European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 10-12 November 2009

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **RESPIPORC FLU3** (inactivated vaccine against swine influenza in pigs), from IDT Biologika GmbH. **RESPIPORC FLU3** is a suspension for injection intended for the active immunisation of pigs from the age of 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection.

The Committee adopted by consensus a positive opinion for an initial marketing authorisation application for **Gripovac 3** (inactivated vaccine against swine influenza in pigs), from Merial S.A.S.. **Gripovac 3** is also a suspension for injection intended for the active immunisation of pigs from the age of 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application under exceptional circumstances for **Zulvac 8 Bovis** (inactivated vaccine against the serotype 8 of Bluetongue virus for cattle), from Fort Dodge Animal Health concerning a suspension for injection intended for the active immunisation of cattle from 3 months of age for the prevention of viraemia caused by Bluetongue Virus serotype 8.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application under exceptional circumstances for **Zulvac 8 Ovis** (inactivated vaccine against the serotype 8 of Bluetongue virus for sheep), from Fort Dodge Animal Health concerning a suspension for injection intended for the active immunisation of sheep from 1.5 months of age for the prevention of viraemia caused by Bluetongue Virus serotype 8.

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

Renewals of Marketing Authorisations

The Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for **Purevax RCPCh FeLV**, **Purevax RCPCh**, **Purevax RCP FeLV**, **Purevax RCP**, **Purevax RC** and **Purevax RCCh**. 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 indefinite renewal of the marketing authorisations.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Community Referrals

The Committee considered the grounds for appeal from Pharmagal Bio, s.r.o., against the opinion adopted during its July 2009 meeting concerning **APPM Respipharm** (*strains of Actinobacillus pleuropneumoniae* (serotypes 2, 9 and 11), *Pasteurella multocida* (serotype A)*)* in the context of an arbitration procedure under Article 33 of Directive 2001/82/EC. The Committee concluded that their previous opinion should stand as the application does not satisfy the criteria for authorisation in respect of efficacy. Therefore, the Committee adopted by consensus an opinion concluding that the existing marketing authorisations should be suspended and applications for new authorisations should be refused.

The Committee considered the grounds for re-examination of the CVMP opinion for **Tildren 500 mg lyophilisate for solution for infusion** (*tiludronic acid)* adopted on 15 July 2009 in the context of an arbitration procedure initiated under Article 33 of Directive 2001/82/EC. A proposal for amending the opinion adopted in July 2009 was discussed and rejected. The conclusion of the CVMP was therefore that the existing marketing authorisations should be suspended and applications for new authorisations should be refused.

The Committee concluded the referral procedure for all veterinary medicinal products containing **quinolones including fluoroquinolones** intended for use in food-producing species. The matter was referred to the CVMP by the European Commission under the Article 35 of Directive 2001/82/EC in order to ensure that the warnings on prudent use included in the Summary of Product Characteristics of these classes of veterinary medicinal products were harmonised in line with the recommendations for precautionary phrases in the *CVMP Reflection Paper on the use of fluoroquinolones in food-producing animals – Precautions for use SPC regarding prudent use guidance* (EMEA/CVMP/416168/2006). The Committee adopted by consensus an opinion concluding that the marketing authorisations of the concerned products should be varied in order to amend the Summary of Product Characteristics (SPC) and Package Leaflet in those cases where these are not in line with the CVMP Reflection Paper.

The Committee started a referral procedure for **Fortekor vet and associated names** (5 mg benazepril hydrochloride, film-coated tablets). The matter was referred to the Committee by Sweden 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 for an immunological product for poultry.

Pharmacovigilance

The Committee reviewed the PSURs for **EQUIOXX and Previcox oral paste for horses, Meloxidyl**, **Startvac** and **Ypozane** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Safety

The Committee adopted a "*Guideline on data to be provided in support of a request to include substance in the list of substances considered as not falling within the scope of regulation (EC) No. 470/2009*" (EMEA/CVMP/516817/2009-CONSULTATION) for a 6-month period of public

consultation. This guideline has been developed with the aim of providing advice on the approach to be used to support an argument that an excipient is not pharmacologically active.

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

Pharmacovigilance

The Committee adopted a "*Reflection paper on Risk Management Plans for Centrally Authorised Veterinary Medicinal Products"* (EMEA/CVMP/126726/2007-CONSULTATION) for a 4-month period of public consultation. The document reflects on the implementation of Article 12(3)(k) of Directive 2001/82/EC whereby applicants are requested to submit a detailed description of a risk management system (risk management plan) with the application for a marketing authorisation, where appropriate.

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

MUMS/Limited markets

The Committee reviewed two requests for classification under the new MUMS/limited markets policy concerning a product for an orthopaedic indication in dogs and a product for the treatment of bacterial disease in bees. Both of these requests were considered as MUMS, but neither product was considered eligible for financial incentives.

Work Programmes

The Committee endorsed the work programmes for 2010 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/htms/general/contacts/CVMP/CVMP_WPs.html

The next meeting of the CVMP will be held on 8-10 December 2009.

David Mackay
Head, Veterinary Medicines and Inspections Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.europa.eu