European Medicines Agency
Veterinary Medicines and Inspections

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PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 14 to 16 March 2006

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the extension of the current Annex I entry of Council Regulation (EEC) No. 2377/90 for **ceftiofur** to all mammalian food producing species. While the extension application was made for sheep only this recommendation to extrapolate the MRLs to all mammalian species was made in accordance with the review of the risk assessment approach for the establishment of maximum residue limits with a view to establishing a more pragmatic approach in securing the provision of medicines for treating animals especially those classed as minor species. The application procedure was initiated on 5 December 2005 and an opinion recommending the establishment of MRLs for ceftiofur in all mammalian species was adopted on 15 March 2006 with an active review time of 87 days.

The Committee adopted by consensus an opinion recommending the modification of the current entry in Annex II of Regulation (EEC) No 2377/90 for polyoxyethylene sorbitan monooleate to **polyoxyethylene sorbitan monooleate and trioleate** further to a request from a company. The current Annex II entry covering the substances Polysorbate 80 and 81 is now recommended to be extended to also include the similar substance Polysorbate 85.

The Summary opinions will be available on Monday 20 March 2006 on the EMEA web site: http://www.emea.eu.int

Community Referrals

The Committee considered the notification for a referral for arbitration under article 33(4) of Directive 2001/82/EC, as amended for Cobactan IV 4.5%. The referral concerns a mutual recognition procedure initiated due to a safety issue concerning the product. The 60 day procedure has now commenced at the March meeting.

The Committee also considered the notification for a referral for arbitration under article 33(4) of Directive 2001/82/EC, as amended for Dolovet/ Rifen. The referral concerns a mutual recognition procedure initiated due to concerns regarding the demonstration of efficacy of the product. The 60 day procedure has now commenced at the March meeting.

Scientific Advice

The Committee adopted scientific advice on the recommendation of the Veterinary Scientific Advice Working Party (SAWP-V) concerning the establishment of the acceptable daily intake (ADI) and withdrawal period for a new substance with antimicrobial activity.

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Pharmacovigilance

The Committee reviewed the Periodic Safety Update Report (PSUR) for **Virbagen Omega** and concluded that no further action or change to the product literature of the product is required. The Committee considered the PSUR for **Equilis StrepE** and agreed to seek clarification from the MAH on some aspects of the report.

Antimicrobial resistance

The Committee adopted a new CVMP strategy on antimicrobials for the years ahead and a status report on the CVMP work in previous years regarding antimicrobial resistance (*CVMP Strategy on Antimicrobials for 2006-2010 and Status Report on activities on antimicrobials* (EMEA/CVMP/353297/2005)). Having almost completed the actions of the previous *Risk management strategic action plan for controlling antimicrobial resistance through authorisation of veterinary medicines* (EMEA/CVMP/818/99) the new strategy focuses now in particular on ensuring appropriate conditions for marketing authorisations of antimicrobial veterinary medicinal products in respect to the dossier assessment and conditions of use of the products as well as the intensified contributions to international activities in the field of antimicrobials.

The document will be available on Monday 20 March 2006 on the EMEA web site: http://www.emea.eu.int

Concept Papers, Guidelines and SOPs

Immunologicals

The Committee adopted a guideline on User Safety for Immunological Veterinary Medicinal Products for release for a 6-month period of public consultation (EMEA/CVMP/54533/2006-CONSULTATION).

Quality

The Committee adopted two revised guidelines on herbal medicinal products following 2 months of public consultation. These guidelines have been updated to take account of the newly introduced definitions and responsibilities introduced by Directive 2004/24/EC (for traditional herbal medicinal products for human use). Some clarifications and corrections to the existing texts have also been introduced.

- Guideline on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products (EMEA/CVMP/814/00-Rev.1)

- Guideline on Specifications: Test Procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products (EMEA/CVMP/815/00-Rev.1)

Publication of these two joint guidelines will follow their final adoption by the CHMP, which is foreseen for its next meeting on 20-23 March 2006.

The Committee also adopted a guideline on Parametric Release for release for a 3 month period of public consultation (EMEA/CVMP/QWP/339588/2005-CONSULTATION).

The documents will be available on Monday 20 March 2006 on the EMEA web site: http://www.emea.eu.int

The next meeting of the CVMP will be held on 18-20 April 2006

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