The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

16th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Mr. C. O'Sullivan the sixteenth meeting of the Committee for Veterinary Medicinal Products took place in London on 10-11 December 1996.

CENTRALISED PROCEDURES

2. The Committee discussed the draft assessment reports prepared by the rapporteur and the co-rapporteur on an application received by the Agency for the granting of a marketing authorisation for a vaccine for food-producing animals falling under the scope of part B to the Annex of Council Regulation (EEC) No 2309/93. The Committee agreed on a list of questions to be sent to the applicant.

3. The Committee considered the report of the rapporteur concerning periodic safety update for a product authorised through the centralised procedure.

SCIENTIFIC ADVICE

4. In response to earlier requests from two companies for scientific advice, the Committee agreed with the proposals of the appointed co-ordinators and adopted their recommendations concerning two immunological medicinal products under development.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee recommended the extension of MRLs for a substance already classified into Annex I to an additional species.

6. The Committee adopted status reports and lists of questions in consideration of two other applications for the establishment of MRLs for new substances.

7. The Committee appointed rapporteurs and co-rapporteurs for two new applications for the establishment of maximum residue limits, for which a letter of intent had been received.

8. Regarding the establishment of maximum residue limits for applications received prior to 1 January 1995 by the European Commission and transferred to the Agency, the Committee recommended the inclusion of two old substances in Annex II.

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9. In addition, status reports and accompanying consolidated list of questions to the applicant were adopted for 4 old substances currently under evaluation.

NOTES FOR GUIDANCE AND SOPs

10. The Committee adopted a Note for Guidance on Additional quality requirements for products intended for incorporation into animal feeding-stuffs (medicated premixes) (EMEA/CVMP/080/95).

11. The Committee reviewed the CPMP SOP *Centralised Procedure: from assessment reports to EPAR* and agreed to conduct its work along the same principles.

INTERNATIONAL HARMONISATION

12. The Committee agreed proposals for input into VICH initiative as presented by nominated experts on the subjects of genotoxicity and reproductive toxicity and on efficacy testing of anthelmintics.

1996 AT A GLANCE

13. The first Community marketing authorisation for a veterinary medicinal product was granted by the European Commission on 29 February 1996 following the positive opinion adopted in July 1995.

14. The Committee delivered in September 1996 a positive opinion for the granting of a Community marketing authorisation for the first application submitted under the centralised procedure. A total of 10 new applications were submitted in 1996.

15. 22 new applications for the establishment of MRLs and 10 applications for the extension/modification of existing MRLs were received in 1996 for new substances or for substances which had not been defended earlier by the deadline for submission laid down by Council Regulation (EEC) No 2377/90. The Committee delivered in 1996 9 recommendations for such substances.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	2	10	3
MRL procedures*	10	22	10

* Applications submitted to the EMEA after 1.1.1996

16. The next meeting of the Committee will be held on 14-16 January 1997.

General information about EMEA, Guidelines, SOPs 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/emea.html