European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 8-10 December 2009

CVMP Opinions on Veterinary Medicinal Products

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

Metacam – addition of a new therapeutic indication for pigs;
Porcilis PCV – change of vaccination scheme and change in indications;

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

Previcox – additional information related to the potential for the development of nervous system disorders in treated dogs;
Profender – change in the finished product specification;
Reconcile –change in the Detailed Description of the Pharmacovigilance System
BTVPUR Alsap 8 – addition of a new manufacturing site.

In addition, the Committee adopted by majority a positive opinion for a type II variation application for:
Convenia – additional indication.

Renewals of Marketing Authorisations

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Incurin**, **Ibraxion** and **Rabigen SAG2**. 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, and therefore, recommended the indefinite renewal of the marketing authorisations.

Community Referrals

The Committee noted a request for re-examination of the CVMP opinion adopted on 11 November 2009 in the context of a referral procedure initiated under Article 35 of Directive 2001/82/EC for all veterinary medicinal products containing **quinolones including fluoroquinolones** intended for use in food-producing species. The procedure will be initiated once the grounds for the re-examination are submitted.

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The Committee concluded the referral procedure for **CEVAZURIL 50 mg/ml oral suspension for piglets** (*toltrazuril)*. The matter was referred to the CVMP by France, as the reference Member State in the decentralised procedure, under Article 33 of Directive 2001/82/EC, due to concerns raised by Germany, the United Kingdom, Portugal, Spain and Poland in relation to a potential serious risk to the environment from use of the product. The Committee adopted by consensus an opinion concluding that the objections raised during the decentralised procedure should not prevent the granting of a Marketing Authorisation.

The Committee concluded the referral procedure for **Vasotop P** (1.25, 2.5 and 0.625 mg) (*ramipril*). 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 adopted by majority an opinion concluding that the variation application does not satisfy the criteria for approval.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of provisional maximum residue limits in accordance with Regulation (EC) No. 470/2009 for **tildipirosin** in bovine, porcine and caprine species.

The Committee adopted a revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMEA/CVMP/519714/2009), in order to include:

- Polyoxyethylene oleate (CAS No. 9004-96-0): at doses up to 1.15 mg/kg bw
- Polyoxyethylene oleic alcohol (CAS No 9004-98-2): at doses up to 0.95 mg/kg bw
- Polyethylene glycol-75 lanolin (CAS no 8039-09-6 and 61790-81-8): for topical use only.

The documents are available on the Agency web site:
http://www.ema.europa.eu/htms/vet/mrls/mrlop.htm

Scientific Advice

The Committee agreed scientific advice for the clinical development of a product for the treatment of a physiological condition in cats.

MUMS/Limited markets

The Committee reviewed a request for classification under the new MUMS/limited markets policy which commenced on 1 September 2009. The request which is in relation to an immunological product for a wildlife species, was considered as eligible for financial incentives as intended for MUMS/limited markets.

Pharmacovigilance

The Committee reviewed the PSURs for **Cortavance**, **Equilis Te**, **Loxicom**, **Medicinal Oxygen Air Liquide Santé**, **Porcilis PCV**, **Porcilis Porcoli**, **Reconcile**, **Rheumocam**, **Suprelorin** and **Zactran** and concluded that no further action or changes to the product literatures were required. The Committee also reviewed the PSUR for **Slentrol** and recommended the inclusion of information on new adverse reactions in the product literature.

