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

London, 18 June 1999
EMEA/CVMP/329/99

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

44th MEETING

Under the chairmanship of Dr. J. G. Beechinor the forty-fourth meeting of the Committee for Veterinary Medicinal Products took place in London on 15 to 17 June 1999.

On the occasion of the joint TAIEX EMEA CENTRAL and EASTERN EUROPEAN COUNTRIES Forum on the Regulation of Veterinary Medicines, the Committee welcomed Officials from the Regulatory Authorities of the Central and Eastern European Countries as Observers to the section of the CVMP meeting devoted to reports from Working Parties, International Harmonisation and organisational issues.

Opinions

- The Committee adopted a unanimous positive Opinion and CVMP Assessment Report for a product assessed under the Centralised Procedure and indicated for the prevention and reduction of neonatal diarrhoea in calves.

MRLs	New Substances: Annex III to Annex I Change	New Substances: Extensions to further species	"Old" Substances:
Opinions adopted at this meeting	**2**	**3**	**11**[a]

[a] *Including 4 substances where no MRL was set*

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**14**	**20**	**3**
MRL procedures*	**61****	**16**	**5**

* Applications submitted to the EMEA after 1.1.1995

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

Antimicrobial Resistance

- The Committee held a discussion on the draft report on the Development of Antimicrobial Resistance in the EU, which reflects the work carried out over the last two years. The Committee intends to finalise its Report at its July meeting prior to making the document public at a meeting of CVMP Interested Parties. The Committee took note of the Opinion of the Scientific Steering Committee on Antimicrobial Resistance which had been forwarded to the Committee by DG XXIV of the European Commission (details available from http://europa.eu.int/comm/dg24/health/sc/scmp/outcome_en.html).

Appointment of Chair of the SRWP

- The Committee elected Madame Michèle Dagorn as Chair of the SRWP. Madame Dagorn's term of office will take effect from September 1999 to replace the incumbent Chairman Dr. J. G. Beechinor.

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Notes for Guidance, Position Papers, SOPs

- Dr. J. Boisseau presented an in-depth review of the risk assessment approach to be undertaken for the establishment of MRLs. This review will form an integral part of the Committee's policy later in the year.
- Further to the close of the consultation period, the Committee adopted a Position Paper on Compliance of Veterinary Vaccines with Veterinary Vaccine Monographs of the European Pharmacopoeia (EMEA/CVMP/140/97-FINAL).
- Further to the close of the consultation period, the Committee adopted a revised the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Veterinary Medicinal Products (EMEA/CVMP/145/97 - REVISION).
- The Committee adopted, for release for a 6 month consultation period, Guidelines for the Conduct of Efficacy Studies for Intramammary Products for Use in Cattle (EMEA/CVMP/344/99-CONSULTATION).

Miscellaneous Items

- The next meeting of the CVMP will be held on 13 – 15 July 1999.
- The Committee adopted the following dates for meetings in the year 2001:

January	9 - 11
February	13 -15
March	13 - 15
April	17 - 19
May	15 - 17
June	12 - 14
July	10 - 12
August	(7 - 9)*
September	11 - 13
October	9 - 11
November	6 - 8
December	4 - 6

** to be confirmed*

- The dates for the year 2000, previously adopted by the Committee are as follows:

January	11-13
February	8-10
March	7-9
April	18-19
May	16-18
June	20-22
July	18-20
(August	16-17)*
September	12-14
October	10-12
November	7-9
December	5-7

**to be confirmed*

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: June 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
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: June 1999)

TOTAL 506			
Annex I	Annex II	Annex III	Annex IV
61	387	47	11
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Veterinary Medicinal Products that have been granted a Community marketing authorisation under the centralised procedure

(Status: June 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 immuno-globin c) Part A	a) Biokema b) E.E.A.	a) Calves b) Colostrum based immunoglobin	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