The European Agency for the Evaluation of Medicinal Products

London, 16 January 1997
EMEA/CVMP/018/97

PRESS RELEASE

17th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Prof. R. Kroker the seventeenth meeting of the Committee for Veterinary Medicinal Products took place in London on 14-16 January 1997.

2. The Committee welcomed Mrs Ann Pii in replacement of Mrs Birgit Kristensen. Mrs Pii is coming from the Danish Medicines Agency where she has been working as a pharmaceutical assessor for many years.

CENTRALISED PROCEDURES

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 vaccine for food-producing animals falling under the scope of part A to the Annex of Council Regulation (EEC) No 2309/93. The Committee agreed on a list of questions to be sent to the applicant.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	2	10	3
MRL procedures*	10	23	9

* Applications submitted to the EMEA after 1.1.1996

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

4. 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.

5. 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 made the following recommendations:

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

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

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7. The Committee adopted a Position Paper on *Requirements for LOQ/MRL ratio* (EMEA/CVMP/274/96) which is annexed to this press release.

NOTES FOR GUIDANCE AND SOPs

8. The Committee adopted a Note for Guidance on *Environmental Risk Assessment for Veterinary Medicinal Products* (EMEA/CVMP/055/96).

9. The next meeting of the Committee will be held on 10-11 February 1997.

General information about EMEA, Guidelines, SOPs, EPAR (European Public Assessment Report) of veterinary medicinal products which have been granted a Community marketing authorisation and summary reports of substances for which Maximum Residue Limits have been established by the Community are available on Internet and E-mail at the following addresses:

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