The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

London, 11 June 1998
EMEA/CVMP/257/98

PRESS RELEASE

33rd MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the thirty-third meeting of the Committee for Veterinary Medicinal Products took place in London on 9-11 June 1998.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**9**	**8**	**10**
MRL procedures*	**32**	**22**	**8**

*Applications submitted to the EMEA after 1.1.1995

CENTRALISED PROCEDURES

2. The Committee appointed Rapporteurs and Co-Rapporteurs for two new applications for the granting of a Community Marketing Authorisation for products falling under Part B of the Annex of Council Regulation (EEC) No. 2309/93, being new molecules for non food-producing animals.

3. The Committee also appointed Rapporteurs and Co-Rapporteurs for an extension to an existing Community Marketing Authorisation for the granting of a Community Marketing Authorisation and falling under Part B of the Annex of Council Regulation (EEC) No. 2309/93.

4. The Committee agreed to a delay in the submission of answers to questions for two products under evaluation in the Centralised Procedure, as sufficient justification had been given by the Applicants concerned.

5. The Committee reviewed advertising copy for a centrally approved product to examine whether it complied with the approved SPC. The Committee asked that their recommendations be transmitted to the European Commission for appropriate action.

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ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

6. The Committee recommended that 1 new substance be included in Annex I of Council Regulation (EEC) No. 2377/90 for one target species and in Annex II for foodstuffs (honey). It also recommended that another new substance be included in Annex II and provisional MRLs be set for a new animal species for one substance which is already included in Annex I of Council Regulation (EEC) No. 2377/90.

7. A Rapporteur was appointed for the extension of existing MRLs for one substance.

8. The Committee recommended the inclusion of one old substance into Annex I and that 15 old substances be included in Annex II, and one substance be included into Annex III to the Council Regulation (EEC) No. 2377/90. The Committee also recommended an Annex II and an Annex III entry for a further old substance regarding different target tissues, and three Annex II entries for old substances of vegetable origin.

9. The Committee, considering the assessment of the data provided by the applicant to the list of questions previously issued for one old substance, was unable to conclude on a recommendation for inclusion of the substance into any of the annexes of Council Regulation due to the inadequacy of the information submitted.

10. The Committee also agreed on the list of questions to be addressed to applicants concerning 16 specified old substances used in veterinary homeopathy and requested additional information for the remaining defended substances.

11. The Committee considered the appeal from one company with regard to the levels of recommended MRLs. Having considered the arguments provided the Committee confirmed the previous decision, which had been taken in accordance with Volume VI of the Rules Governing Medicinal Products in the European Community.

PHARMACOVIGILANCE

12. The Committee adopted, for release for consultation, a Note for Guidance on Rapid Alert Systems in Veterinary Pharmacovigilance.

ANTIMICROBIAL RESISTANCE

13. The Committee noted the conclusions of the WHO meeting in Geneva on 2-5 June 1998.

INTERNATIONAL HARMONISATION

14. The Committee agreed on a position regarding the draft Codex guideline on injection site residues in preparation of an EU position for forthcoming session of the 11th Codex Committee in autumn 1998.

ANY OTHER BUSINESS

15. The next meeting of the Committee will be held on 7 - 9 July 1998.

Peter G.H. Jones
Head, Veterinary Medicines Evaluation Unit

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Maximum Residue Limits for New Substances adopted by the Community since 1.1.1995

(Status: June 1998)

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) Difloxacin	a) Chicken, turkeys	a) 16.05.95 b) 15.12.95 c) 134 days d) 49 days	a) 13.02.96 b) 08.07.96 c) OJ No. L 170 of 09.07.96
a) Ketoprofen (extension)	a) Porcine	a) 15.05.95 b) 22.03.96 c) 85 days d) 217 days	a) 25.04.96 b) 06.09.96 c) OJ No. L 226 of 07.09.96
a) Diclazuril	a) Ovine	a) 12.12.95 b) 24.04.96 c) 104 days d) 0	a) 24.05.96 b) 21.10.96 c) OJ No. L 269 of 22.10.96
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
a) Cefazolin (extension)	a) Ovine and Caprine	a) 05.06.97 b) 10.09.97 c) 97 days d) 0	a) 10.10.97 b) 16.01.98 c) OJ No. L 11 of 17.01.98

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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) Isoflurane	b) Equine	a) 13.05.96 b) 07.05.97 c) 200 days d) 158 days	a) 05.06.97 b) 23.02.98 c) OJ No. L 53 of 24.02.98
a) Teflubenzuron	a) Fish	a) 20.01.97 b) 07.05.97 c) 105 days d) 0	a) 05.06.97 b) 23.02.98 c) OJ No. L 53 of 24.02.98
a) Florfenicol (extension)	a) Fish	a) 29.01.96 b) 16.07.97 c) 129 days d) 404 days	a) 12.08.97 b) 18.03.98 c) OJ No. L 82 of 19.03.98
a) Moxidectin (extension)	a) Equidae	a) 09.04.97 b) 16.07.97 c) 96 days d) 0	a) 12.08.97 b) 18.03.98 c) OJ No. L 82 of 19.03.98

Maximum Residue Limits for Old Substances adopted by the CVMP and the Community

(Status: June 1998)

TOTAL 403			
Annex I	Annex II	Annex III	Annex IV
50	308	34	11
Published in the Official Journal of the European Communities: 276			

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

(Status: June 1998)

Product a) Brandname b) INN c) Part 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) Part 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. C96 of 29.03.96
a) Pentofel b) Vaccine c) Part 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. C63 of 28.02.97
a) Quadrisol b) Vedaprofen c) Part B	a) Intervet International b) NL	a) Horses b) Control of inflammation	a) Oral gel b) 100mg/ml c) 1	a) 07.05.96 b) 16.07.97 c) 209 days d) 235 days	a) 14.08.97 b) 04.12.97 c) 05.12.97 d) OJ No. C392 of 24.12.97
a) Metacam b) Meloxicam c) Part B	a)Boehringer Ingelheim b) DE	a) Cattle b) Adjunctive therapy in acute respiratory infection	a) Solution for injection b) 5mg/ml c) 1	a) 24.06.96 b) 16.07.97 c) 208 days d) 180 days	a) 14.08.97 b) 07.01.98 c) 08.01.98 d) OJ No. C32 of 30.01.98
a) Dicural b) Difloxacin c) Part B	a) Fort Dodge Animal Health b) NL	a) Poultry b) Antibacterial for systematic use	a) Oral solution b) 100mg/ml c) 2	a) 06.12.95 b) 11.06.97 c) 218 days d) 337 days	a) 11.07.97 b) 16.01.98 c) 20.01.98 d) OJ No. C63 of 27.02.98
a) Clomicalm b) Clomipramine c) Part B	a) Ciba-Geigy b) FR	a) Dogs b) Treatment of anxieties	a) Tablets b) 5, 20 and 80mg c) 3	a) 13.11.96 b) 12.11.97 c) 210 days d) 156 days	a) 12.12.97 b) 01.04.98 c) 02.04.98 d) OJ No. C126 of 24.04.98
a) Neocolipor b) Inactivated vaccine c) Part A	a) Rhône-Mérieux b) FR	a) Piglets b) Passive immunisation against neonatal colibacillosis	a) Suspension for injection b) 2ml c) 5	a) 02.10.96 b) 10.12.97 c) 191 days d) 245 days	a) 09.01.98 b) 14.04.98 c) 15.04.98 d) OJ No. C126 of 24.04.98

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