



London, 9 December 1999
EMA/CVMP/858/99

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
50th MEETING

Under the Chairmanship of Professor R. Kroger the fiftieth meeting of the Committee for Veterinary Medicinal Products took place in London on 7 - 9 December 1999.

CVMP Opinions

- The Committee adopted unanimous positive Opinions and CVMP Assessment Reports for two vaccines falling under Part A of the Annex to Council Regulation (EEC) No. 2309/93 and indicated for feline leukaemia and for rabies in foxes respectively.
- The Committee also adopted by majority, a positive Opinion and CVMP Assessment Report for a product falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93 and indicated for incontinence in ovariohysterectomised bitches.
- Further to the request of the European Commission to reconsider the MRL assessment for natural and synthetic hormones used in veterinary therapy in light of new data having become available, the CVMP confirmed the previous opinions to recommend the inclusion of the substances concerned in Annex II or Annex III respectively of Council Regulation (EEC) No. 2377/90
- The Committee considered appeals in respect of MRL Opinions for 3 substances, for which the Committee upheld the previous decisions.

MRLs	New Substances	New Substances: Extensions to further species/ Modifications	"Old" Substances
Opinions adopted at this meeting	-	-	5 ^a

a: including 2 substances for which no MRLs were set

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	25	13	5
New MRL procedures*	73**	4	6

* Applications submitted to the EMEA after 1.1.1995

** including 11 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Availability of Medicines

- The Committee adopted a recommendation to include Thiamylal in Annex II of Council Regulation (EEC) No. 2377/90, this substance having been identified previously as essential (see CVMP Position Papers on Availability of Veterinary Medicines EMA/CVMP/151/99-FINAL and EMA/CVMP/731/99) and for which further data in the public domain had become available.

- The CVMP however concluded that despite concerted efforts made to obtain further data, no recommendation to include narcobarbital, etorphine, diprenophine, propionylpromazine, acepromazine, diazepam, yohimbine or fumagillin in any of the annexes to Council Regulation (EEC) No. 2377/90 was possible.
- Following further scrutiny of the substances recently evaluated, for which MRLs no can be established, guaifenesin (indication: muscle relaxation, target species: horse) was added to the list of substances considered essential.

Guidelines, SOPs

The Committee adopted, for release for 6 months consultation, a Note for Guidance on the Stability Testing of Existing Active Substances and Related Finished Products (EMEA/CVMP/846/99).

The Committee agreed to the release of the following VICH final guidelines at Step 7:

GL7 Efficacy requirements for anthelmintics: overall guidelines (EMEA/CVMP/832/99)

GL8 Stability testing for medicated premixes (EMEA/CVMP/836/99)

GL10 Impurities in new veterinary drug substances (EMEA/CVMP/837/99)

GL11 Impurities in new veterinary medicinal products (EMEA/CVMP/838/99)

GL12 Efficacy of anthelmintics: specific recommendations for bovines (EMEA/CVMP/ 839/99)

GL13 Efficacy of anthelmintics: specific recommendations for ovines (EMEA/CVMP/840/99)

GL14 Efficacy of anthelmintics: specific requirements for caprines (EMEA/CVMP/841/99)

The Committee also endorsed the following draft VICH guidelines for release for 6 months consultation;

GL15 – Efficacy of anthelmintics: specific requirements for equines - (EMEA/CVMP/833/99).

GL16 – Efficacy of anthelmintics: specific requirements for swine - (EMEA/CVMP/834/99).

GL19 – Efficacy of anthelmintics: specific requirements for canine - (EMEA/CVMP/835/99).

The Committee also adopted the following SOP:

Submission of MRL applications further to the amendment of Regulation 2377/90
(EMEA/CVMP/819/99).

The next meeting of the CVMP will be held on 11-13 January 2000.

Peter G.H. Jones
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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: December 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) Tilimicosin (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
a) Thiamphenicol (extension)	a) Porcine, Ovine, Fish, Turkeys	a) 15.05.98 b) 09.09.98 c) 117 days d) 0	a) 08.10.98 b) 16.04.99 c) OJ No. L 102 of 17.04.99
a) Cefquinome (extension)	a) Porcine	a) 14.05.97 b) 08.04.98 c) 188 days d) 141 days	a) 08.05.98 b) 05.05.99 c) OJ No. L 118 of 06.05.99
a) Cypermethrin (extension)	a) Fish	a) 29.07.96 b) 06.05.98 c) 162 days d) 483 days	a) 05.06.98 b) 05.05.99 c) OJ No. L 118 of 06.05.99
a) Carazolol (extension)	a) Bovine	a) 12.06.96 b) 06.05.98 c) 185 days d) 507 days	a) 05.06.98 b) 05.05.99 c) OJ No. L 118 of 06.05.99
a) Danofloxacin (extension)	a) Porcine	a) 25.07.97 b) 10.06.98 c) 183 days d) 137 days	a) 10.07.98 b) 05.05.99 c) OJ No. L 118 of 06.05.99
a) Praziquantel (extension)	a) Sheep milk	a) 14.07.98 b) 11.11.98 c) 120 days d) 0	a) 10.12.98 b) 11.05.99 c) OJ No. L 122 of 12.05.99
a) Difloxacin (extension)	a) Bovine, Porcine	a) 14.07.98 b) 11.11.98 c) 120 days d) 0	a) 10.12.98 b) 11.05.99 c) OJ No. L 122 of 12.05.99
a) Diflubenzuron	a) Salmonidae	a) 23.03.98 b) 11.11.98 c) 107 days d) 0	a) 10.12.98 b) 11.05.99 c) OJ No. L 122 of 12.05.99
a) Halofuginone	a) Bovine	a) 10.12.96 b) 11.11.98 c) 197 days d) 505 days	a) 10.12.98 b) 11.05.99 c) OJ No. L 122 of 12.05.99
a) Danofloxacin (extension)	a) Bovine	a) 19.05.98 b) 09.12.98 c) 113 days d) 0	a) 08.01.99 b) 11.05.99 c) OJ No. L 122 of 12.05.99
a) Emamectin	a) Fish	a) 18.05.98 b) 13.01.99 c) 200 days d) 40 days	a) 12.02.99 b) 09.09.99 c) OJ No. L 240 of 10.09.99

