



London, 12 May 1999  
EMEA/CVMP/305/99

**PRESS RELEASE**  
**COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS**  
**43rd MEETING**

Under the chairmanship of Professor R. Kroker the forty-third meeting of the Committee for Veterinary Medicinal Products took place in London on 11 and 12 May 1999.

**Opinions**

- Further to an oral explanation by the Applicant, the Committee adopted an Opinion and CVMP Assessment Report in respect of a product for the treatment of periodontal disease in dogs and falling under Part B (new delivery system) of the Annex to Council Regulation (EEC) No. 2309/93.
- The Committee adopted lists of questions for 6 applications (4 full and 2 extensions) in respect of 2 products falling under Part A and 3 falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93.
- The Committee adopted a Summary Report recommending the inclusion in Annex II for one new substance. For another full MRL application for a new substance the Committee adopted a status report including a list of questions.
- The Committee considered an appeal from one company in respect of an old substance and subsequently amended the provisional MRLs previously established.
- For a further two substances, both of vegetable origin, the previous decisions were upheld.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
<b>Centralised procedures</b>	<b>13</b>	<b>21</b>	<b>3</b>
<b>MRL procedures*</b>	<b>56**</b>	<b>15</b>	<b>6</b>

\* Applications submitted to the EMEA after 1.1.1995

\*\* including 9 Opinions recommending definitive MRLs for substances with previously provisional MRLs

**Notes for Guidance, Position Papers, SOPs**

- The Committee adopted, for release for 6 months consultation, a Note for Guidance on the Assessment of the Effect of Antimicrobial Substances on Dairy Starter Cultures (EMEA/CVMP/276/99 - CONSULTATION).
- Further to the close of the consultation period, the Committee adopted the Note for Guidance on the Procedure for Competent Authorities for Pharmacovigilance Information of Veterinary Medicinal Products (EMEA/CVMP/345/98 -FINAL) *This Note for Guidance comes into immediate effect.*

**Miscellaneous Items**

- The next meeting of the CVMP will be held on 15 -17 June 1999.

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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: May 1999)

<b>Substance</b> a) INN	<b>Therapeutic area</b> a) Target species	<b>EMEA/CVMP</b> a) Validation b) Opinion c) Active time d) Clockstop	<b>Commission</b> 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

<b>Substance</b> a) INN	<b>Therapeutic area</b> a) Target species	<b>EMEA/CVMP</b> a) Validation b) Opinion c) Active time d) Clockstop	<b>Commission</b> 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

<b>Substance</b> a) INN	<b>Therapeutic area</b> a) Target species	<b>EMEA/CVMP</b> a) Validation b) Opinion c) Active time d) Clockstop	<b>Commission</b> 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 06.05.98

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

<b>TOTAL 499</b>			
Annex I	Annex II	Annex III	Annex IV
59	383	46	11
Published in the Official Journal of the European Communities: <b>408</b>			

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

(Status: May 1999)

<b>Product</b> a) Brandname b) INN c) Part A/B	<b>Company</b> a) Name b) Origin	<b>Therapeutic area</b> a) Target species b) Indication	<b>Presentation</b> a) Form b) Dosage c) No. of presentations	<b>EMEA/CVMP</b> a) Validation b) Opinion c) Active time d) Clockstop	<b>Commission</b> 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
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

<b>Product</b> a) Brandname b) INN c) Part A/B	<b>Company</b> a) Name b) Origin	<b>Therapeutic area</b> a) Target species b) Indication	<b>Presentation</b> a) Form b) Dosage c) No. of presentations	<b>EMEA/CVMP</b> a) Validation b) Opinion c) Active time d) Clockstop	<b>Commission</b> 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