The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

25th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Mr C. O'Sullivan the twenty-fifth meeting of the Committee for Veterinary Medicinal Products took place in London on 14 - 16 October 1997.

CENTRALISED PROCEDURES

2. The Committee decided that the Applicant for the granting of a Community marketing authorisation for a veterinary medicinal product intended for food-producing animals be invited to provide oral explanations before the Committee on outstanding issues before the Committee delivers its opinion.

3. The Committee adopted Lists of Questions for two products, one falling under Part A of the Annex to Council Regulation (EEC) No. 2309/93 and the other under Part B.

4. A Rapporteur and Co-Rapporteur were appointed for an intended application falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93.

SCIENTIFIC ADVICE

5. The Committee provided scientific advice concerning the design of various tests and trials necessary to demonstrate the safety and efficacy of a product under development and considered to be falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93; this was the eighth provision of scientific advice by the Committee since 1 January 1995.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

6. The Committee adopted a status report and a list of questions for one new substance under evaluation.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	5	8	4
MRL procedures*	19	25	11

* Applications submitted to the EMEA after 1.1.1995

7. The Committee recommended that five old substances, with previous provisional MRLs be included in Annex I of Council Regulation (EEC) No 2377/90. The provisional MRL of one old substance was recommended to be extended by two years to allow for completion of studies in progress.

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8. The Committee also recommended the inclusion of three old substances into Annex III and one substance into Annex IV of Council Regulation (EEC) No. 2377/90.

9. The Committee considered the pyrazolidone derivatives under Article 1 of Council Regulation (EC) No. 434/97 but was unable to conclude on any recommendation for inclusion of the substances into any of the Annexes of Council Regulation (EEC) No. 2377/90 due to outstanding questions regarding safety and residues.

10. Furthermore the Committee adopted status reports and list of questions for seven old substances.

11. Rapporteurs were appointed for applications for the extension of existing MRLs for seven substances.

INTERNATIONAL HARMONISATION

12. The Committee agreed on a position regarding the MRLs for consideration at the forthcoming session of the Codex Committee in Spring 1998.

13. The Committee nominated three Experts to participate in the VICH Expert Working Group on Biologicals Quality Monitoring on the following three topics; extraneous agents, mycoplasma, and moisture and formaldehyde.

ANY OTHER BUSINESS

14. The next meeting of the Committee will be held on 11 - 13 November 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 adopted by the Community since 1.1.1997

(Status: October 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) 0	a) 12.03.97 b) 24.09.97 c) OJ No. L 263 of 25.09.97

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

(Status: October 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