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) Teflubenzuron	a) Fish	a) 20.01.97 b) 13.01.99 c) 213 days d) 510 days	a) 12.02.99 b) 09.09.99 c) OJ No. L 240 of 10.09.99
a) Cefquinome (extension)	a) Porcine	a) 14.05.97 b) 13.01.99 c) 257 days d) 352 days	a) 12.02.99 b) 09.09.99 c) OJ No. 240 of 10.09.99
a) Florfenicol (extension)	a) Porcine	a) 15.12.98 b) 14.04.99 c) 120 days d) 0	a) 12.05.99 b) 10.09.99 c) OJ No. L 241 of 11.09.99
a) Moxidectin (extension)	a) Equidae	a) 09.04.07 b) 14.04.99 c) 174 days d) 561 days	a) 12.05.99 b) 10.09.99 c) OJ No. L 241 of 11.09.99
a) Danofloxacin (extension)	a) Pigs	a) 25.07.97 b) 14.04.99 c) 241 days d) 387 days	a) 12.05.99 b) 10.09.99 c) OJ No. L 241 of 11.09.99
a) Eprinomectin (modification)	a) Bovine	a) 19.06.98 b) 14.10.98 c) 114 days d) 0	a) 13.11.98 b) 10.09.99 c) OJ No. L 241 of 11.09.99
a) Dicyclanil	a) Ovine	a) 25.02.97 b) 17.02.99 c) 191 days d) 797 days	a) 12.03.99 b) 11.11.99 c) OJ No. L 290 of 12.11.99
a) Tosylchloramide sodium	a) Fin fish	a) 20.10.98 b) 17.02.99 c) 103 days d) 0	a) 12.03.99 b) 10.11.99 c) OJ No. L 288 of 11.11.99
a) Meloxicam	a) Bovine	a) 28.03.96 b) 17.02.99 c) 301 days d) 755 days	a) 12.03.99 b) 11.11.99 c) OJ No. L 290 of 12.11.99
a) Amitraz (extension)	a) Bees	a) 12.03.97 b) 17.02.99 c) 200 days d) 507 days	a) 12.03.99 b) 11.11.99 c) OJ No. L 290 of 12.11.99
a) Flubendazole (extension)	a) Turkey	a) 17.11.98 b) 17.03.99 c) 120 days d) 0	a) 13.04.99 b) 10.11.99 c) OJ No. L 288 of 11.11.99.
a) Florfenicol (extension)	a) Chicken	a) 17.11.98 b) 17.03.99 c) 120 days d) 0	a) 13.04.99 b) 10.11.99 c) OJ No. L 288 of 11.11.99

Maximum Residue Limits for Old Substances adopted by the CVMP and the Community
 (Status: December 1999)

TOTAL 562			
Annex I	Annex II	Annex III	Annex IV
68	431	52	11
Published in the Official Journal of the European Communities: 462			

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

(Status: December 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) Fevaxyn Pentofel (previously 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

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) 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
a) Econor b) Valnemulin c) Part B	a) Novartis b) UK	a) Pigs b) Prevention and treatment of dysentery and treatment and control of enzootic pneumonia	a) 50% microgranules/ 1% and 10% premix b) various c) 7	a) 18.06.97 b) 14.10.98 c) 210 days d) 274 days	a) 13.11.98 b) 12.03.99 c) 16.03.99 d) OJ No. C84 of 26.03.99
a) Quadrisol b) Vedaprofen c) Part B extension	a) Intervet b) NL	a) Dogs b) Control of inflammation	a) Gel b) 5mg/ml c) 2	a) 12.11.97 b) 14.10.98 c) 210 days d) 126 days	a) 13.11.98 b) 15.02.99 c) 24.02.99 d) OJ No. C84 of 26.03.99
a) Locatim (previously Serinucoli) b) Oral colostrum based immunoglobulin c) Part A	a) Biokema b) E.E.A.	a) Calves b) Colostrum based immunoglobulin	a) Oral Solution b) 60 ml c) 1	a) 18.06.97 b) 09.12.98 c) 209 days d) 330 days	a) 11.01.99 b) 29.03.99 c) 28.04.99 d) OJ No. C148 of 28.05.99
a) HESKA PERIOceutic b) Doxycycline c) Part B	a) Heska b) USA	a) Dogs b) Periodontal disease	a) Solution b) - c) 2	a) 11.03.98 b) 12.05.99 c) 182 days d) 281 days	a) 11.06.99 b) 15.09.99 c) 23.09.99 d) OJ No. C 311 of 29.10.99