The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

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PRESS RELEASE

11th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the eleventh meeting of the Committee for Veterinary Medicinal Products took place in London on 23-24 April 1996.

CENTRALISED PROCEDURES

2. The Committee considered the assessment report prepared by the Rapporteur in respect of a centralised application for the granting of a Community marketing authorisation for an antibiotic for use in poultry. The Committee agreed with the conclusions of the Rapporteur and Co-rapporteur and adopted a list of questions to be sent to the applicant.

3. The Committee responded positively to the request of a company to consider a product intended for use in companion animals, as having a new indication of significant therapeutic interest. This decision, and similar ones in future, shall be valid for six months after which consideration will be given as to whether the criteria of innovation still applies.

4. The Committee also considered a third request from a company for scientific advice concerning a product derived from recombinant DNA technology under development. Moreover, given the increased number of such requests, it was decided that a Standard Operating Procedure to inform all interested parties of the procedure to be followed in such cases should be prepared by the Secretariat.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

5. The Committee accepted the conclusion of the rapporteurs in consideration of two applications for the establishment of a Maximum Residue Limit (MRL) for two new substances and agreed to recommend one for inclusion in Annex II of Council Regulation (EEC) No 2377/90 and to adopt for the other a consolidated list of questions to be sent to the applicant.

6. Rapporteurs and co-rapporteurs were appointed for the establishment of MRLs for 4 new substances and for the extension to another species of one existing MRL.

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7. Regarding the establishment of maximum residue limits for applications received prior to 1 January 1995 by the European Commission and transferred then to the Agency, the Committee recommended the inclusion of two old substances in Annex II of Council Regulation (EEC) No 2377/90.

6. The Committee recommended that two fee waivers be granted by the EMEA Executive Director in respect of two applications for the establishment of maximum residue limits for new substances to be used in food-producing species, in accordance with the provisions of Article 7 of Council Regulation (EC) 297/95.

NOTES FOR GUIDANCE

7. The Committee adopted a note for guidance on the Approach towards Harmonisation of Withrawal Periods in Tissues (document EMEA/CVMP/036/95).

INTERNATIONAL

8. The Committee was informed of the conclusions of the first Steering Committee of the Veterinary Intrnational Conference on Harmonisation (VICH), which met in Paris on 10-11 April 1996. Having reviewed the work programme and the priority topics to be addressed, the Committee undertook to identify topic leaders and working groups experts who would participate on behalf of the European Union.

BSE

9. The Committee endorsed the recommendation of the ad hoc group of experts on bovine spongiform encephalopathy (BSE), which met together with representatives of the Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products) and members of the CPMP Biotechnology Working Party, to consider specific questions raised by the European Commission services concerning the potential risk associated with medicinal products in relation to BSE (see attachement).

REGULATORY AFFAIRS

10. The Committee was requested to consider whether any two products containing the same active ingredient, but differing in the nature of the formulation, meet the strict requirements of essential similarity for the purpose of abridged applications. It was concluded that they do not, but that they are nevertheless sufficiently similar so that the new formulation can qualify for a semi-abridged application. This would require a cross reference to the same applicant's original data files, together with a full quality dossier, and the results of bioequivalence studies according to the Guidelines on the Conduct of Bioequivalence Studies in Volume VII of the Rules Governing Medicinal Products in the European Community.

11. The next meeting of the Committee will be held on 26-27 June 1996.

General information about EMEA and EPAR (European Public Assessment Report) for centrally approved veterinary products are available on Internet and E-mail at the following addresses:

- E-mail: mail@emea.eudra.org;
- Internet: www.eudra.org.

16th April 1996, EMEA/354/96

OPINION OF THE EMEA ON THE POTENTIAL RISK ASSOCIATED WITH MEDICINAL PRODUCTS IN RELATION TO BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

An ad hoc group of BSE experts, representatives of the Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products (CVMP) as well as members from the Biotechnology Working Party (BWP) (see Annex 1) met on Monday 15 April 1996, under the chairmanship of Prof. Vicari, to discuss the questions posed by the Commission Services to the European Medicines Evaluation Agency (EMEA) on 29 March and 10 April 1996.

The CPMP meeting in plenary session on 16 April 1996 endorsed the following conclusions made by the ad hoc group in response to the Commission's questions:

- The current CPMP/CVMP guideline (Minimising the risk of transmitting agents causing spongiform encephalopathy via medicinal products, December 1991) as re-affirmed in November 1995 and February 1996, emphasises three principles to minimise the risk of transmission of BSE which are still scientifically sound: selective sourcing, tissue of origin and safety of extraction process. The CPMP/CVMP will be ready to reconsider the guideline in the light of the present opinon and any new available scientific information.

- The opinion of the Scientific Veterinary Committee of the 9 April 1996 in relation to the safety of gelatin and tallow in the pharmaceutical field and the results of the WHO Consultation Meeting of 3 April 1996 were carefully considered. While agreeing with the general conclusions of these meetings the group emphasises the following:

  i) The tallow component obtained from carcass rendering systems showed no detectable infectivity. In addition raw tallow is not used in the pharmaceutical field. Tallow derivatives (e.g. stearate, glycerol) prepared under extreme conditions (temperatures of 250°C, pressure of 50 bar and duration of 3 hours and subsequent distillation at 200°C) are used in pharmaceutical products and are considered as safe for this purpose.

  ii) Three cumulative factors contribute to the safety of gelatin used in pharmaceuticals:
  - manufacturers of gelatin used for pharmaceutical use should not use tissues derived from bovine animals slaughtered in the UK; and
  - the additive effects of washing, acid decalcification, followed by acid and prolonged alkaline treatment, filtration and sterilisation are sufficient to eliminate any possible risk; and
  - source tissues used in the manufacture of gelatin are classified as having no detectable infectivity.

  iii) For all other components used as active ingredients or reagents in the manufacturing process, the combination of the three principles underlined in the existing guidelines provide for satisfactory safety.

- Provided that it is well established that the "starting material" for pharmaceutical use (active ingredients or excipients) is safe regarding the BSE risk, on the basis of the various measures proposed in the EU guidelines and documented in the application dossier, the "finished product" is also safe. 'Starting material' should be understood as meaning any substance derived, with further processing, from tissue of bovine origin and used in the manufacture of a medicinal product, and 'finished product' as a medicinal product incorporating the above mentioned substances.

- At the request of the European Medicines Evaluation Agency, all Community marketing authorisation holders, or applicants with a positive opinion from the CPMP or CVMP, have confirmed that the products concerned do not contain bovine tissue of UK origin.
  Regarding nationally authorised medicinal products containing bovine tissue marketed in the Member States the CPMP was informed that the guideline has been implemented under the supervision of the competent national authorities.
  The CPMP therefore concluded that the application of the above mentioned measures guarantees that medicinal products containing such materials are safe.

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