European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/194935/2007
London, 16 May 2007

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 14-15 May 2007

CVMP Opinions on Veterinary Medicinal Products

Following the request for a re-examination of the opinion adopted on 14 March 2007 with regard to **Suprelorin**, the Committee considered the detailed grounds provided by the Applicant and agreed to a modification of the Summary of Product Characteristics for the wording of the special warnings for the product.
The Summary of Opinion, as published on the EMEA web site (*http://www.emea.europa.eu*) in March 2007, remains unchanged.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **monensin** in Annex I of Council Regulation (EEC) No. 2377/90 for bovine species.

The Committee adopted by consensus a positive opinion recommending the inclusion of **lasalocid** in Annex I of Council Regulation (EEC) No. 2377/90 with regard to poultry eggs further to the establishment of provisional MRLs expiring on 1 January 2008. Lasalocid is already included in Annex I for poultry tissues.

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

Scientific Advice

The Committee agreed scientific advice regarding quality, safety and efficacy issues for a vaccine for the prevention of a bacterial disease in ruminants.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Gonazon, Locatim, Draxxin, Equilis Prequenza** and **Equilis Prequenza Te** and concluded that no further action or changes to the product literature were required.

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

Concept Papers, Guidelines and SOPs

Safety

The Committee adopted a "*Reflection paper on assessment of bioavailability of bound residues in food commodities of animal origin in the context of Council Regulation (EEC) No 2377/90"* for release for a 6-month period of public consultation (EMEA/CVMP/95682/2007-CONSULTATION). The reflection paper provides criteria on how and when the information on bioavailability of bound residues might be used in the assessment of MRLs and advice on the most suitable experimental approach to be followed.

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

Availability of Veterinary Medicines

The Committee reflected on the criteria and procedures to be applied when considering requests to classify indications as limited markets (including use in Minor Use/ Minor Species). The Committee will consult in the first instance with the Co-ordination Group for Mutual Recognition and Decentralised Procedures – veterinary CMD(v) and the outcome will form the basis for an update of advice to applicants at a later date.

Organisational Matters

The Committee noted the outcome of a Focus Group meeting held on 25 April 2007 in preparation of a new guideline on dossier requirements for oncology products for dogs and cats. Participants of the meeting came from regulatory authorities, representatives of the pharmaceutical industry as well as veterinary oncologists working in practice/universities. Topics discussed were in relation to target animal safety, efficacy, user safety and environmental safety. The outcome of the Focus Group will be taken into account in preparing the final version of the guideline.

The next meeting of the CVMP will be held on 12-14 June 2007

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