European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 12-14 May 2009

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for **Melovem** (*meloxicam*), from Dopharma Research B.V., an SME company, intended for the treatment of acute respiratory infections in cattle, for use in diarrhoea in calves and young cattle and for use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation in pigs.

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application for the vaccine **Suvaxyn PCV** (inactivated porcine cirovirus recombinant virus (cPCV) 1-2), from Fort Dodge Animal Health, intended for active immunisation of pigs over the age of 3 weeks against Porcine Circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues, and the lesions in lymphoid tissues associated with PCV2 infections, as well as to reduce clinical signs – including loss of daily weight gain, and mortality associated with Post-Weaning Multisystemic Wasting Syndrom (PWMS).

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 a positive opinion for a type II variation application for **ProMeris** regarding the removal of a warning in Section 4.7 of the Sumarry of Product Characterists (SPC) concerning use in pregnant and lactating cats and inclusion of information on a new adverse reaction in section 4.6.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Nobivac Piro**. The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Community Referrals

The Committee concluded the referral procedure for **Clavobay Lactating Cow** (*amoxicillin and clavulanic acid).* The matter was referred to the CVMP by the United Kingdom, as the reference Member State in a decentralised procedure, under Article 33 of Directive 2001/82/EC, due to disagreement among the Concerned Member States on the granting of a marketing authorisation following the decentralised procedure. The main area of disagreement related to concerns regarding the efficacy and dosage of the product. The Committee adopted by majority an opinion concluding that the application does not satisfy the criteria for authorisation with respect to efficacy and therefore recommended the refusal of the granting of the marketing authorisations.

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The Committee concluded the referral procedure for **Shotaflor** (*florfenicol)*. The procedure was referred to the Committee by the United Kingdom, as the reference Member State in the mutual recognition procedure, under Article 33 of Directive 2001/82/EC, due to concerns raised by Germany and The Netherlands regarding the environmental risk assessment. The Committee adopted by majority an opinion concluding that the use of the product as recommended does not constitute a risk for the environment and therefore the concerns raised by Germany and The Netherlands should not prevent the granting of the marketing authorisations.

The Committee concluded the referral procedure for **Fenflor** (*florfenicol)*. The procedure was referred to the Committee by the United Kingdom, as the reference Member State in the mutual recognition procedure, under Article 33 of Directive 2001/82/EC, due to concerns raised by Germany and The Netherlands regarding the environmental risk assessment. The Committee adopted by majority an opinion concluding that the use of the product as recommended does not constitute a risk for the environment and therefore the concerns raised by Germany and The Netherlands should not prevent the granting of the marketing authorisations.

The Committee concluded the referral procedure for **Pulmotil AC** (*tilmicosin)*. The matter was referred to the CVMP by Germany, under Article 34 of Directive 2001/82/EC, due to different decisions taken by Member States on the use in target species turkeys. The Committee adopted by consensus an opinion recommending a harmonised wording for the Summary of Product Characteristics.

The Committee concluded the referral procedure for **Pulmotil 40/100/200 VET Premix** (*tilmicosin*) and associated names. The matter was referred to the CVMP by Belgium, under Article 34 of Directive 2001/82 due to divergent decisions taken by Member States on the dosage and withdrawal period. The Committee adopted by consensus an opinion recommending a harmonised wording for the Summary of Product Characteristics.

The Committee started a referral procedure for all veterinary medicinal products containing **quinolones or fluoroquinolones** for all food-producing species. The matter was referred to the CVMP by the European Commission under the Article 35 of Directive 2001/82/EC on the basis that it is in the interests of the Community for CVMP to consider harmonising the Summary of Product Characteristics of these products with a view to ensuring the prudent use of these classes of antimicrobials in veterinary medicine across the EU.

The Committee considered a referral notification for **Pregsure 3 BVD1 BVD2 IBR Marker** (inactivated Bovine Viral Diarrhoea (BVD) vaccine) from Belgium, as the reference Member State in the decentralised procedure, under Article 33 of Directive 2001/82/EC, citing concerns raised by the reference Member State and concerned Member States that the product might represent a potential serious risk to human or animal health. Given that serious risk concerns should not arise when concerned Member States follow the conclusion of the reference Member State of an unfavorable benefit-risk balance, the Committee considered that there was no legal base on which to accept the referral.

The Committee started a referral procedure for **Cevazuril 50 mg/ml oral suspension for piglets** (*toltrazuril*). The matter was referred to the Committee 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 potential serious risk to the environment from authorisation of the product.

Maximum Residue Limits

The Committee adopted a revised list of substances not falling within the scope of the Council Regulation (EEC) No 2377/90, in order to include:

- 4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES) - for use as a buffering agent in vaccines and vaccine diluents;
- maleic acid - for use in buffering systems at doses of up to 0.39 mg/kg bw;
- sulfolipo-cylclodextrin;
- trometamol - for use in buffering systems at doses of up to 0.65 mg/kg bw;
- zymosan A – for use as an adjuvant at doses of up to 0.12 mg/kg bw.

The list of substances not falling within the scope of Council Regulation 2377/90 was updated accordingly (EMEA/CVMP/046/00).

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

Pharmacovigilance

The Committee reviewed the PSURs for **Cerenia**, **Circovac**, **Equilis Te**, **Gonazon**, **Medicinal Oxygen Air Liquide Sante**, **Meloxidyl**, **Prac-Tic, ProMeris** and **ProMeris Duo** and concluded that no further action or changes to the product literatures were required.

Concept Papers, Guidelines and SOPs

Following the finalisation of the revision of Annex I of Directive 2001/82/EC and after consultation with the CMDv, the CVMP agreed to discontinue work on a concept paper proposed in 2004 by EWP and SWP to develop a guidance document on bibliographic applications. In view of the limited number of bibliographic applications expected to be submitted in the near future, the need for such guidance was considered low.

The next meeting of the CVMP will be held on 16-18 June 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