London, 24 July 1996
EMEA/CVMP/161/96

PRESS RELEASE

13th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

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

CENTRALISED PROCEDURES

2. Having considered eligibility under the criteria in part B of the Annex to Council Regulation (EEC) no 2377/90, the Committee appointed a rapporteur and a co-rapporteur for one new application for a product intended for use in companion animals, for which a letter of intent had been received.

3. The CVMP considered and agreed with a Secretariat proposal to identify recommended submission dates for applications under the centralised procedure, to optimise use of the time clock so that the major milestones of the procedure coincide with meetings of the Committee. These dates will now be communicated to industry.

SCIENTIFIC ADVICE

4. The Committee considered and agreed with the opinion of its Working Party on Immunological Veterinary Medicinal Products, in relation to an application from a potential applicant for scientific advice relating to the development of a new vaccine.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

5. The Committee adopted a status report and a list of questions in consideration of two applications. One for the establishment of a Maximum Residue Limit (MRL) for a new substance and one for the extension of existing MRLs to additional species.

6. The Committee also agreed with the proposal from the rapporteur to modify existing MRLs for one substance.

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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 made the following recommendations:

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

8. In addition, status reports and consolidated lists of questions to the applicant for 10 old substances currently under evaluation were adopted.

9. The Committee added star anis, chinchona bark, frangula, rhubarb, boldo, condurango and gentian to the open list of substances considered as not being subject to the scope of Council Regulation (EEC) No 2377/90.

NOTES FOR GUIDANCE

10. In response to a request from the Commission, the Committee confirmed its earlier position that Salmonid fish be considered as a major species in terms of requirements for data to establish MRLs. The Committee further requested its Safety of Residues Working Party to re-examine the minimum data requirements to extend the MRL from a major mammalian species to fish.

11. The Committee continued to examine its current policy on Injection Site Residues and evaluated different approaches to address this issue.

12. The Committee adopted a Note for Guidance on the Environmental Risk Assessment for Immunological Veterinary Medicinal Products (EMEA/CVMP/074/95).

13. The Committee agreed to release for a 6-month consultation period an Annex to an existing Note for Guidance on the *Manufacture of the finished dosage form* concerning the *Start of shelf-life of the finished dosage form* (EMEA/CVMP/144/96).

14. The Committee also agreed to release for a 6-month consultation period a CPMP Note for Guidance on Inclusion of Antioxidants and Antimicrobial Preservatives in Medicinal Products (CPMP/QWP/115/95) and a Note for Guidance on Chiral Substances (EMEA/CVMP/128/95).

15. The next meeting of the Committee will be held on 17-18 September 1996.