



PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

61st MEETING

Under the Chairmanship of Professor R. Kroger the sixty-first meeting of the Committee for Veterinary Medicinal Products took place in London on 5 – 7 December 2000.

The Committee expressed its gratitude and appreciation to Professor Reinhard Kroger at the end of his term of office for his outstanding service to the Committee as Chairman for the past six years.

CVMP Opinions

The Committee unanimously adopted a positive opinion and CVMP assessment report for the renewal of the Marketing Authorisation of a product falling under Part A of the Annex to Council Regulation (EEC) No. 2309/93.

MRLs	Full Applications	Extensions to further species/ modifications
Opinions adopted at this meeting	0	2

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	37	8	5
New MRL procedures¹	93²	10	7

¹ Applications submitted to the EMEA after 01.01.1995

² Including 13 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Centralised Procedures

The Committee agreed with a decision by the Executive Director agreeing to a fee reduction of 50% in the fee for a company intending to submit an application for a new medicinal product intended for use in a minor species.

Guidelines, SOPs and Position Papers

The Committee adopted the following revised Note for Guidance for release for 3 months consultation:

- Note for Guidance: Acceptability of tradenames for veterinary medicinal products processed through the centralised procedure (EMA/CVMP/328/98 Rev.1-CONSULTATION).

The Committee adopted the following revised SOP:

- Appeals against CVMP Opinions on the establishment of MRLs and provision of detailed Grounds for Appeals (EMA/CVMP/931/00 - FINAL).

The next meeting of the CVMP will be held on 9 - 11 January 2001.

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 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) 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
a) Bismuth subnitrate (extension)	a) Bovine	a) 18.06.99 b) 13.10.99 c) 113 days d) 0	a) 12.11.99 b) 19.06.00 c) OJ No. L 145 of 20.06.00
a) Acetyl isovaleryl tylosin tartrate	a) Porcine	a) 18.10.95 b) 13.10.99 c) 195 days d) 1260 days	a) 12.11.99 b) 19.06.00 c) OJ No. L 145 of 20.06.00
a) Methylprednisolone	a) Bovine	a) 13.07.99 b) 13.10.99 c) 92 days d) 0	a) 12.11.99 b) 19.06.00 c) OJ No. L 145 of 20.06.00
a) Deltamethrin (extension)	a) Fin fish	a) 09.12.99 b) 08.03.00 c) 90 days d) 0	a) 07.04.00 b) 15.09.00 c) OJ No. L234 of 16.09.00
a) Tylosin (extension)	a) Eggs	a) 09.11.99 b) 08.03.00 c) 90 days d) 0	a) 07.04.00 b) 15.09.00 c) OJ No. L234 of 16.09.00
a) Dicyclanil	a) Ovine	a) 25.02.97 b) 08.03.00 c) 281 days d) 825 days	a) 07.04.00 b) 15.09.00 c) OJ No. L234 of 16.09.00
a) Tilimicosin (extension)	a) Rabbit	a) 16.07.99 b) 13.10.99 c) 86 days d) 0	a) 12.11.99 b) 20.10.00 c) OJ No. L269 of 21.10.00
a) Flumequine (extension)	a) Bovine milk & turkey	a) 27.07.99 b) 10.11.99 c) 89 days d) 0	a) 09.12.99 b) 20.10.00 c) OJ No. L269 of 21.10.00
a) Tiamulin (extension)	a) Rabbit	a) 14.10.99 b) 12.01.00 c) 90 days d) 0	a) 11.02.00 b) 20.10.00 c) OJ No. L269 of 21.10.00
a) Dicyclanil (modification)	a) Sheep fat	a) 23.02.00 b) 17.05.00 c) 84 days d) 0	a) 16.06.00 b) 27.10.00 c) OJ No. L276 of 28.10.00

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) Butafosfan (extension)	a) Dairy cattle	a) 19.01.00 b) 19.04.00 c) 90 days d) 0	a) 19.05.00 b) 27.10.00 c) OJ No. L276 of 28.10.00
a) Tilmicosin (extension)	a) Bovine milk	a) 22.02.99 b) 19.04.00 c) 203 days d) 210 days	a) 19.05.00 b) 27.10.00 c) OJ No. L276 of 28.10.00
a) Phoxim (extension)	a) Ovine	a) 19.01.00 b) 19.04.00 c) 90 days d) 0	a) 19.05.00 b) 27.10.00 c) OJ No. L276 of 28.10.00
a) Flumethrin (extension)	a) Ovine	a) 19.01.00 b) 19.04.00 c) 90 days d) 0	a) 19.05.00 b) 27.10.00 c) OJ No. L276 of 28.10.00

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

Status: December 2000

TOTAL 577			
Annex I	Annex II	Annex III	Annex IV
74	440	52	11
Published in the Official Journal of the European Communities: 534			

