



PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
64th MEETING

Under the Chairmanship of Mr S. Dean the sixty-fourth meeting of the Committee for Veterinary Medicinal Products took place in London on 13-15 March 2001.

MRL Recommendations

The Committee unanimously adopted a positive opinion on the extension of the Annex II entry for a substance to its use in a further species (cattle).

The Committee recommended the inclusion of 2 old substances, having provisional MRLs, in Annex I of Council Regulation (EEC) No. 2377/90 and the extension of the provisional MRL for one of the substances for a different animal species.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	39	10	4
New MRL procedures¹	100²	2	8

¹ Applications submitted to the EMEA after 01.01.1995

² Including 15 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Guidelines, SOPs and Position Papers

The Committee adopted the following CVMP Note for Guidance for release for consultation:

- Note for Guidance for the Conduct of Efficacy Studies for Non-steroidal Anti-inflammatory Drugs (EMA/CVMP/237/01-CONSULTATION)

The Committee adopted the following CPMP/CVMP Note for Guidance with immediate effect:

- Note for Guidance on the Limitations of the use of Ethylene Oxide in Manufacture of Medicinal Products (CPMP/QWP/2845/00; EMA/CVMP/271/01).

This Note for Guidance is scheduled to be adopted by the CPMP at its meeting of 27-29 March 2001. Following the adoption of the guideline by the CPMP the Note for Guidance will be made available on the Website of the EMA.

The Committee held the first meeting of its recently created Strategic Planning Group intended to discuss general organisation issues of the CVMP, define strategic goals/priorities at CVMP, ensure and co-ordinate links between working parties, review CVMP functioning, and encourage better communication with other parties. The composition of the Group is the Chairman, Vice-Chairman, Chairpersons of the working parties, representatives of EMEA Secretariat and CVMP members of the country of EU Presidency as well as those of the country of the previous EU Presidency and the next EU Presidency. The Group is chaired by the Vice-Chairman of the CVMP. The meetings will be held 3-4 times a year in the margins of the CVMP and the next meeting is scheduled for 13 June 2001.

The next meeting of the CVMP will be held on 18-19 April 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 January 2000

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) 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
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) Tilimicosin (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

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) 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
a) Flunixin (extension)	a) Equidae	a) 23.03.00 b) 21.06.00 c) 90 days d) 0	a) 21.07.00 b) 29.12.00 c) OJ No. L336 of 30.12.00
a) Toltrazuril (extension)	a) Porcine	a) 16.02.99 b) 21.06.00 c) 206 days d) 284 days	a) 21.07.00 b) 29.12.00 c) OJ No. L336 of 30.12.00
a) Halofuginone	a) Bovine	a) 10.12.96 b) 21.06.00 c) 281 days d) 1008 days	a) 21.07.00 b) 29.12.00 c) OJ No. L336 of 30.12.00
a) Difloxacin (extension)	a) Bovine, Porcine	a) 14.07.98 b) 21.06.00 c) 205 days d) 503 days	a) 21.07.00 b) 29.12.00 c) OJ No. L336 of 30.12.00

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

Status: January 2001

TOTAL 577			
Annex I	Annex II	Annex III	Annex IV
74	440	52	11
Published in the Official Journal of the European Communities: 535			

Veterinary Medicinal Products that have been granted a Community marketing authorisation since 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) 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
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

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 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
a) Porcilis AR-T-DF b) Inactivated vaccine c) Part A	a) Intervet b) NL	a) Pigs b) Vaccine against atrophic rhinitis	a) Suspension for injection b) 2 ml c) 2	a) 12.01.99 b) 19.07.00 c) 204 days d) 336 days	a) 18.08.00 b) 13.11.00 c) 20.11.00 d) OJ No. C 2 of 05.01.01
a) Poulflox b) Difloxacin c) Part B	a) Virbac S.A. b) FR	a) Poultry b) Antibacterial for systemic use	a) Oral solution b) 100 mg/ml c) 3	a) 09.12.99 b) 21.06.00 c) 152 days d) 43 days	a) 21.07.00 b) 16.11.00 c) 20.11.00 d) OJ No. C 2 of 05.01.01
a) Pruban b) Resocortol butyrate c) Part B	a) Intervet b) NL	a) Dogs b) Anti-inflammatory for cutaneous inflammatory disorders	a) Cream b) 1 mg/ml c) 1	a) 15.09.98 b) 19.07.00 c) 196 days d) 477 days	a) 18.08.00 b) 16.11.00 c) 20.11.00 d) OJ No. C 2 of 05.01.01
a) Pirsue b) Pirlimycin c) Part B	a) Pharmacia b) BE	a) Dairy cattle b) Subclinical mastitis	a) Sterile solution b) 5 mg/ml c) 4	a) 12.01.99 b) 11.10.00 c) 210 days d) 428 days	a) 10.11.00 b) 29.01.01 c) 31.01.01 d) OJ No. C 53 of 20.02.01

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>