



London, 14 October 1999
EMA/CVMP/726/99

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
48th MEETING

Under the Chairmanship of Professor R. Kroker the forty-eighth meeting of the Committee for Veterinary Medicinal Products took place in London on 12 - 14 October 1999.

CVMP Opinions

- The Committee adopted a unanimous positive Opinion and CVMP assessment report for a vaccine falling under Part A of the Annex to Council Regulation (EEC) No. 2309/93 and indicated for Classical Swine Fever.
- The Committee considered appeals in respect of MRL Opinions for 2 substances, neither of which was successful.

MRLs	New Substances:	New Substances: Extensions to further species/ Modifications	"Old" Substances (incl. substances of vegetable origin and those used in veterinary homeopathy)
Opinions adopted at this meeting	2	2	8^a

^a Including 3 substances where no MRL was set

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	19	20	5
New MRL procedures*	72**	5	4

* Applications submitted to the EMEA after 1.1.1995

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

Guidelines and SOPs

The Committee adopted the following Note for Guidance for release for 6 months consultation:

- Note for Guidance on Duration of Protection Achieved by Veterinary Medicines (EMA/CVMP/682/99).

The Committee also adopted the following SOPs:

- Procedure for Management of a Serious Adverse Drug Reaction (SADR) (CVMP/SOP/693/99)
- Procedure for Management of Periodic Safety Update Reports (PSURs) (CVMP/SOP/692/99)

Availability of Medicines

Following further scrutiny of the substances recently evaluated, for which no MRLs can be established, the list of substances considered essential in veterinary medicine was updated (EMEA/CVMP/731/99).

Promotional Material

The Committee considered a case where the advertising material for a centralised product contravened the terms of the marketing authorisation and recommended that the company concerned should be requested to withdraw this inaccurate literature immediately.

The next meeting of the CVMP will be held on 9 – 11 November 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: October 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

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

(Status: October 1999)

TOTAL 558			
Annex I	Annex II	Annex III	Annex IV
68	428	51	11
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Veterinary Medicinal Products that have been granted a Community marketing authorisation under the centralised procedure

(Status: October 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
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) 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