



European Medicines Agency
Veterinary Medicines and Inspections

EMA/CVMP/80966/2005
London, 11 March 2005

PRESS RELEASE
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
Meeting of 8 to 10 March 2005

The Committee expressed their deepest sympathy at the sad news that Prof. Marques Fontes, the member of CVMP from Portugal, had recently died after a brief illness and stood for a minute's silence as a mark of respect for this colleague.

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion on an initial marketing authorisation application from Bayer HealthCare AG for **Profender**, containing emodepside and praziquantel, for the treatment of cats suffering from, or at risk from, mixed endoparasitic infections.

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

The Committee adopted by consensus a positive opinion for a type II variation for **Aivlosin** to change the wording in Section 6.1 of the SPC relating to major incompatibilities.

The Committee adopted by consensus a positive opinion for a type II variation for **Nobilis IB4-91** to add a production site for the IB-4-91 antigen.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the inclusion of **acetylisovaleryltylosin** in Annex I of Council Regulation (EEC) No. 2377/90 for poultry further to establishment of provisional MRLs, expiring on 1 July 2006.

The Committee adopted by consensus a positive opinion recommending the establishment of provisional maximum residue limits in accordance with Council Regulation (EEC) No 2377/90, as amended, for **fluaruzon** for cattle.

*The summary opinions will be available on Monday 14 March 2005 on the EMEA web site:
<http://www.emea.eu.int>*

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for **Draxxin**, **Sevoflo**, **Equilis StrepE** and **Virbagen Omega** concluded that no further action or changes to the product literature of the products were required.

Concept Papers, Guidelines and SOPs

The Committee adopted a draft concept paper on further guidance on interpretation of the data from VICH GL27 - guidance on pre-approval information for registration of new veterinary medicinal products for food-producing animals with regard to antimicrobial resistance, for release for a 3-month period of public consultation (EMEA/CVMP/1034/04-CONSULTATION).

The Committee continued its consideration of draft guidelines from all the working parties of CVMP on testing requirements for products intended for use in minor uses and minor species, as previewed in the CVMP position paper adopted in June 2004; their finalisation is anticipated in the April and May meetings.

*The documents will be available on Monday 14 March 2005 on the EMEA web site:
<http://www.emea.eu.int>*

Post –authorisation monitoring

The Committee endorsed list of centrally authorised products to be tested in the year 2006 under the Sampling and Testing Programme.

Regulatory issues

The Committee agreed on comments on the draft revision of Annex I of Directive 2001/82/EC, as amended, which has been prepared by the European Commission, following the request in this respect by the Commission.

CVMP was addressed by the Managing Director and President of IFAH-Europe on recent changes in the organisation of the Federation, as well as issues of current interest and concern and then engaged in discussion on key points.

Organisational issues

The Committee appointed Prof. Lourenzo José Fraile Sauce from Spain as co-opted member to complement the expertise of the Committee in clinical medicine in intensive production. With the appointment of Prof. Fraile the composition of the Committee is now complete.

The Committee agreed on a detailed action plan to address all issues raised in the October 2004 audit of the Committee and prepare for the next audit to be held in October 2005

The CVMP meeting was followed by a meeting of the Committee with its Interested Parties, which included representatives of IFAH-Europe, Association of Veterinary Consultants and Federation of Veterinarians of Europe (agenda attached)

The next meeting of the CVMP will be held on 12 to 14 April 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>

London, 28 February 2005
Doc. Ref: EMEA/78068/2005

CVMP INTERESTED PARTIES MEETING

AGENDA

Wednesday 9 March 2005
17:00 – 19:00

Room 4A

1. Welcome and Introduction of delegates
2. Impact assessment of guidelines: How can an impact assessment be made of the overall impact of the accumulated stock of data requirements arising from a steady flow of new and revised guidelines?

Background: The CVMP takes the medicines availability issue seriously. It has introduced a concept paper and impact assessment system for new individual guidelines: how is this carried out? The impact of the total package of guidelines on industry's ability to develop new products, and ways of assessing that impact, need to be addressed. A general introduction to this topic will be provided by Susanne Zänker at 14.00
3. In the new legislation there is a greater emphasis on risk: benefit. Is a CVMP policy emerging as a result of this issue being taken into consideration when reviewing applications
4. Progress with MUMS Policy, including next steps for MRL extrapolation
5. Implementation of new legislation at EMEA - update on critical issues
6. Update on SAGAM's consideration of fluoroquinolones and 3rd generation cephalosporins
7. Close of meeting