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

London, 8 April 1998
EMEA/CVMP/162/98

PRESS RELEASE

31st MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the thirty-first meeting of the Committee for Veterinary Medicinal Products took place in London on 7 – 8 April 1998.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**9**	**8**	**9**
MRL procedures*	**25**	**26**	**9**

*Applications submitted to the EMEA after 1.1.1995

CENTRALISED PROCEDURES

2. The Committee adopted an Opinion for a live vaccine for the active and passive immunisation of pigs against Aujeszky's Disease.

3. The Committee adopted two Opinions for Scientific Advice to Companies. The first concerned safety tests and justification of the proposed claim for a live poultry vaccine. The second request concerned the data to be submitted for a new inactivated vaccine, also for poultry.

4. The Committee also confirmed eligibility under Part B of the Annex to Council Regulation (EEC) No. 2309/93 for a vaccine intended for use in dogs, having a new indication.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee recommended provisional MRLs for a new animal species for a substance which is already included in Annex I to Council Regulation (EEC) No. 2377/90 for another species.

6. The Committee adopted a status report and a list of questions for another substance where an application was made to extend existing MRLs.

7. The Committee recommended that 22 old substances be included in Annex II and 2 old substances be included in Annex III to Council Regulation (EEC) No. 2377/90 and adopted the Summary Reports presenting these recommendations.

8. For one old substance, where additional data are required with regard to one specific administration route, the Committee adopted a status report with a list of questions.

9. The Committee also adopted Summary Reports with the recommendation for inclusion in Annex II to Council Regulation (EEC) No. 2377/90) for 5 substances of vegetable origin.

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10. The Committee also agreed on the list of questions to be addressed to applicants concerning 9 old substances used in veterinary homeopathy.

11. Rapporteurs were appointed for the extension of existing MRLs for 2 substances.

12. The Committee having considered the objections made by one company to the MRLs previously recommended, the Committee accepted the arguments provided, and amended the MRL recommendations accordingly.

13. Members also considered another substance, for which the applicant had objected to the Committee's recommendation. The Committee concluded that the explanations provided by the company and confirmed non-compliance with the CVMP minor species guideline did not justify a change to the previous recommendation.

GUIDELINES, POSITION PAPERS AND SOPs

14. The Committee adopted, for release for consultation, a Position Paper on an Accelerated Procedure for Products Indicated for Serious Diseases.

INTERNATIONAL HARMONISATION

15. The Committee adopted, for release for consultation, 3 VICH Guidelines on: Stability Testing of New Drug Substances and Products, Stability Testing of New Dosage Forms and Photostability Testing of New Drug Substances and Products.

16. The Committee heard an update from Dr. S. Pyörälä, the E.U.Expert, on the work of the VICH Expert Working Group on Good Clinical Practice.

ANY OTHER BUSINESS

17. Recognising the intensity of the work programme which lies ahead of the Safety of Residues Working Party before 1st January 2000, the Committee was pleased to appoint Mme. Michèle Dagorn, the delegate from France, as Vice Chairman of the Working Party.

18. The Committee noted the publication of Commission Regulation (EC) No. 649/98 amending the Annex to Council Regulation (EEC) No. 2309/93, and thus also allowing access to the Centralised Procedure for products containing new active substances for use in non-food animals.

19. The next meeting of the Committee will be held on 5 – 7 May 1998.

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

(Status: April 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: April 1998)

TOTAL 360			
Annex I	Annex II	Annex III	Annex IV
49	268	32	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: April 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