European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/153635/2005
London, 19 May 2005

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 17 to 18 May 2005

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an extension application for **Metacam** from Boehringer Ingelheim Vetmedica GmbH. The extension concerns a new strength (Metacam 0.5 mg/ml oral suspension for dogs).

The Committee adopted by consensus a positive opinion for a type II variation for **Draxxin** regarding an addition of a new indication for the treatment and prevention of bovine respiratory disease associated with *Mycoplasma bovis*.

The Summary of Opinions are available on the EMEA web site: http://www.emea.eu.int

The Committee also adopted by consensus positive opinions with regard to three type II variations for:

- **Aivlosin** (change in the manufacturing site of the intermediate product);
- **Neocolipor** (replacement of a manufacturer responsible for batch release and replacement of a site where batch control/testing takes place).
- **Nobilis OR inac** (change to the maximum size of production batches).

Further to an appeal from the Applicant, the Committee confirmed the positive opinion with regard to the initial marketing authorisation application for **Profender** from Bayer HealthCare AG, which was initially adopted at the March 2005 CVMP meeting. The amendments concern the wording of the package insert (special warnings) and the labelling of the outer cartons (indications).

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **flugestone acetate** in Annex I of Council Regulation (EEC) No 2377/90, for sheep and goats tissues, further to establishment of provisional MRLs expiring on 1 January 2008. Flugestone acetate has already final MRLs established for sheep and goats milk.

The Summary opinion will be available on Monday 23 May 2005 on the EMEA web site: http://www.emea.eu.int

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.eu.int http://www.emea.eu.int

With this recommendation for flugestone acetate the CVMP, with the support of its Safety Working Party, has now fully completed the evaluation of all applications submitted under Article 7 of Council Regulation 2377/90 for the establishment of maximum residue limits, the procedure for the so-called "old" substances. In total over 700 substances have been evaluated in respect to their safety regarding possible residues in foodstuffs originating from animals treated with veterinary medicines containing these substances. More than 600 substances could be recommended for inclusion in Annex I, II or III of the Regulation. 11 substances were considered to be of health concern due their properties and were included in Annex IV and are therefore prohibited from use in veterinary medicines. For ca. 100 substances the assessments resulted in the conclusion that no recommendations for inclusion in any of the annexes was possible due to the deficiencies of the data submitted, or the applications were withdrawn by the applicants further to the initial evaluation and sending a list of questions to the applicant. Another group of substances were, after initial assessment, considered as not falling within the scope of Regulation 2377/90.

Scientific Advice

The Committee adopted advice on the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) concerning residue studies and the clinical development of a veterinary medicinal product for use in rabbits as a minor species.

Pharmacovigilance

The Committee reviewed the Periodic Safety Update Report (PSUR) for **Bayovac CSF E2, Pirsue, Metacam and Novem** and concluded that no further action or changes to the product literature of the product was required.

Concept Papers, Guidelines and SOPs

Safety

The Committee adopted a Concept Paper on a Guideline on the Assessment of pharmacological/ pharmacodynamic data to establish a pharmacological ADI, for release for a 2-month period of public consultation (EMEA/CVMP/SWP/122154/2005-CONSULTATION). The Concept Paper proposes the development of a guideline to define the studies required for the establishment a pharmacological ADI relating to pharmacological/pharmacodynamic effects. While the evaluation of pharmacodynamic effects is part of the safety evaluation of a substance there are no specific guidance at present on which studies should be performed nor how they should be evaluated.

The document will be available on Monday 23 May 2005 on the EMEA web site:
http://www.emea.eu.int

Quality

Following the close of their consultation periods and their adoption by the CHMP, the Committee adopted the following guidelines prepared by the Joint CHMP/CVMP Quality Working Party:

- Guideline on Plastic Immediate Packaging Materials (EMEA/CVMP/205/04-FINAL)
- Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation (EMEA/CVMP/373/04-FINAL)

The guidelines will come into effect on 1 December 2005.

The documents will be available on Monday 23 May 2005 on the EMEA web site:
http://www.emea.eu.int

The Committee adopted a Revised Guideline for an Assessor Preparing Assessment Reports for Veterinary Medicinal Products (EMEA/CVMP/115769/2005).

This guideline is a revision of the previous guideline published in November 1994 and currently included in Volume 7 of the Rules Governing Medicinal Products in the European Union. The guideline has been updated in line with current legislation. Furthermore, Part 3 of the pharmaceuticals section has been updated in relation to MRLs and ecotoxicity. This guideline is principally directed to assessors of the National Competent Authorities and experts supporting the CVMP assessment work. Consequently, public consultation was not considered appropriate.

The document will be available on Monday 23 May 2005 on the EMEA web site: http://www.emea.eu.int

International Harmonisation

The Committee adopted the revised VICH guideline VICH GL28 "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing" (CVMP/VICH/645/01-Rev.1 FINAL). VICH guideline 28 has been revised to harmonise the target organs to be examined with those in the guideline on Repeated dose (chronic) toxicity testing (VICH guideline 37).

The document will be available on Monday 23 May 2005 on the EMEA web site: http://www.emea.eu.int

Availability of Medicines

The Committee adopted a revised proposal for a list of substances essential for the treatment of horses further to the request from the European Commission for review and consideration of comments and questions as to the choice and justifications of some substances proposed. The revised list will be submitted to the Commission for adoption by the Standing Committee procedure in accordance in Article 10 (3) of Directive 2001/82/EC, as amended. Once adopted, the list will eventually provide for the use of products by veterinarians in the horse under the conditions of the “cascade” containing the listed substances for which no MRLs are established, providing a minimal withdrawal period of 6 months is applied.

Regulatory issues

The Committee reviewed certain aspects of the implementation of the new legislation for the authorisation of veterinary medicinal products and considered proposals for reference to the Commission regarding:

- Scope of centralised procedure
- New requirements regarding environmental risk assessment
- New requirements regarding validation of analytical methods.

The documents will be published following consultation with the European Commission on the EMEA web site http://www.emea.eu.int

Organisational issues

The Committee discussed the preparation of the Informal CVMP meeting to be held in Oslo, Norway on 2-3 June 2005 at the initiative of the Norwegian Authorities. The Committee agreed that the meeting would consider the following items:

- Marker vaccines and diagnostic test in the EU;
- SPC harmonisation and other referrals: Implications for CVMP;
- Readability of package leaflets;
- Review of current organisation and functioning of Scientific Advice Working Party;
- Review of criteria for appointment of rapporteurs;
- Fish farming and availability of medicines.

The next meeting of the CVMP will be held on 14-16 June 2005

Peter G.H. Jones
Head, Veterinary Medicines Evaluation Unit
This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int