



London, 13 January 2000
EMEA/CVMP/049/00

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
51st MEETING

Under the Chairmanship of Professor R. Kroker the fifty-first meeting of the Committee for Veterinary Medicinal Products took place in London on 11 – 13 January 2000.

Referrals to CVMP

The CVMP adopted an Opinion on the referral procedure regarding safety issues resulting from reported Bovine Viral Diarrhoea (BVD) contamination of a live Infectious Bovine Rhinotracheitis vaccine. This CVMP Opinion requires a variation of the current Marketing Authorisations to provide for the inclusion of additional quality control tests to ensure that contamination of the finished product by BVD virus is prevented.

MRLs	New Substances	New Substances: Extensions to further species/ Modifications	"Old" Substances
Opinions adopted at this meeting	--	1	14^a

a: including 5 Opinions recommending definitive MRLs for substances with previously provisional MRLs, 2 recommending the extension of provisional MRLs and 7 substances of vegetable origin previously included in the "Out of scope" list.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	25	15	5
New MRL procedures*	74**	4	7

* Applications submitted to the EMEA after 1.1.1995

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

Guidelines, SOPs

The Committee adopted, for release for 6 months consultation, a Guideline for the conduct of bioequivalence studies for veterinary medicinal products (EMEA/CVMP/016/00-CONSULTATION) and a Guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats (EMEA/CVMP/005/00-CONSULTATION).

Subsequent to the publication of the CVMP Report and Qualitative Risk Assessment on Antibiotic Resistance in the European Union Associated with the Therapeutic Use of Veterinary Medicines (EMEA/CVMP/342/99-FINAL) in July 1999, the Committee adopted a Risk Management Strategic Plan for Controlling Antimicrobial Resistance through the authorisation of veterinary medicines (EMEA/CVMP/818/99-FINAL).

The next meeting of the CVMP will be held on 8-10 February 2000.

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: January 2000)

Substance	Therapeutic area	EMEA/CVMP	Commission
a) INN	a) Target species	a) Validation b) Opinion c) Active time d) Clockstop	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) 84 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) 79 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) 69 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
a) N-methyl-pyrrolidone	a) Bovine, Swine & Ovine	a) 12.01.99 b) 12.05.99 c) 112 days d) 0	a) 10.06.99 b) 08.12.99 c) OJ No. L 315 of 09.12.99
a) Spiramycin (extension)	a) Swine	a) 22.02.99 b) 16.06.99 c) 114 days d) 0	a) 15.07.99 b) 08.12.99 c) OJ No. L 315 of 09.12.99

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) Diflubenzuron	a) Atlantic salmon	a) 23.03.98 b) 16.06.99 c) 185 days d) 275 days	a) 15.07.99 b) 08.12.99 c) OJ No. L 315 of 09.12.99
a) Toltrazuril (extension)	a) Swine	a) 16.02.99 b) 16.06.99 c) 120 days d) 0	a) 15.07.99 b) 08.12.99 c) OJ No. L 315 of 09.12.99
a) Tilmicosin (extension)	a) Bovine milk	a) 22.02.99 b) 16.06.99 c) 114 days d) 0	a) 15.07.99 b) 08.12.99 c) OJ No. L 315 of 09.12.99
a) Abamectin (extension)	a) Ovine	a) 23.04.99 b) 18.08.99 c) 115 days d) 0	a) 31.08.99 b) 20.12.99 c) OJ No. L 328 of 22.12.99
a) Doramectin (extension)	a) Reindeer	a) 11.12.97 b) 14.07.99 c) 203 days d) 377 days	a) 12.08.99 b) 20.12.99 c) OJ No. L 328 of 22.12.99
a) Rafoxanide	a) Bovine & Ovine	a) 11.02.97 b) 14.07.99 c) 193 days d) 690 days	a) 12.08.99 b) 20.12.99 c) OJ No. L 328 of 22.12.99

Maximum Residue Limits for Old Substances adopted by the CVMP and the Community
 (Status: January 2000)

TOTAL 562			
Annex I	Annex II	Annex III	Annex IV
68	431	52	11
Published in the Official Journal of the European Communities: 496			

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

(Status: January 2000)

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
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

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) 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
a) Halocur b) Halofuginone c) Part B	a) Hoechst Roussel Vet b) FR	a) Bovine b) Cryptosporidiosis in calves	a) Oral solution b) 0.05g/100ml c) 2	a) 10.12.96 b) 16.06.99 c) 210 days d) 708 days	a) 16.07.99 b) 29.10.99 c) 09.11.99 d) OJ No. C 339 of 26.11.99
a) Stronghold b) UK-124,114 c) Part B	a) Pfizer b) UK	a) Dogs & Cats b) Endectocide	a) Topical solution b) 6% w/v, 12% w/v c) 5	a) 17.11.98 b) 14.07.99 c) 183 days d) 56 days	a) 13.08.99 b) 25.11.99 c) 03.12.99 d) OJ No. C 375 of 24.12.99
a) Oxyglobin b) Haemoglobin c) Part B	a) Biopure Corporation b) USA	a) Dogs b) Anaemia	a) Intravenous infusion b) 130mg/ml c) 1	a) 12.05.98 b) 14.07.99 c) 210 days d) 218 days	a) 13.08.99 b) 29.11.99 c) 01.12.99 d) OJ No. C 375 of 24.12.99