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

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EMEA/CVMP/053/96

PRESS RELEASE

10th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the tenth meeting of the Committee of Veterinary Medicinal Products took place in London on 20-22 March 1996.

CENTRALISED PROCEDURES

2. The Committee accepted the advice of its working party on immunological veterinary medicinal products that a vaccine containing a new serotype against an existing disease could be considered a new biological active substance. As this new substance was not authorised prior to 1.1.1995 for use in veterinary medicinal products, it therefore meets the last criteria of Part B of the Annex to Council Regulation (EEC) No 2309/93 for the granting of a Community marketing authorisation through the centralised procedure. A rapporteur and co-rapporteur were appointed for this application.

3. The Committee appointed a rapporteur and co-rapporteur for an application for the granting of a Community marketing authorisation for a new vaccine which meets the criteria laid down in Part A of the annex to Council Regulation (EEC) No 2309/93.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

4. The Committee accepted the conclusion of the rapporteur in consideration of an application for the establishment of a Maximum Residue Limit (MRL) for a new substance and agreed on a consolidated list of questions to be sent to the applicant.

5. Rapporteurs and co-rapporteurs were appointed for the establishment of MRLs for 1 new substance.

6. Regarding the establishment of maximum residue limits and the inclusion of substances used in food-producing animals in one of the annexes of Council Regulation (EEC) No 2377/90 the Committee made the following recommendations for applications received prior to 1 January 1995 by the European Commission and transferred then to the Agency:

	Annex I	Annex II	Annex III	Annex IV
New Substances (Article 6)	1	1	2	-
Old Substances (Article 7)	-	5	1	-

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6. Representative from the Commission informed the Committee that steps are underway to change Council Regulation 2377/90 to allow for an extension of the deadline of 1 January 1997, by which MRLs for all old substances have to be established.

NOTES FOR GUIDANCE

7. The Committee adopted the EMEA proposal for a new Chapter on the Centralised Procedure for veterinary medicinal products to replace existing Chapter IV in the Draft Notice to Applicants III/5056/95. This proposal will now be communicated to the European Commission.

8. The Committee discussed and agreed to release for a six-month consultation period the Guideline on environmental risk assessment for veterinary medicinal products (excluding genetically modified organisms and immunological products).

9. The Committee adopted guidelines on in-use stability testing of veterinary medicinal products.

GENERAL

10. The Committee reviewed and agreed tentative Priority Topics for Harmonisation for veterinary medicines under the VICH initiative.

11. The Committee revised its procedure for co-ordinating foreign and community pre-authorisation inspections during assessment of applications submitted to the EMEA.

12. A post CVMP meeting was held by CVMP members with Interested Parties including delegates from FEDESA and BEUC.

13. The Committee agreed to the proposed EMEA/FEDESA Info-Day to be held on 28 June 1996 in London (programme to be finalised).

14. The next meeting of the Committee will be held on 23-24 April 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.