, in accordance with Regulation (EC) No 470/2009. Maximum residue limits have previously been established for the substance in bovine edible tissues.

The summary opinion is available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/mrls/a.htm

Scientific Advice

The Committee agreed scientific advice regarding safety and efficacy aspects of a veterinary medicinal product for horses and also agreed advice on a request to determine whether an excipient does not fall within the scope of Council Regulation (EEC) No 2377/90.

Pharmacovigilance

The Committee reviewed the PSURs for **Convenia**, **Ingelvac CircoFLEX**, **Nobilis Influenza H5N2**, **Nobilis Influenza H7N1**, **Poulvac Flufend H5N3 RG**, **Purevax RC**, **Purevax RCCh**, **Slentrol** 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 endorsed a revised SOP for Management of 15-day Suspected Adverse Reaction (SAR) report for Centrally Authorised Veterinary Medicinal Product (SOP/V/4052). The revision reflects the use of the electronic reporting via EudraVigilance Veterinary (EVVet) as the only acceptable way to report adverse drug reactions by Marketing Authorisation Holders and Member States and the introduction of the use of the Eudra DataWareHouse (DWH) to retrieve and analyse the data contained in the EVVet database.

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/general/sop/sop.htm#Vets

Immunologicals

The Committee adopted a "*Guideline on the requirements for the replacement of established Master Seeds (MS) already used in authorised immunological veterinary medicinal products*" (EMEA/CVMP/IWP/105504/2007) following the close of public consultation. The guideline applies to the replacement of a vaccine organism (e.g. virus, bacteria, fungus) master seed by a master seed of the same origin. It applies also to the replacement of the master cell seed used to produce a vaccine organism by a master cell seed of the same origin. The guideline provides advice on the scientific data to be presented whenever a variation of established master seeds will be applied. It will come into effect on 1 February 2010.

The overview of comments received during the public consultation of this guideline will be published on the EMEA website (EMEA/CVMP/IWP409485/2009).

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/vetguidelines/immunologicals.htm

Antimicrobial Resistance

The Committee adopted a "*Concept paper on meticillin-resistant Staphylococcus (pseud)intermedius*" for release for a 2-month period of public consultation (EMEA/CVMP/SAGAM/386369/2009-CONSULTATION). This concept paper is published with a view to receiving comments for consideration in the development of a reflection paper addressing meticillin-resistant *Staphylococcus (pseud)intermedius* (MRSP), which has recently emerged as a significant animal health problem in veterinary medicine. Infections with MRSP are common in dogs and to a lesser extent cats.

The document will be available on the EMEA web site:
http://www.emea.europa.eu/htms/vet/vetguidelines/safety.htm

General

The CVMP endorsed the recommendations from the Focus Group meeting on substances of animal origin which took place on 30 June 2009. The recommendations together with the report of the Focus Group meeting will be available on the EMEA website:
http://www.emea.europa.eu/htms/vet/statements/statements.htm

Minor Uses and Minor Species (MUMS)/Limited Markets

The CVMP endorsed the procedure for classification of a veterinary medicinal product as intended for MUMS/limited markets and endorsed guidance to applicants which will be published shortly on the EMEA website. The intended start date for the receipt of applications for classification by CVMP in line with this new policy is 1 September 2009. Full details will be published shortly in a procedural announcement.

The next meeting of the CVMP will be held on 15-17 September 2009

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