European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 14-16 October 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for **Onsior** (*robenacoxib*), tablets and solution for injection for dogs and cats, intended for the treatment of pain and inflammation.

The Committee adopted by consensus a positive opinion for **Acticam** (*meloxicam*), oral suspension for dogs and solution for injection for dogs and cats, intended for alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and reduction of postoperative pain.

The Committee adopted by consensus a positive opinion for **Flexicam** (*meloxicam*), an extension to include a solution for injection for dogs and cats, intended for alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and reduction of postoperative pain.

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

Following the request for a re-examination of the opinion adopted on 18 June 2008, the Committee adopted by majority a negative opinion with regard to a variation for **Porcilis Porcoli** to change to the use of an animal component free media for the production of one of the antigens. The Committee confirmed its previous conclusion that the data presented were insufficient to allow a complete assessment of the variation.

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

Cerenia - changes to section 4.6 (adverse reactions) of the solution for injection of the SPC, following a PSUR assessment;

Convenia - changes in the manufacturing process for the finished product;

Reconcile - change in the detailed description of the pharmacovigilance system;

Meloxivet - change in the detailed description of the pharmacovigilance system;

Yarvitan - change in the detailed description of the pharmacovigilance system;

Suvaxyn Aujeszky 783 + O/W - addition of 3 manufacturers of foetal bovine serum;

Suvaxyn Aujeszky 783 + O/W - addition of type I glass vials to the currently approved type II glass vials for 50 and 100-dose presentations of the solvent.

The Committee was informed of the formal notification from S-P Animal Health of their decision to withdraw the extension application for a new pharmaceutical form (oral solution) for **Zubrin.** More information about this extension application and the current 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 applicant will be published on the EMEA website in due course.

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Renewals of Marketing Authorisations

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

Maximum Residue Limits

Further to an appeal from the applicant, with regard to the opinion adopted on 18 June 2008 recommending the inclusion of **isoeugenol** in Annex IV of Council Regulation (EC) No 2377/90, the Committee agreed to revise their previous opinion and concluded that on the basis of the data available no recommendations for inclusion of isoeugenol in any of the annexes to Regulation 2377/90 could be made.

Referrals

The Committee started a 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 related to quality and efficacy that Spain, as a Concerned Member State, considers present a serious risk to animal health.

The Committee started a referral procedure for **Tiamutin Premix** (*tiamulin fumarate)*, from V.M.D.n.v. and Novartis Animal Health Ireland Ltd. The matter was referred to the CVMP by Belgium and Ireland, under Article 34 of Directive 2001/82/EC, due to divergent decisions concerning the marketing authorisations of the product resulting in discrepancies in the summaries of product characteristics (SPCs).

Scientific advice

The Committee agreed scientific advice regarding bioequivalence issues for a generic medicinal product for dogs.

Pharmacovigilance

The Committee reviewed the PSURs for **Nobilis Influenza H5N2**, **Nobilis Influenza H7N1**, **Naxcel**, **Rheumocam**, **Pruban**, **Porcilis AR-T DF**, **PRILACTONE** and **Yarvitan** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Pharmacovigilance

The Committee adopted a "*Recommendation on management and assessment of Periodic Safety Update Reports (PSURs) of veterinary medicinal products*" (EMEA/CVMP/PhVWP/4550/2006) following the close of the public consultation. This recommendation* gives guidance to assessors in their scientific and regulatory assessment of PSURs and aims at assessments of high quality as well as standardisation of the format of PSUR assessment reports across the EU. The recommendation has been updated to take account of comments received during the public consultation. The recommendation will come into effect on 1 January 2009.

The overview of the comments received during the public consultation of this recommendation will be published on the EMEA website (EMEA/CVMP/PhVWP/4559/2006).

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

Quality

The Committee adopted a draft 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) for release for a 3-month period of public consultation. The original guideline focussed solely on how to ensure precision and consistency in the declarations of content in herbal substances/herbal preparations in the SPC of finished herbal medicinal products. This draft revision now extends, in the form of an annex to the guideline, this guidance to the declarations used in labelling and package leaflets.

The publication of the document on the EMEA web site: http://www.emea.europa.eu will follow its adoption by the CHMP at the October meeting (23 October 2008).

Antimicrobials

The Committee adopted a "*Reflection paper on antimicrobial resistance surveillance as post-marketing authorisation commitment*" (EMEA/CVMP/SAGAM/428938/2007) following the close of the public consultation. This reflection paper has been updated to take account the 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/SAGAM/341254/2008).

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

Regulatory Issues

The Committee adopted a "*Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products*" (EMEA/CVMP/248499/2007) following the close of the public consultation for release for a further 3-month period of public consultation. This recommendation* has been revised to take account of the comments received during the first public consultation.
A second, albeit shorter public consultation was considered useful as the revision addressed a large part of the document, as detailed in the Note regarding the draft CVMP Recommendation (EMEA/425495/2007).

The overview of the comments received during the public consultation of this document will be published on the EMEA website (EMEA/CVMP/220526/2008).

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

* The Committee took note of an agreement between the European Commission and the EMEA on the categorisation of regulatory documents. Under this agreement the term "recommendation" will in future be used for documents that are not specifically mentioned in the pharmaceutical legislation, including in particular those that explain how processes are to be operated. This change in nomenclature comes into immediate effect and has no implications on the intent or legal status of the documents concerned. Existing documents that should more correctly be named "Recommendation" will be renamed at their next scheduled review.

Organisational Matters

The Committee endorsed the work programmes for 2009 for the CVMP Working Parties on Scientific Advice, Pharmacovigilance, Efficacy, Safety, Immunologicals and Environmental Risk Assessment as well as for the Joint CHMP/CVMP Quality Working Party and the CVMP Scientific Advisory Group on Antimicrobials.

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

The next meeting of the CVMP will be held on 11-13 November 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