London, 19 September 1996
EMEA/CVMP/202/96

PRESS RELEASE

14th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the fourteenth meeting of the Committee for Veterinary Medicinal Products took place in London on 17-18 September 1996.

   The Committee welcomed Dr. Jill Ashley-Smith from the Veterinary Medicines Directorate (UK) in replacement of Dr. Kevin Woodward. Dr. Ashley-Smith is senior veterinary assessor at the VMD for pharmaceuticals and feed additives.

CENTRALISED PROCEDURES

2. The Committee agreed to recommend the granting of a Community marketing authorisation for a feline pentavalent inactivated vaccine falling under the scope of part A to the Annex of Council Regulation (EEC) No 2309/93.

3. 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 non-steroidal anti-inflammatory drug for food-producing animals falling under the scope of part B to the Annex. The Committee agreed on a list of questions to be sent to the applicant.

4. Having considered eligibility under the criteria in part A of the Annex, the Committee appointed a rapporteur and a co-rapporteur for one new application for a recombinant vaccine intended for use in pigs, for which a letter of intent had been received.

	Opinions delivered	Applications under evaluation	Applications under validation	Applications anticipated within the next 4 months
Centralised procedures	2	5	1	4
MRL procedures*	8	13	7	8

* Applications submitted to the EMEA after 1.1.1996

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ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee recommended the inclusion into Annex I of Council Regulation (EEC) No 2377/90 of a substance previously included into Annex III and the extension to additional species of a substance already classified into Annex II.

6. The Committee adopted a status report and a list of questions in consideration of one application for the establishment of a MRL for an existing substance.

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

8. Members of the Committee were consulted on the draft Council Regulation and explanatory memorandum, amending Council Regulation (EEC) No 2377/90 on the Establishment of Maximum Residue Limits, and provided detailed inputs to the European Commission.

NOTES FOR GUIDANCE AND SOPs

9. The Committee adopted a Standard Operating Procedure on *Article 18 of Council Directive 81/851/EEC on Arbitration under the Decentralised Procedure for Marketing Authorisations* (EMEA/CVMP/191/96).

10. The Committee agreed to release for a 6-month consultation period a Note for Guidance on *Pharmacovigilance* of *Veterinary Medicinal Products* (EMEA/CVMP/183/96-rev1) to replace Chapter V in the current Notice to Applicants.

11. The next meeting of the Committee will be held on 22-23 October 1996.

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.