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

London, 12 February 1998
EMEA/CVMP/069/98

PRESS RELEASE

29th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

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

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	8	6	9
MRL procedures*	21	28	9

*Applications submitted to the EMEA after 1.1.1995

CENTRALISED PROCEDURES

2. The Committee noted that Community marketing authorisations had been granted by the European Commission for Quadrisol, Dicural and Metacam to Intervet International, Fort Dodge and Boehringer Ingelheim Vetmedica, respectively.

3. The Committee endorsed the recommendation of the Rapporteur and Co-Rapporteur that the follow-up measures, as provided by the Applicant, were satisfactory for a product which had been the subject of a positive Opinion under the Centralised Procedure and which fell under Part B of the Annex to Council Regulation (EEC) No. 2309/93.

4. The Committee appointed a Rapporteur and Co-Rapporteur for a new application for the granting of a Community Marketing Authorisation for a product falling under **Part A** of the Annex to Council Regulation (EEC) No. 2309/93.

5. The Committee appointed a Rapporteur and Co-Rapporteur for a new application for the granting of a Community Marketing Authorisation for a product falling under **Part B** of the Annex to Council Regulation (EEC) No. 2309/93

SCIENTIFIC ADVICE

6. The Committee appointed two Co-ordinators for provision of Scientific Advice concerning 2 requests from an Applicant concerning the safety and efficacy testing for two intended applications under the Centralised Procedure.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

7. The Committee agreed to the extension of provisional MRLs for a further period for two substances.

8. The Committee recommended that 1 old substance having previously been assigned provisional MRLs be included in Annex I, 4 old substances be included in Annex II, and 1 old substance be included in Annex III to Council Regulation (EEC) No. 2377/90.
9. The Committee also adopted status reports and lists of questions for 8 old substances.

10. The Committee adopted 3 Summary Reports (with the recommendation for inclusion in Annex II of to Council Regulation (EEC) No. 2377/90) and 4 Status Reports and Lists of Questions for substances of vegetable origin.

11. The Committee considered the written explanations in support of an appeal against the CVMP recommendation to include a substance in Annex IV to Council Regulation (EEC) No. 2377/90. However, the Committee could not agree with the argumentation proposed by the company, because residues of the substance, at whatever limit, constitute a hazard to the health of the consumer, and confirmed its previous decision that the substance should be included in Annex IV.

12. The Committee noted the Objections to a CVMP Decision on MRLs from another Applicant and decided to grant a hearing at a future meeting.

WORKING PARTIES OF THE CVMP

Antimicrobial Resistance

13. The report of the WHO meeting of the Impact on the Use of Antimicrobials in Food Producing Animals, held in Berlin in October 1997, was noted by the Committee. In addition the Committee reaffirmed its reservations concerning the draft agenda for the next WHO meeting on the use of fluoroquinolones in veterinary medicine, to be held in Geneva in June 1998.

GUIDELINES AND SOPs

14. The Committee adopted a Note for Guidance on the Use of Adjuvanted Veterinary Vaccines for release for a 6 month consultation period (CVMP/IWP/043/97- CONSULTATION).

15. The Committee, following a 6 month consultation period, adopted a Position Paper on the Definition of a New Biological Active Substance within the context of Part B of the Annex to Council Regulation (EEC) No. 2309/93 (CVMP/IWP/029/97 – FINAL).

16. The Committee noted the revisions which had been made to 2 EMEA Standard Operating Procedures, one concerning the submission of applications for the establishment of MRLs (EMEA/CVMP/013/95 – rev 5) and the other for submission of applications for the granting of Community marketing authorisations (EMEA/CVMP/008/95 – rev 9).

ANY OTHER BUSINESS

17. The Committee noted and endorsed the Draft Work Programme of the EMEA for 1998/1999.

18. The Committee took note that the EMEA would hold an Open Day for Veterinary Consultants in Regulatory Affairs on 24 February 1998. Details are available from the EMEA Secretariat.

19. The Committee noted the Programme for the forthcoming FEDESA/EMEA Info Day, to be held on 13 March 1998.

20. The next meeting of the Committee will be held on 10 – 12 March 1998.

Maximum Residue Limits for New Substances adopted by the Community since 1.1.1995
(Status: February 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

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

TOTAL 323			
Annex I	Annex II	Annex III	Annex IV
49	233	30	11
Published in the Official Journal of the European Communities: 273			

Veterinary Medicinal Products which have been granted a Community marketing authorisation under the centralised procedure
(Status: February 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