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

London, 18 March 1999
EMEA/CVMP/154/99

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

41st MEETING

Under the chairmanship of Professor R. Kroker the forty-first meeting of the Committee for Veterinary Medicinal Products took place in London on 16 - 18 March 1999.

Dr J. Boisseau, having announced that he would be unable to continue as a CVMP Member due to work commitments, was thanked by the Chairman and the Committee for his contribution to the work of the CVMP over the years, both as a Member and as previous Chairman of the old CVMP.

Opinions

- The Committee adopted lists of questions for 2 applications, in respect of one product falling under Part A and one falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93.
- The Committee agreed eligibility for 2 products, both eligible under Part B of the Annex to Council Regulation (EEC) No. 2309/93.
- The Committee adopted Opinions for 2 substances extending the existing entries under the Annexes of Council Regulation (EEC) No.2377/90) to further species.
- The Committee made recommendations for the inclusion of 9 substances of vegetable origin in Annex II but was unable to make recommendations for a further 2 such substances. No recommendation was possible for 1 substance used in veterinary homeopathic therapy at concentrations greater than 1:10,000.
- The Committee agreed that 1 old substance would not fall within the scope of Council Regulation (EEC) No.2377/90 at the concentrations used.
- Further to appeals received from companies, the Committee decided to recommend amended MRLs for 1 old substance. For two other old substances the previous decisions were upheld.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**12**	**20**	**4**
MRL procedures*	**51****	**19**	**7**

* Applications submitted to the EMEA after 1.1.1995
** including 6 Opinions recommending definitive MRLs for substances with previously provisional MRLs

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Switchboard: (+44-171) 418 8400 Fax: (+44-171) 418 8447
E_Mail: mail@emea.eudra.org http://www.eudra.org/emea.html

Notes for Guidance, Position Papers

1. The Committee adopted, for release for 6 months consultation, VICH Guideline 12 on the Efficacy of Anthelmintics: Specific Recommendations for Bovine, Ovine and Caprine species (EMEA/CVMP/111/99).
2. The Committee also adopted Guidelines for the Conduct of Pharmacokinetic Studies in Animals (EMEA/CVMP/133/99) for release for 6 months consultation.
3. A note for Guidance on the Requirements for Combined Vaccines (CVMP/IWP/052/97) was also adopted for 6 months consultation.
4. The Committee adopted a Note for Guidance on the Conduct of Pharmacovigilance for Veterinary Medicinal Products authorised through the Mutual Recognition Procedure (EMEA/CVMP/143/99). This document will be forwarded immediately to the European Commission for inclusion in Volume 9 of the Notice to Applicants.
5. The Committee adopted a revised note, to be made available on the EMEA Website, on the Role of the Rapporteur and Co-Rapporteur in the assessment of applications for the granting of a Community Marketing authorisation (EMEA/CVMP/077/99).
6. The Committee agreed on a position paper addressing the availability of veterinary medicines and recommending to the Commission a draft list of therapeutic gaps and their respective medicines considered indispensable in veterinary practice today. The paper and the working documentation leading to the CVMP's conclusions will be made available to interested parties for comment and will be published on the web-site.

Working Parties of the CVMP

The Committee appointed Dr. Gabriella Conti as Chairman of the Pharmacovigilance Working Party for a period of 3 years. Dr Conti will take up office as Chairman on the expiry of the mandate of the current Chairman, Prof. A. Macri.

Miscellaneous Items

- The Committee endorsed the joint initiative of FEDESA and the EMEA on a Questionnaire relating to the operation of the Centralised Procedure. This questionnaire will be made available on the EMEA Website.
- The next meeting of the CVMP will be held on 13 - 15 April 1999.

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: March 1999)

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	a) 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
a) Meloxicam	a) Bovine	a) 28.03.96 b) 11.06.97 c) 212 days d) 229 days	a) 09.07.97 b) 17.07.98 c) OJ No. L 205 of 22.07.98
a) Tilmicosin (extension)	a) Chicken	a) 14.07.97 b) 12.11.97 c) 111 days d) 0	a) 12.12.97 b) 09.09.98 c) OJ No. L 250 of 10.09.98
a) Valnemulin	a) Porcine	a) 02.08.96 b) 06.05.98 c) 207 days d) 435 days	a) 05.06.98 b) 27.11.98 c) OJ No. L 320 of 28.11.98
a) Alfaprostol (extension)	a) Rabbits	a) 15.05.97 b) 06.05.98 c) 200 days d) 156 days	a) 05.06.98 b) 27.11.98 c) OJ No. L 320 of 28.11.98
a) Rifaximin	a) All mammalian food producing species	a) 09.01.97 b) 06.05.98 c) 180 days d) 303 days	a) 05.06.98 b) 27.11.98 c) OJ No. L 320 of 28.11.98
a) Bronopol	a) Salmonidae	a) 07.05.97 b) 10.06.98 c) 198 days d) 202 days	a) 10.07.98 b) 11.12.98 c) OJ No. L337 of 12.12.98
a) Flumethrin	a) Bovine, Ovine, Caprine, Honey bees	a) 11.11.96 b) 10.06.98 c) 197 days d) 380 days	a) 10.07.98 b) 11.12.98 c) OJ No. L 337 of 12.12.98
a) Enrofloxacin (modification)	a) Bovine, Porcine, Poultry	a) 03.02.97 b) 08.07.98 c) 183 days d) 336 days	a) 30.07.98 b) 17.12.98 c) OJ No. L 343 of 18.12.98
a) Enrofloxacin (extension)	a) Dairy cattle, Ovine, Rabbits	a) 03.02.97 b) 08.07.98 c) 183 days d) 336 days	a) 30.07.98 b) 17.12.98 c) OJ No. L 343 of 18.12.98

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) Sodium 2-methyl-2-phenoxy-propionate	a) Bovine, Porcine, Caprine, Equidae	a) 26.11.96 b) 08.07.98 c) 201 days d) 388 days	a) 30.07.98 b) 17.12.98 c) OJ No. L 343 of 18.12.98
a) Ivermectin (extension)	a) Deer	a) 20.08.96 b) 08.07.98 c) 170 days d) 518 days	a) 30.07.98 b) 17.12.98 c) OJ No. L 343 of 18.12.98
a) Diethylene glycol monoethyl ether	a) Bovine, Porcine	a) 14.02.97 b) 08.07.98 c) 170 days d) 337 days	a) 30.07.98 b) 17.12.98 c) OJ No. L 343 of 18.12.98

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

(Status: March 1999)

TOTAL 479			
Annex I	Annex II	Annex III	Annex IV
55	368	45	11
Published in the Official Journal of the European Communities: **388**			

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

(Status: March 1999)

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

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) 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
a) Nobilis IB4-91 b) Live vaccine c) Part B	a) Intervet International b) NL	a) Poultry, chicken b) Live vaccine against infectious bronchitis	a) Solution b) 30ml/1000 doses c) 5	a) 16.10.96 b) 12.11.97 c) 210 days d) 184 days	a) 12.12.97 b) 09.06.98 (corrigendum 05.08.98) c) 10.06.98 d) OJ No. C200 of 26.06.98
a) Suvaxyn Aujeszky 783+ O/W b) Live vaccine c) Part A	a) Solvay Duphar b) NL	a) Pigs b) Vaccine against Aujeszky disease	a) Solution for injection b) 2ml c) 3	a) 19.10.96 b) 08.04.98 c) 208 days d) 328 days	a) 08.05.98 b) 07.08.98 c) 10.08.98 d) OJ No. C269 of 28.08.98