The European Agency for the Evaluation of Medicinal Products

London, 11 December 1997
EMEA/CVMP/425/97

PRESS RELEASE

27th MEETING OF THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the twenty-seventh meeting of the Committee for Veterinary Medicinal Products took place in London on 9 - 11 December 1997.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	8	6	9
MRL procedures*	20	29	9

* Applications submitted to the EMEA after 1.1.1995

CENTRALISED PROCEDURES

2. The Committee adopted an Opinion on an inactivated vaccine for reduction of neonatal *E.coli* enterotoxicosis of piglets and falling under Part A of the Annex to Council Regulation (EEC) 2309/93.

3. The Committee agreed to recommend a fee reduction for an extension to a pharmaceutical authorised under the centralised procedure and falling under Part B of the Annex to Council Regulation (EEC) 2309/93.

SCIENTIFIC ADVICE

4. The Committee provided scientific advice concerning the adequacy of clinical trial data relating to a novel antimicrobial under development and considered to be falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93. This was the ninth provision of scientific advice by the Committee since 1 January 1995.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee recommended that 2 old substances be included in Annex I and 16 substances be included in Annex II of Council Regulation (EEC) 2377/90.

6. The Committee also adopted status reports and lists of questions for 21 old substances.

7. A Rapporteur and a Co-rapporteur were appointed for an application for the establishment of MRLs for a new substance.

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8. At a previous meeting, the Committee had been unable to recommend the establishment of final MRLs for an old substance for which the provisional MRLs were due to expire. At the request of the applicant, the Committee reviewed the additional information submitted in support of the application and agreed to revise its previous recommendation and to propose the inclusion of the substance into Annex I.

9. Members also reconsidered another substance, for which the applicant had objected to the Committee's recommendation not to set final MRLs regarding one of the species applied for. The Committee concluded that the explanations provided by the company did not justify a change to the previous recommendation and was unable to establish final MRLs on the basis that no fully validated analytical method for that species had been provided by the company.

ANTIMICROBIAL RESISTENCE AD HOC WORKING PARTY

10. The Committee discussed the draft agenda for a proposed WHO meeting on the use of fluoroquinolones in veterinary medicine. The Committee agreed that the sponsors be requested to postpone the meeting until the second half of 1998 to allow further deliberations on the format and timing of the meeting.

INTERNATIONAL HARMONISATION

11. Two VICH Notes for Guidance, one on Definition and Terminology and one on Methodology were released for consultation for a 4-month period.

ANY OTHER BUSINESS

12. The next meeting of the Committee will be held on 13-15 January 1998.

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: December 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: December 1997)

Total 304 Substances			
Annex I	Annex II	Annex III	Annex IV
47	220	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: December 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