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

London, 9 July 1998
EMEA/CVMP/350/98

PRESS RELEASE

34th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the thirty-fourth meeting of the Committee for Veterinary Medicinal Products took place in London on 7-9 July 1998.

2. Following the request to the Management Board at its June 1998 meeting, the Committee agreed to the Contingency Plan to be adopted in the light of budget cuts proposed by the EMEA and decided on priority work until the end of 1998 which may result in some Working Party meetings having to be deferred to early 1999.

3. The Committee re-elected Prof. P-P. Pastoret for a further term of 3 years as Chairman of the Immunological Working Party.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**9**	**8**	**10**
MRL procedures*	**35****	**21**	**6**

*Applications submitted to the EMEA after 1.1.1995
** including 2 Opinions recommending definitive MRLs for substances with previously provisonal MRLs

CENTRALISED PROCEDURES

4. The Committee discussed the draft assessment reports prepared by the Rapporteur and Co-Rapporteur for applications received by the Agency for Community Marketing Authorisations for 2 Veterinary medicinal products, one each falling under parts A and B of the Annex of Council Regulation No. (EEC) 2309/93. The Committee adopted the lists of questions to be sent to the Applicants concerned.

5. The Committee also agreed that an inspection should take place for a product under evaluation and falling under Part B of the Annex of Council Regulation No. (EEC) 2309/93.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

6. The Committee recommended that 1 new substance be included in Annex II and one further new substance be included in Annex III of Council Regulation (EEC) No. 2377/90. The Committee recommended definitive MRLs for an additional target species of a substance where previously only provisional MRLS had been set.

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7. The Committee, considering the assessment of the data provided by the applicant to the list of questions previously issued for one new 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.

8. Rapporteurs were appointed for the extension of existing MRLs for two substances.

9. The Committee recommended the inclusion of six old substances into Annex II and 2 old substances in Annex III to Council Regulation (EEC) No. 2377/90. The Committee also recommended an Annex II entry for an old substance of vegetable origin.

10. The Committee considered appeals from three companies concerning decisions on MRLs with regard to three substances (one per Applicant). The Committee, having considered the written explanations and further information presented, decided that in one case revised MRLs could be set and in two other cases that the Annex II recommendations be amended as supported by the companies.

11. The Committee agreed on an approach on the establishment of a legal status for pharmacologically active substances included in the list of questions previously considered as falling out of scope of Council Regulation (EEC) No. 2377/90.

GUIDELINES, POSITION PAPERS AND SOPs

12. The following Guideline was adopted for release for consultation:

- Guideline for Competent Authorities for the Verification and Evaluation of Pharmacovigilance Information for Veterinary Medicinal Products (EMEA/CVMP/345/98 - CONSULTATION)

13. The Committee agreed to grant the Efficacy Working Party a mandate to develop a new guideline for non-steroidal anti-inflammatory drugs.

ANY OTHER BUSINESS

14. The next meeting of the Committee will be held on 8 - 10 September 1998.

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

This press release and other documents are available on the Internet at the following address:
http://www.eudra.org/emea.html

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

(Status: July 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	a) 10.10.97 b) 16.01.98 c) OJ No. L 11 of

		d) 0	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
a) Praziquantel (extension)	a) Equidae	a) 15.09.97 b) 14.01.98 c) 120 days d) 0	a) 09.02.98 b) 27.05.98 c) OJ No. L 154 of 28.05.98

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

(Status: July 1998)

TOTAL 412			
Annex I	Annex II	Annex III	Annex IV
50	315	36	11
Published in the Official Journal of the European Communities: 283			

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

(Status: July 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