The European Agency for the Evaluation of Medicinal Products

London, 14 March 1997
EMEA/CVMP/104/97

PRESS RELEASE

19th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Prof. R. Kroker the nineteenth meeting of the Committee for Veterinary Medicinal Products took place in London on 11-13 March 1997.

CENTRALISED PROCEDURES

2. The Committee discussed the draft assessment report prepared by the rapporteur and the co-rapporteur on an application received by the Agency for the granting of a Community marketing authorisation for a veterinary medicinal product intended for companion animals and presented for a new indication of significant therapeutic interest. The Committee agreed on a list of questions to be sent to the applicant.

3. The Committee adopted a position paper on *Non Compliance with Follow-up Measures* (EMEA/CVMP/092/97).

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	2	10	3
MRL procedures*	13	24	13

* Applications submitted to the EMEA after 1.1.1995

SCIENTIFIC ADVICE

4. The Committee adopted the mandate of the ad hoc group to be set up to investigate the current status of antimicrobial resistance in animals and the potential for its transfer to man. The group will be composed of eight experts from the EU and shall present its conclusions to the Committee by the end of 1997.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee considered that one substance, for which an application for the establishment of MRLs had been received, was not falling within the scope of Council Regulation (EEC) No 2377/90.

6. The Committee adopted a status report and a list of questions in consideration of an other application for the establishment of MRLs for a new substance.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Switchboard: (+44-171) 418 8400 Fax: (+44-171) 418 8551
E_Mail: mail@emea.eudra.org http://www.eudra.org/w3/emea.html

7. The Committee appointed rapporteurs and co-rapporteurs for five 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 made the following recommendations:

	Annex I	Annex II	Annex III	Annex IV
New Substances (Article 6)	-	-	-	-
Old Substances (Article 7)	4	1	-	-

9. The Committee also adopted four recommendations concerning substances for which provisional MRLs are due to expire shortly.

10. In addition, the status reports and the accompanying consolidated lists of questions to the applicant were adopted for 4 old substances.

NOTES FOR GUIDANCE AND SOPs

11. Regarding the applicability of the Note for Guidance on Environmental Risk Assessment for Veterinary Medicinal Products (EMEA/CVMP/055/96), adopted in January 1997, to old products, the Committee agreed to recommend that this Note for Guidance should apply similarly to old products at the time of application for 5 year renewals as of 1 January 1998.

12. The Committee adopted the EMEA contribution to Chapter I of the Notice to Applicants, which is currently under review by the European Commission.

13. The next meeting of the Committee will be held on 8-10 April 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.