European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 11-13 December 2007

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Ingelvac CircoFLEX**, from Boehringer Ingelheim Vetmedica GmbH, intended for active immunisation of pigs over the age of 2 weeks against porcine circovirus type 2.

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

The Committee adopted positive opinions for Type II variations with regard to:

- **Purevax range (FeLV, RCPCh FeLV, RCPCh, RCP FeLV, RCP, RC, RCCh)** for the change of manufacturing site of biological active substance;
- **Purevax range (RCPCh FeLV, RCPCh, RCP FeLV, RCP, RC, RCCh)** to shorten the onset of immunity of the R (feline rhinotracheitis herpesvirus), C (feline calicivirus), P (feline panleucopenia virus) and Ch (*Chlamydophila felis*) components of the vaccines;
- **Purevax range (RCPCh FeLV, RCPCh, RCP FeLV, RCP, RC, RCCh)** to amend the product literature to indicate compatibility with Rabisin;
- **ProteqFlu** and **ProteqFlu-Te** to change the manufacturing site of biological active substance;
- **Cerenia** for some changes to the wording of the SPC;
- **Fevaxyn Pentofel** to add additional manufacturers for some of the starting materials.

Following the request for a re-examination of the opinion adopted on 11 July 2007 granting a Marketing Authorisation for **Nobilis Influenza H5N2** subject to a requirement to include a special warning relevant for this type of vaccine, the Committee adopted by majority a revised opinion upholding its previous opinion.

Following the request for a re-examination of the opinion adopted on 11 July 2007 granting a Marketing Authorisation for **Nobilis Influenza H5N6** subject to a requirement to include a special warning relevant for this type of vaccine, the Committee adopted by majority a revised opinion upholding its previous opinion.

Maximum Residue Limits

The Committee adopted by majority an opinion recommending the extension of the current Annex II entry of Council Regulation (EEC) No. 2377/90 for **sodium salicylate** to oral use in turkeys.

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

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Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Advocate**. 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. Furthermore, it was agreed one further renewal would be required to complete outstanding studies in relation to pharmacovigilance information.

Community Referrals

The Committee concluded the referral procedure for **Equibactin vet *(trimethoprim and sulfadiazine)***, an oral paste for horses from LeVet BV. The procedure was referred to the Committee by the reference Member State in the decentralised procedure, the Netherlands, under Article 33(4) of Directive 2001/82/EC, as amended, due to concerns raised by France on the adequacy of the dose regime of the product. The Committee adopted by consensus an opinion concluding that it was proven that the product was essentially similar to the reference product, Tribrissen, and therefore the same conclusions on efficacy and safety should apply to both products. The Committee considered that the objections raised should not prevent the granting of the marketing authorisation. However, the marketing authorisation should be varied as necessary to take into account the outcome of the referral procedure under Article 35 of Directive 2001/82/EC for the originator product Tribrissen oral paste (as authorised in The Netherlands).

The Committee concluded the referral procedure for **Tribrissen *(trimethoprim and sulfadiazine)*** (including associated names) and other authorised products for which the product served as reference product. The procedure was referred to the Committee by France, under Article 35 of Directive 2001/82/EC, as amended, due to concerns of possible under-dosing that could lead to lack of efficacy and potential antimicrobial resistance development. The Committee adopted by majority an opinion concluding that there is no documented evidence from the field related to lack of efficacy or any change in the resistance situation of the relevant target pathogens that would constitute a concern to human or animal health. Furthermore the CVMP concluded that no dose could be established for salmonellosis. The Committee recommended to vary the marketing authorisations to retain only the recommended dose 30 mg/kg bw, once a day, over 5 days, to delete the salmonellosis indication, and to add a recommendation for susceptibility testing. The opinion would be forwarded to the Commission.

The Committee started a referral procedure for **Solacyl (*sodium salicylate*)**, powder for oral solution for calves and pigs, from Eurovet Animal Health B.V.. The matter was referred to the CVMP by the Netherlands, the reference Member State for the decentralised procedure, under Article 33(4) of Directive 2001/82/EC, as amended, due to concerns raised by Ireland that the therapeutic benefit of the product had not been proven.

The Committee started a referral procedure for oral soluble powders containing **sodium salicylate**, for calves and pigs. The matter was referred to the CVMP by Ireland, under Article 35 of Directive 2001/82/EC, as amended, on the basis that it is in the interests of the Community for the Committee to consider concerns raised in relation to possible lack of efficacy for this group of products. The Committee is requested to consider if the data available are adequate to substantiate the efficacy of the products, the recommended dose regimes, and if the overall benefit/risk balance of the products is positive when given orally for mass administration to cattle and pigs. The Committee is expected to consider the questions to be addressed to the concerned Marketing Authorisation Holders at their January 2008 meeting.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Medicinal oxygen**, **Vaxxitek HVT+IBD**, **Nobilis Influenza H5N2**, **Poulvac Flufend H5N3** and **Prac-Tic** and concluded that no further action or changes to the products literature were required.

Concept Papers, Guidelines and SOPs

Immunologicals

The Committee adopted a reflection paper on consideration of adjuvants and preservatives under Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (EMEA/CVMP/IWP/339116/2007-CONSULTATION) for release for a 3-month period of public consultation. This reflection paper intends to clarify the approach currently followed for adjuvants and preservatives with regard to the establishment of maximum residues limits when such substances are to be used in veterinary medicinal products intended for food-producing species.

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

Quality

The Committee adopted a "*Guideline on the quality aspects of single-dose veterinary spot-on products*" (EMEA/CVMP/QWP/544461/2007-CONSULTATION) for release for a 6-month period of public consultation. The guideline provides recommendations on certain quality-related issues for single-dose spot-on products.

The Committee adopted a revised "*Guideline on the declaration of storage conditions*" (EMEA/CVMP/422/99-Rev.3). This revision includes only editorial amendments, in line with the revised Human guideline, for clarity.

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

Organisational Issues

CVMP Working Parties

The Committee elected chairpersons for working parties for which the 3-year mandate had been completed. The following chairs were elected:

- Efficacy Working Party: Michael Holzhauser-Alberti
- Immunologicals Working Party: Jean-Claude Rouby
- Pharmacovigilance Working Party: Cornelia Ibrahim
- Safety Working Party: Johan Schefferlie

The Committee also elected Joop de Knecht as chairperson of the Environmental Risk Assessment Working Party (ERAWP). Dr de Knecht was previously the Vice-chair of the ERAWP.

The Committee adopted a reviewed the mandate for the Safety Working Party for 2008-2010 following the completion of the 3-year period for revision. The Committee also updated the mandates of the CVMP Efficacy, Immunologicals, Pharmacovigilance and Environmental Risk Assessment working parties to harmonise the part concerning the rules of procedure with the revised CVMP Rules of Procedure.

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 15-17 January 2008

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http://www.emea.europa.eu