European Medicines Agency
*Veterinary Medicines and Inspections*

London, 11 February 2005
EMEA/CVMP/39701/2005

# PRESS RELEASE

# COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

**Meeting of 8 to 10 February 2005**

## CVMP Opinions on Veterinary Medicinal Products

Further to an appeal from the Applicant, the Committee confirmed the positive opinion with regard to the initial marketing authorisation application for **Naxcel** from Pfizer, adopted at the January 2005 meeting, with a change on wording of the SPC under the section to Pharmacodynamic properties.

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

## Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **Oxolinic acid** in Annex I of Council Regulation (EEC) No. 2377/90 for all food producing species further to establishment of provisional MRLs for cattle. Oxolinic acid had already maximum residue limits established for pigs, chicken and fin fish. The recommendation for all food producing species was made in accordance with the CVMP guidance on extrapolation of MRLs.

The Committee adopted by consensus an opinion recommending the extension of the current Annex I entry of Council Regulation (EEC) No. 2377/90 for **morantel** to all ruminants**,** further to a request from a company. This recommendation for all food producing species was made in accordance with the CVMP guidance on extrapolation of MRLs.

*For further details please see the Summary opinions, which will be available on Monday 14 February 2005 on the EMEA web site: http://www.emea.eu.int*

## Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Incurin**. 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. The Summary of Product Characteristics (SPC) and product literature were updated in accordance with current guidelines and templates.

The Committee adopted by consensus a positive opinion by for the renewal of the marketing authorisation for **Rabigen SAG2**. 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. The Summary of Product Characteristics (SPC) and product literature were updated in accordance with current guidelines and templates.

The Committee adopted by consensus a positive opinion by for the renewal of the marketing authorisation for **Eurifel FeLV**. 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. The Summary of Product Characteristics (SPC) and product literature were updated in accordance with current guidelines and templates

## Annual Reassessment of Marketing Authorisations

The Committee adopted an opinion on the annual reassessment for **Econor,** further to the evaluation of the data submitted by Novartis. The Committee concluded that the Marketing Authorisation Holder had fulfilled its obligation regarding the investigation into the cause of adverse reactions that were observed in Danish and Swedish Landrace breeds and therefore no further studies would be required. The Committee recommended to revise Annex II of the Commission Decision accordingly, and annual reassessment will no longer be required, although annual Periodic Safety Update Reports (PSURs) are still considered necessary to ensure adequate monitoring of adverse reactions.

## Scientific advice

The Committee agreed scientific advice regarding quality issues for the development of an immunological product to be used in controlling boar taint.

The Committee agreed scientific advice regarding an intended MRL application for a substance to be used against nosemosis in bees and for proliferative kidney disease in trout.

## Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Eurifel FeLV**, , **Porcilis AR-T DF** and **Advocate** and concluded that no further action or changes to the product literature of the product(s) were required. The Committee also reviewed a PSUR for **Econor**, in conjunction with the annual reassessment of the product reported above and concluded that no further action in addition to that detailed above or changes to the product literature were required.

The Committee has taken note of recent developments concerning the increased risks of cardiovascular events in man following use of Cox-2 inhibitors, and is considering their implications for target animal safety and consumer safety in the veterinary sector. Pending the outcome of the review of data submitted to CHMP in their review of safety of Cox-2 inhibitors in man, CVMP will further consider and conclude on the safety of this class of medicinal products when used in animals.

## Guidelines, SOPs and Position Papers

The CVMP agreed the procedure for the involvement of the Scientific Advisory Group on Antimicrobials (SAGAM) in the evaluation of centralised marketing authorisations applications containing antimicrobial substances. The procedure details the criteria for such involvement. This procedure was set up in accordance with the mandate of SAGAM to provide expertise to CVMP relating to the consideration of antimicrobials and their risk assessment.

*The document will be available on the EMEA web site on Monday 14 February 2005:*
*http://www.emea.eu.int*

## Organisational Matters

The Committee endorsed Dr. Jean Louis Robert from Luxembourg as Chairman of the Joint CHMP/CVMP Quality Working Party and Dr. Susanne Keitel from Germany as Vice-Chair (human). The Committee elected Ms. Jacqueline Atkinson from the United Kingdom as the Veterinary Vice-Chair. She will be responsible for veterinary topics in the Quality Working Party and for the liaison with CVMP on such issues.

The Committee agreed to convene a meeting with Interested Parties to be held in the margins of CVMP meeting, on Wednesday, 9 March 2005.

The next meeting of the CVMP will be held on 8-10 March 2005

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This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int