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

London, 12 March 1998
EMEA/CVMP/095/98

PRESS RELEASE

30th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the thirtieth meeting of the Committee for Veterinary Medicinal Products took place in London on 10 – 12 March 1998.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**8**	**8**	**9**
MRL procedures*	**24**	**26**	**8**

*Applications submitted to the EMEA after 1.1.1995

CENTRALISED PROCEDURES

2. The Committee discussed the draft assessment reports prepared by the Rapporteur and the Co-rapporteur for applications received by the Agency for the granting of 2 extensions to a Community marketing authorisation for a veterinary medicinal product falling under Part B of the Annex to Council Regulation No. (EEC) 2309/93. The Committee adopted the lists of questions to be sent to the Applicant concerned.

3. 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.

4. The Committee considered 2 requests from Applicants for extensions to the deadline for the response to the CVMP list of questions, for one product falling under Part A and one falling under Part B to the Annex of Council Regulation (EEC) No. 2309/93 and agreed that sufficient justification had been given in each case to grant the delay.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee concluded the assessment for 3 new substances. For one substance the existing MRLs were recommended to be modified and extended to further species and target tissues. For another substance, after consideration of the request for the modification of MRLs previously established, the previous MRLs were, however, confirmed. For a third substance for which provisional MRLs had already been recommended, the Committee adopted final MRLs after receipt of the outstanding data on the analytical method.

6. The Committee also recommended that 1 old substance be included in Annex III and 4 other substances be included in Annex II to Council Regulation (EEC) No. 2377/90.

7. The Committee adopted status reports and lists of questions for 11 old substances.

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8. The Committee reconsidered a substance, which is used both as a pesticide and in veterinary medicinal products and recommended MRLs consistent with the values fixed in EU legislation for pesticides.

9. The Committee, on request of the European Commission, reconsidered the interpretation of the substances falling under the pyrazolidone group and confirmed the scientific interpretation and recommendations given at the meeting in October 1997.

WORKING PARTIES OF THE CVMP

Antimicrobial Resistance

10. The Committee noted further communication concerning the WHO meeting on Quinolones to be held in Geneva on 2-5 June 1998, which it now supports in principle.

GUIDELINES, POSITION PAPERS AND SOPs

11. The Committee adopted, for release for consultation, a Note for Guidance on the Harmonisation of requirements for Equine Influenza Vaccines: Specific Requirements for substitution or addition of a strain or strains (EMEA/CVMP/112/98- CONSULTATION).

INTERNATIONAL HARMONISATION

12. The Committee nominated Professor C Sinogas from Portugal as an expert adviser for the group preparing quality guidance within the VICH process on the stability of immunologicals.

13. The Committee heard an oral report from the EU Co-ordinator on the 3rd VICH Steering Committee meeting held in Paris on 26 and 27 February 1998.

ANY OTHER BUSINESS

14. The Committee noted the EMEA Work Plan for 1998/99.

15. The next meeting of the Committee will be held on 7 – 8 April 1998.

Maximum Residue Limits for New Substances adopted by the Community since 1.1.1995
(Status: March 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 days	a) 05.06.97 b) 23.02.98 c) OJ No. L 53 of 24.02.98

Maximum Residue Limits for Old Substances adopted by the CVMP and the Community
(Status: March 1998)

TOTAL 331			
Annex I	Annex II	Annex III	Annex IV
49	241	30	11
Published in the Official Journal of the European Communities: 273			

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

(Status: March 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