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

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PRESS RELEASE

32nd MEETING OF THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the thirty-second meeting of the Committee for Veterinary Medicinal Products took place in London on 5 – 7 May 1998.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**9**	**8**	**10**
MRL procedures*	**29**	**23**	**8**

*Applications submitted to the EMEA after 1.1.1995

CENTRALISED PROCEDURES

2. The Committee appointed Rapporteurs and Co-Rapporteurs for 1 new application for the granting of a Community Marketing Authorisation for products falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93, being a new molecule for non food-producing animals.

3. The Committee considered the Follow-Up Measures as submitted by the Marketing Authorisation Holder for a product authorised under Part B of the Annex to Council Regulation (EEC) No. 2309/93.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

4. The Committee recommended that 1 new substance be included in Annex II to Council Regulation (EEC) No. 2377/90.

5. The Committee recommended provisional MRLs for new animal species for one substance which is already included in Annex I to Council Regulation (EEC) No. 2377/90 and also for another substance, for which provisional MRLs have been previously recommended for other species.

6. The Committee recommended the inclusion in Annex II of 2 substances which are already included in Annex II and III of Council Regulation (EEC) No. 2377/90 for other species and/or another route of administration.

7. The Committee adopted Status Reports and Lists of Questions for 2 other substances where applications were made to extend existing MRLs to further target species.

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8. The Committee recommended that 7 old substances be included in Annex II to Council Regulation (EEC) No. 2377/90 and adopted the Summary Report presenting these recommendations. The Committee adopted 3 Status Reports and lists of questions concerning old substances.

9. The Committee also adopted Summary Reports with the recommendation for inclusion in Annex II to Council Regulation (EEC) No. 2377/90) for 15 substances of vegetable origin.

10. The Committee heard an appeal from a company to an earlier decision of the Committee not to set MRLs for a new substance. The Committee concluded that it would be possible to set MRLs on the basis of the justifications provided by the company and subsequently recommended inclusion of the substance into Annex I of Council Regulation (EC) No. 2377/90.

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

12. The Committee noted the draft Workplan of the Safety of Residues Working Party. This Workplan is based on the foreseen submission of the responses to the list of questions for old substances and intends to ensure the completion of the assessment of old substances in the remaining time allowed by Council Regulation (EC) No. 434/97.

ORGANISATIONAL MATTERS

10. The Committee agreed to change the CVMP Rules of Procedure such that a Chairman of a Working Party may be re-elected for a further term of 3 years.

11. The Committee agreed that the Rapporteurs' and Co-Rapporteurs' Assessment Reports for both Centralised and MRL Applications, should be released to the Applicants at key stages of the evaluation.

ANY OTHER BUSINESS

12. The Committee considered the availability of veterinary medicines and made recommendations for discussion at the June Management Board.

13. In the margins of the Committee, a meeting with Interested Parties was held and a fruitful discussion took place, in particular on the current and future availability of veterinary medicines.

14. The next meeting of the Committee will be held on 9 -11 June 1998.

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

(Status: May 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

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: May 1998)

TOTAL 382			
Annex I	Annex II	Annex III	Annex IV
49	290	32	11
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Veterinary Medicinal Products that have been granted a Community marketing authorisation under the centralised procedure

(Status: May 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