Concept Papers, Guidelines and SOPs

Quality

The CVMP adopted the revised 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products (EMEA/HMPC/CHMP/CVMP/287539/2005 Rev.1). After adoption by the CHMP, the guideline together with the overview of comments received during public consultation will be available at the EMEA website: http://www.ema.europa.eu/htms/human/humanguidelines/quality.htm

International Harmonisation

The Committee adopted the draft VICH guidelines in relation to metabolism and residue kinetics following sign-off by the VICH Steering Committee at its 23rd meeting held on 5-6 November 2009 for a 6-month period public consultation:

- GL46: Metabolism study to determine the quantity and identify the nature of residues (EMEA/CVMP/VICH/463072/2009),
- GL47: Comparative metabolism studies in laboratory animals (EMEA/CVMP/VICH/463104/2009);
- GL48: Marker residue depletion studies to establish product withdrawal periods (EMEA/CVMP/VICH/463199/2009);
- GL49: Validation of analytical methods used in residue depletion studies (EMEA/CVMP/VICH/463202/2009).

The documents will be available on the Agency web site:
http://www.ema.europa.eu/htms/vet/vetguidelines/safety.htm

Working Parties

The Committee established the CVMP Environmental Risk Assessment Working Party as a standing Working Party and adopted a revised mandate (EMEA/CVMP/ERA/705470/2009-Rev.2) for a three-year period.

The Committee also adopted a revised mandate for the CVMP Scientific Advisory Group on Antimicrobials for a three-year period (EMEA/CVMP/SAGAM/241147/2006-Rev.1).

The document will be available on the Agency web site:
http://www.ema.europa.eu/htms/general/contacts/CVMP/CVMP_WPs.html

The Committee elected L. Vesterager Borge as vice-chair of the Pharmacovigilance Working Party and S. Jones as vice-chair of the Safety Working Party, both for a 3-year mandate.

Organisational issues

General guidance – variations

The Committee endorsed a procedural document for appointment of Rapporteurs for work-sharing of Variations under the new Variations Regulation (Commission Regulation (EC) No. 1234/2008) when one of the authorisations concerned is for a centrally authorised product. It is highly recommended that proposals to submit such applications be communicated to the Agency at least three months in advance.

The documents will be available on the Agency web site:
http://www.ema.europa.eu/htms/vet/genguidance/genreg.htm

Pandemic H1N1 influenza A strain vaccines in pigs

The CVMP considered issues related to the possible authorisation of vaccines for use in pigs against the pandemic H1N1 influenza A strain. In view of the potential for the epidemiological situation to change and vaccination to become an element of disease control policy, the CVMP considered that the Agency should be prepared to accept applications for authorisation under exceptional circumstances for vaccines for use in pigs against the pandemic H1N1 influenza A strain. As the criteria for requirements for either 'routine' or exceptional authorisation have yet to be defined for pandemic H1N1 influenza A strain vaccines for pigs, the Agency plans to hold a workshop on this subject in the first quarter of 2010 and would encourage any potential applicant to contact the Agency.

PROCEDURAL ANNOUNCEMENT BY THE AGENCY

Implementation of Variation Regulation (EC) No 1234/2008

Applications for variations and/or extensions will be processed according to the current Variation Regulation (EC) No 1085/2003 or the new Variation Regulation (EC) No 1234/2008, based on the date of submission of the application (i.e. date of receipt by the European Medicines Agency).

As the European Medicines Agency will be closed between 24 December 2009 and 1 January 2010 (inclusive), Marketing Authorisation Holders (MAHs) are requested not to submit Type IA variation applications to the Agency between 14 and 23 December 2009 (inclusive) because the 14-day timeframe for the Agency to acknowledge the validity of the submitted Type IA variation(s) (see article 4 of Commission Regulation (EC) No 1085/2003) would coincide with the official closure of the Agency.

Marketing Authorisation Holders intending to submit applications for other variations and/or extensions according to Variation Regulation (EC) No 1085/2003 are advised to submit their application at the latest by 23 December 2009.

Marketing Authorisation Holders intending to submit applications for variations and/or extensions according to Variation Regulation (EC) No 1234/2008 for a start of procedure in January 2010 are therefore advised to submit their application after 1 January 2010 and at the latest by the recommended submission dates published on the Agency website.

The next meeting of the CVMP will be held on 12-14 January 2010.

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