



PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 13-15 May 2008

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for **EQUIOXX** (*firocoxib*), 8.2 mg/g, oral paste for horses which is intended for the alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses.

The Committee adopted by consensus a positive opinion for **Zactran** (*gamithromycin*), 150 mg/ml, solution for injection, intended for the therapeutic and preventive treatment of bovine respiratory disease (BRD) in cattle associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*.

The Committee adopted by consensus a negative opinion for **Masivet** (*masitinib*) which was intended to treat dogs with mast cell tumours, Grade 2 or 3, non-resectable or recurrent after surgery. The Committee considered that the data presented to date do not substantiate that the benefits of the product, as measured by delay in the time-to-tumour-progression, outweigh the risk of adverse reactions likely to decrease the quality of life of treated dogs.

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

The Committee adopted by consensus positive opinions for extension applications for **Equilis Prequenza** and **Equilis Te** to introduce an extra supplier of the active ingredient "tetanus toxoid".

The Committee adopted by consensus a positive opinion for a type II variation for **Draxxin** (*tulathromycin*) regarding the addition of a pathogen (*Haemophilus parasuis*) to the indication for the treatment and prevention of respiratory disease in pigs. The addition of the pathogen *Bordetella bronchiseptica* to the indication for the treatment and prevention of respiratory disease in pigs was withdrawn during the procedure.

The Committee adopted by consensus positive opinions for type II variations for **Equilis Prequenza**, **Equilis Prequenza Te** and **Equilis Te** regarding a change to the finished product control test of the adjuvant.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Suvaxyn Aujeszky 783 OW**. 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

The Committee adopted by consensus opinions recommending the amendment of the current entries in Annex I and II of Council Regulation (EEC) No. 2377/90 for **flumequine**, **cloprostenol** and **R-cloprostenol** in bovine species to cover buffalo, further to a request from a company.

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

The Committee adopted the revised summary report for N-methylpyrrolidone, which has been updated to take account of new publicly available data on carcinogenicity and developmental toxicity (EMEA/MRL/615/99-FINAL-Rev.1). The substance was previously evaluated in 1998 and 1999 and was included in Annex II of Council Regulation (EEC) No. 2377/90 for all food producing animals. The new data do not alter the overall conclusions with regards to the ADI and MRLs.

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

Further to a request from the European Commission the Committee re-considered the opinion adopted in December 2007 recommending the extension of the current entry in Annex II of Council Regulation 2377/90 for sodium salicylate to oral use in turkeys. The Committee reviewed the evaluation together with the comments from the European Commission and confirmed its previous opinion. The summary opinion regarding the CVMP recommendation published in December 2007 remains unchanged.

Referrals

The Committee started a referral procedure for **Enro-K 10% oral solution** (*enrofloxacin*) from Laboratorios Karizoo, S.A and **Unisol (aviflox) 10% oral solution** (*enrofloxacin*), from Universal Farma S.L. The matters were referred to the CVMP by Ireland, the reference Member State for the decentralised procedures, under Article 33(4) of Directive 2001/82/EC due to concerns raised by Germany regarding environmental risk assessment.

The Committee started a referral procedure for **Pharmasin 100% w/w water soluble granules** (*tylosin tartrate*) from Huvepharma NV. 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, due to concerns raised by Germany regarding environmental risk assessment.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Advocate**, **Convenia**, **Gonazon**, **Medicinal Oxygen Air Liquide Santé**, **Meloxidyl**, **Nobivac Piro**, **Prac-tic**, **Slentrol** and **Virbagen Omega** and concluded that no further action or changes to the product literatures were required.

Antimicrobial Resistance

The Committee agreed comments on the Codex document "*Principles and guidelines for the conduct of preliminary antimicrobial resistance risk management activities*" in preparation of the EU position at the meeting of the Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance (Working Group Meeting on Risk Profiling) to be held in Brussels on 26-30 May 2008.

The Committee agreed comments to be sent to EFSA on their draft opinion on "*Foodborne antimicrobial resistance as a biological hazard*".

Regulatory issues

The Committee adopted a “*Reflection paper on Criteria for requiring one additional five-year renewal on pharmacovigilance grounds*”. The main elements of the reflection paper will be included in Volume 9B of the Rules Governing Medicinal Products in the European Union which will itself be subject to public consultation shortly.

Organisational matters

The Committee finalised the preparation of the Informal CVMP and Joint CVMP/CMDv meetings to be held under the Slovenian Presidency of the EU, on 26-27 May. The discussions will focus on:

- Functioning of CVMP and Quality of assessments
- Availability of medicines for bees
- Referrals
- Withdrawal periods for different routes of administration
- Cooperation between CVMP and CMDv in promoting availability of medicines
- Update on pharmacovigilance activities
- Update on labelling and packaging developments

Interested Parties

The Committee held a meeting with the interested parties on 14 May 2008 attended by representatives of International Federation of Animal Health (IFAH)-Europe, International Council on Animal Protection in Pharmaceutical Programs (ICAPPP), Association of Veterinary Consultants (AVC), Federation of Veterinarians of Europe (FVE), Honey International Packers Association (HIPA) and the European Group for Generic Veterinary Products (EGGVP). The topics discussed concerned:

- Procedures for developing CVMP guidelines;
- Minimum data requirements for authorisation of blue tongue vaccines;
- Outcome of consultation by CVMP on Guideline on the evaluation of the benefit/risk balance of veterinary medicinal products;
- CVMP Reflection Paper regarding the assessment of environmental risks veterinary medicinal products;
- CVMP referrals;
- Update on EMEA/CVMP activities to promote availability and to apply the 3 R's principle (Reduction, Replacement and Refinement of the use of animals) in regulatory testing of veterinary medicinal products.

The next meeting of the CVMP will be held on 17-19 June 2008

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>