London, 13 November 1997
EMEA/CVMP/406/97

PRESS RELEASE

26th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R Kroker the twenty-sixth meeting of the Committee for Veterinary Medicinal Products took place in London on 11- 13 November 1997.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	7	6	9
MRL procedures*	20	26	13

* Applications submitted to the EMEA after 1.1.1995

CENTRALISED PROCEDURES

2. The Committee adopted an Opinion on a live attenuated vaccine for immunisation against Infectious Bronchitis in chickens and falling under Part A of the Annex to Council Regulation (EEC) 2309/93.

3. The Committee adopted an Opinion on a pharmaceutical product to be used in dogs for separation related disorders and falling under Part B of the Annex to Council Regulation (EEC) 2309/93.

4. The Committee adopted an Opinion on a variation for a vaccine authorised under the centralised procedure and falling under Part A of the Annex to Council Regulation (EEC) 2309/93.

5. The Committee heard an oral explanation from an Applicant with regard to an application under evaluation and falling under Part A of the Annex of Council Regulation (EEC) 2309/93.

6. A Rapporteur and Co-Rapporteur were appointed for 1 intended application falling under Part A and for 1 intended application falling under Part B of the Annex of Council Regulation (EEC) 2309/93.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

7. The Committee recommended that 1 new substance be included in Annex III of Council Regulation (EEC) 2377/90.

8. The Committee adopted status reports and list of questions for 2 new substances under evaluation.

9. The Committee recommended that 1 old substance, with previous provisional MRLs be included in Annex I and 10 old substances be included in Annex II of Council Regulation (EEC) No 2377/90

10. The Committee also adopted status reports and lists of questions for 4 old substances.

11. Furthermore the Committee reconsidered previous recommendations for 2 pyrethroids for which the adoption had been witheld at Commission level due to conflicts with existing pesticide legislation, now addressed, and adopted amended Annex III recommendations.

12. Rapporteurs were appointed for 1 full MRL application and for the extension of existing MRLs for 1 sustance.

13. The Committee agreed on procedures for the assessment of substances of vegetable origin contained in herbal remedies and for substances used in homeopathic products in concentrations above 1 in 10,000.

NOTES FOR GUIDANCE

14. The Committee adopted a Note for Guidance on the Establishment of MRLs for Minor Animal Species.

15. The Committee adopted a Position Paper concerning definitions of Indications and Claims for Veterinary Vaccines under the Centralised Procedure.

16. The Committee adopted a Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Veterinary Medicinal Products.

ANTIMICROBIAL RESISTENCE AD HOC WORKING PARTY

17. The Committee heard a report from attendees at the WHO meeting in Berlin, held on 13-17 October 1997 on the Medical Impact of the Use of Antimicrobial Drugs in Food Animals.

INTERNATIONAL HARMONISATION

18. The Committee endorsed the request from the COMISA Secretariat to allow VICH guidelines to be released for a 6 month period of consultation.

ANY OTHER BUSINESS

19. The next meeting of the Committee will be held on 9 -11 December 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.

Maximum Residue Limits for New Substances adopted by the Community since 1.1.1997
(Status: November 1997)

Substance a) INN	**Therapeutic area** a) Target species	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Sent to Commission b) Date of the regulation c) OJ No.
a) Eprinomectin	a) Bovine	a) 22.02.96 b) 25.06.96 c) 108 days d) 0	a) 26.07.96 b) 08.01.97 c) OJ No. L 5 of 09.01.97
a) Doramectin (modification)	a) Bovine	a) 14.05.96 b) 24.07.96 c) 70 days d) 0	a) 23.08.96 b) 14.02.97 c) OJ No. L 45 of 15.02.97
a) Praziquantel	a) Ovine	a) 03.08.95 b) 18.09.96 c) 187 days d) 152 days	a) 16.10.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Moxidectin (modification)	a) Bovine and Ovine	a) 12.06.96 b) 18.09.96 c) 97 days d) 0	a) 16.10.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Difloxacin (modification)	a) Chicken, Turkeys	a) 10.07.96 b) 23.10.96 c) 104 days d) 0	a) 19.11.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Ivermectin (extension)	a) Deer	a) 20.08.96 b) 11.12.96 c) 86 days d) 0	a) 09.01.97 b) 23.04.97 c) OJ No. L 106 of 24.04.97
a) Amitraz (extension)	a) Bees	a) 18.10.96 b) 12.02.97 c) 115 days d) 0	a) 12.03.97 b) 24.09.97 c) OJ No. L 263 of 25.09.97
a) Doramectin (extension)	a) Swine and Ovine	a) 10.06.96 b) 12.02.97 c) 118 days d) 127 days	a) 12.03.97 b) 24.09.97 c) OJ No. L 263 of 25.09.97

Maximum Residue Limits for Old Substances adopted by the CVMP and the Community
(Status: November 1997)

Total 304 Substances			
Annex I	Annex II	Annex III	Annex IV
45	213	35	11
Published in the Official Journal of the European Communities: 270			

Veterinary Medicinal Products which have been granted a Community marketing authorisation under the centralised procedure

(Status: November 1997)

Product a) Brandname b) INN c) List A/B	**Company** a) Name b) Origin	**Therapeutic area** a) Target species b) Indication	**Presentation** a) Form b) Dosage c) No. of presentations	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Opinion received b) Decision c) Notification d) OJ No.
a) Nobi-vac-Porcoli b) Inactivated vaccine c) List A	a) Intervet International b) NL	a) Piglets b) Neonatal colibacillosis	a) Solution for injection b) Multidose c) 2	a) 01.01.95 b) 27.07.95 c) 107 days d) 94 days	a) 24.08.95 b) 29.02.96 c) 04.03.96 d) OJ No. C/96 of 29.03.96
a) Pentofel b) Vaccine c) List A	a) Fort Dodge Laboratories b) IRL	a) Cats b) Rhinotracheitis	a) Solution for injection b) Monodose c) 3	a) 16.06.95 b) 18.09.96 c) 208 days d) 235 days	a) 17.10.96 b) 05.02.97 c) 06.02.97 d) OJ No. C/63 of 28.02.97