The European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/4720/2006
London, 19 January 2006

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 17 to 18 January 2006

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application from Omnipharm Ltd for **Flexicam**, a generic product of Metacam 1.5 mg/ml oral suspension for dogs, intended for alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Flexicam is the first generic medicinal product to receive a positive opinion by the Committee.

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

The Committee adopted by consensus a positive opinion on an extension application for **Metacam** from Boehringer Ingelheim Vetmedica GmbH concerning a new pharmaceutical form (chewable tablets).

The Committee adopted by consensus a positive opinion for a type II variation for **Stronghold** to include the control of fleas in areas to which the animal has access. The variation affects sections 4.2, 4.9 and 5.1 of the SPC relating to indication, dosage and pharmacodynamic properties and the corresponding parts of the labels and package leaflet.

The Committee adopted by consensus a positive opinion for a type II variation for **Fevaxyn Pentofel** regarding increase in shelf life of antigen stocks from 18 to 24 months.

Renewals of Marketing Authorisations

The Committee adopted, by consensus, positive opinions for the renewal of the marketing authorisations for **Zubrin** and **Porcilis Porcoli**. The Committee concluded that the quality, safety and efficacy of the products continued to be appropriately demonstrated and therefore recommended the renewal of the marketing authorisations.

Scientific Advice

The Committee adopted scientific advice on the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) concerning clinical development of a long acting canine ectoparasiticide.

Pharmacovigilance

The Committee reviewed the Periodic Safety Update Reports (PSURs) for **Aivlosin**, **Dexdomitor**, **Econor** and the **Purevax** range of vaccines (**Purevax RCPCh FeLV, Purevax RCP FeLV, Purevax RCCh, Purevax RCPCh, Purevax RC** and **Purevax RCP**) and concluded that no further action or changes to the product literature of the products were required.

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Concept Papers, Guidelines and SOPs

Environmental Risk

The Committee adopted a guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 (Phase I) and GL38 (Phase II) for release for a 6-month period of public consultation (EMEA/CVMP/ERA/418282/2005-CONSULTATION). The purpose of the guideline is to provide additional, more specific technical guidance on environmental impact assessment in areas, where the VICH guidelines are more general. In the supporting CVMP guideline in particular algorithms, models as well as default values for the different calculations are proposed for the determination of the concentration in the environment. The guideline is intended to facilitate the preparation of the environmental risk assessment part in marketing authorisation dossiers by applicants and the harmonised interpretation of the VICH guidelines by Member States.

The document will be available on Monday 23 January 2006 on the EMEA web site:
http://www.emea.eu.int

International harmonisation

Further to the request from the Commission the Committee reviewed the Codex documents CX/RVDF 06/16/10 on risk management methodologies, including risk assessment policies in the Codex Committee on Residues of Veterinary Drugs in Foods and CX/RVDF 06/16/13- Part 1 and Part 2, the report of the Working Group on residues of veterinary drugs without ADI/MRL and agreed comments on the proposals. These comments will be submitted to the Commission for the preparation of EU comments.

Antimicrobial resistance

The Committee adopted a reflection paper on the use of fluoroquinolones in food-producing animals in the European Union: development of resistance and impact on human and animal health (EMEA/CVMP/SAGAM/184651/2005-CONSULTATION), based on the proposal of the Scientific Advisory Group on Antimicrobials for a period of 3 months of public consultation. The document critically reviews recent information on the use of fluoroquinolones in food-producing animals in the EU, its effect on the development of resistance to this category of antimicrobial agents in bacterial species that are of importance for human and animal health, and the potential impact on human and animal health. Based on the scientific considerations and conclusions, the CVMP made proposals for risk management actions.

The document will be available on Monday 23 January 2006 on the EMEA web site:
http://www.emea.eu.int

The next meeting of the CVMP will be held on 14-16 February 2006

CVMP Secretariat
Veterinary Medicines and Inspections Unit
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http://www.emea.eu.int