Veterinary Medicinal Products that have been granted a Community marketing authorisation since 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) 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
a) Dicural b) Difloxacin c) Part B extension	a) Fort Dodge Animal Health b) NL	a) Dogs b) Urinary tract infections and superficial pyoderma	a) Coated tablets b) 15,50,100 and 150 mg c) 12	a) 03.03.98 b) 14.07.99 c) 183 days c) 316 days	a) 13.08.99 b) 29.11.99 c) 01.12.99 d) OJ No. C 375 of 24.12.99
a) Quadrisol b) Vedaprofen c) Part B extension	a) Intervet b) NL	a) Horses b) Relief of pain associated with colic	a) Solution for injection b) 50 mg/ml c) 1	a) 12.11.97 b) 14.07.99 c) 204 days d) 407 days	a) 13.08.99 b) 29.11.99 c) 01.12.99 d) OJ No. C 375 of 24.12.99
a) Ibraxion b) Inactivated vaccine c) Part A	a) Merial b) FR	a) Cattle b) Vaccine against IBR	a) Emulsion for injection	a) 17.11.98 b) 10.11.99 c) 210 days d) 176 days	a) 10.12.99 b) 09.03. 00 c) 10.03. 00 d) OJ No. C 95 of 04.04.2000
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Dogs b) Alleviation of pain and inflammation	a) Oral suspension b) 1.5 mg/ml c) 3	a) 12.01.99 b) 10.11.99 c) 210 days d) 92 days	a) 10.12.99 b) 24.03.00 c) 27.03.00 d) OJ No. C 120 of 28.04.00
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Dogs b) Initiation therapy for alleviation of pain and inflammation	a) Solution for injection b) 5 mg/ml c) 1	a) 12.01.99 b) 10.11.99 c) 210 days d) 92 days	a) 10.12.99 b) 24.03.00 c) 27.03.00 d) OJ No. C 120 of 28.04.00
a) Incurin b) Oestriol c) Part B	a) Intervet b) NL	a) Dogs b) Hormone-dependent urinary incontinence	a) Scored tablets b) 1 mg c) 1	a) 14.07.98 b) 08.12.99 c) 210 days d) 302 days	a) 07.01.00 b) 24.03.00 c) 29.03.00 d) OJ No. C 120 of 28.04.00
a) Rabigen SAG2 b) Live vaccine c) Part A	a) Virbac b) FR	a) Foxes b) Vaccine against rabies	a) Liquid within a blister pack embedded in a bait b) 8 log 10 CCID50 c) 2	a) 23.03.98 b) 08.12.99 c) 196 days d) 428 days	a) 07.01.00 b) 06.04.00 c) 10.04.00 d) OJ No. C 120 of 28.04.00

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) Eurifel FeLV b) Live vaccine c) Part A	a) Merial b) FR	a) Cats b) Vaccine against feline leukaemias	a) Pellet + diluent b) 1 ml c) 3	a) 12.01.99 b) 08.12.99 c) 183 days d) 120 days	a) 07.01.00 b) 13.04.00 c) 18.04.00 d) OJ No. C 120 of 28.04.00
a) Porcilis Pesti b) Inactivated vaccine c) Part A	a) Intervet b) NL	a) Pigs b) Marker vaccine against CSF	a) Water in oil emulsion b) 120 Elisa Units/2ml c) 3	a) 14.07.98 b) 13.10.99 c) 210 days d) 246 days	a) 12.11.99 b) 09.06.00 c) 14.06.00 d) OJ No. C 183 of 30.06.00
a) Ibaflin b) Ibafloracin c) Part B	a) Intervet b) NL	a) Dogs b) Pyoderma	a) Tablet b) 150 & 300mg c) 1	a) 12.01.99 b) 09.02.00 c) 210 days d) 184 days	a) 10.03.00 b) 13.06.00 c) 15.06.00 d) OJ No. C 183 of 30.06.00
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Dogs b) Post-operative pain	a) Solution for injection b) 5mg/ml c) 1	a) 02.01.00 b) 19.04.00 c) 101 days d) 7 days	a) 28.04.00 b) 15.09.00 c) 18.09.00 d) OJ No. C 277 of 29.09.00
a) Econor b) Valnemulin c) Part B extension	a) Novartis b) AT	a) Pigs b) Prevention & treatment of dysentery	a) 0.5% premix b) various c) 2	a) 10.08.99 b) 19.04.00 c) 210 days d) 43 days	a) 19.05.00 b) 15.09.00 c) 20.09.00 d) OJ No. C 308 of 27.10.00
a) Econor b) Valnemulin c) Part B extension	a) Novartis b) AT	a) Pigs b) Prevention /treatment of dysentery and treatment/control of enzootic pneumonia	a) 10%/50% premix b) various c) 2	a) 12.10.99 b) 08.03.00 c) 148 days d) 0	a) 07.04.00 b) 15.09.00 c) 20.09.00 d) OJ No. C 308 of 27.10.00
a) Econor b) Valnemulin c) Part B extension	a) Novartis b) AT	a) Pigs b) Prevention /treatment of dysentery and treatment/control of enzootic pneumonia	a) 10%/50% premix b) various c) 2	a) 12.10.99 b) 08.03.00 c) 148 days d) 0	a) 07.04.00 b) 15.09.00 c) 22.09.00 d) OJ No. C 308 of 27.10.00
a) Dicural b) Difloxacin c) Part B extension	a) Fort Dodge Animal Health b) NL	a) Cattle & Dogs b) Antibacterial for systemic use	a) Solution for injection b) 50 mg/ml c) 3	a) 16.12.98 b) 21.06.00 c) 203 days d) 351 days	a) 21.07.00 b) 24.10.00 c) 25.10.00 d) OJ No. C 337 of 28.11.00

Further information is available on Maximum Residue Limits adopted by the Community and Veterinary Medicinal Products that have been granted a Community Marketing Authorisation in the EMEA General Report 1999 on the Internet at the following address: <http://www.eudra.org/emea.html>