



The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines and Inspections

London, 10 January 2002
EMA/CVMP/065/02

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
73rd MEETING

Under the Chairmanship of Mr S. P. Dean the seventy third meeting of the Committee for Veterinary Medicinal Products took place in London on 8 – 10 January 2002.

CVMP Opinions on Medicinal Products

The Committee unanimously adopted a positive opinion and CVMP assessment report for a Type II quality variation with respect to a pharmacological product previously assessed under the centralised procedure.

Establishment of Maximum Residue Limits

The Committee unanimously adopted 3 positive opinions and summary reports on the inclusion of colistin, neomycin and oxyclozanide, which previously had provisional MRLs, in Annex I of Council Regulation (EEC) No. 2377/90.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	41	15	1
New MRL procedures¹	110²	7	8

¹ Applications submitted to the EMA after 01.01.1995

² Including 17 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Availability of Veterinary Medicines

The Committee was pleased to be able to adopt Opinions and Summary Reports recommending the extension of existing MRLs for 12 substances (danofloxacin, difloxacin, enrofloxacin, erythromycin, florfenicol, flumequine, lincomycin, paromomycin, spectinomycin, tilmicosin, trimethoprim, tylosin) to all food-producing animals. Members welcomed this as the first practical example of implementation of measures under the Availability of Medicines initiative. The Committee also adopted a paper explaining the approach for implementation of the Note for Guidance on Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin as a basis for such extrapolations (EMA/CVMP/069/02).

Guidelines, SOPs and Position Papers

The Committee adopted the following final guideline following the close of the consultation period:

- Guideline on Safety Evaluation of Antimicrobial Substances Regarding the Effects on Human Gut Flora (EMEA/CVMP/234/01-FINAL)

Pharmacovigilance issues

Periodic Safety Update Reports (PSURs) on 3 centrally authorised products were considered by the Committee. The Committee concluded that the information available did not create a need for further action or changes to the respective Summary of Product Characteristics (SPC).

International Harmonisation

The Committee considered comments received at the close of the consultation period for VICH draft guideline; topic GL27 on pre-approval information for registration of new veterinary medicinal products for food-producing animals with respect to antimicrobial resistance. Members agreed to defer any final commentary on the VICH guideline pending finalisation of the CVMP revised Guideline on the same topic after completion of its consultation phase in April 2002.

Referrals

The Committee reviewed the status of the ongoing referral under Article 20 of Council Directive 2001/82 in respect of injectable veterinary medicinal products containing benzathine penicillin. The Committee furthermore confirmed that the legislative basis for this referral supports this as a class action referral which applies to all veterinary medicinal products including those authorised nationally in the European Union containing benzathine penicillin.

The next meeting of the CVMP will be held on 12-14 February 2002

Peter G.H. Jones

Head, Veterinary Medicines Evaluation Unit

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<http://www.emea.eu.int>

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

Substance a) INN	Therapeutic area a) Target species	EMEA/CVMP a) Validation b) Opinion c) Active time d) Clockstop	Commission) 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
a) Linear dodecyl benzene sulfonic acid	a) Bovine	a) 22.01.99 b) 19.07.00 c) 195 days d) 321 days	a) 18.08.00 b) 25.04.01 c) OJ No. L118 of 27.04.01
a) Phoxim (extension)	a) Ovine	a) 19.01.00 b) 19.07.00 c) 120 days d) 0	a) 18.08.00 b) 25.04.01 c) OJ No. L118 of 27.04.01
a) Florfenicol (extension)	a) Fin fish	a) 29.10.96 b) 11.10.00 c) 212 days d) 1230 days	a) 08.11.00 b) 29.06.01 c) OJ No. L177 of 30.06.01
a) Meloxicam (extension)	a) Porcine	a) 07.09.00 b) 06.12.00 c) 90 days d) 0	a) 04.01.01 b) 27.06.01 c) OJ No. L175 of 28.06.01
a) Tilimicosin (extension)	a) Turkey	a) 07.09.00 b) 06.12.00 c) 90 days d) 0	a) 04.01.01 b) 27.06.01 c) OJ No. L175 of 28.06.01
a) Doramectin (extension)	a) Reindeer	a) 11.12.97 b) 10.01.01 c) 203 days d) 923 days	a) 09.02.01 b) 18.07.01 c) OJ No. L195 of 19.07.01
a) Rafoxanide	a) Bovine, ovine	a) 11.02.97 b) 10.01.01 c) 193 days d) 1236 days	a) 09.02.01 b) 18.07.01 c) OJ No. L195 of 19.07.01

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) Tiludronate	a) Equine	a) 12.10.00 b) 10.01.01 c) 90 days d) 0	a) 09.02.01 b) 18.07.01 c) OJ No. L195 of 19.07.01
a) Moxidectin (extension)	a) Bovine milk	a) 09.10.00 b) 14.02.01 c) 90 days d) 0	a) 16.03.01 b) 30.07.01 c) OJ No. L205 of 31.07.01
a) Tosychloramide Sodium (extension)	a) Bovine	a) 20.01.00 b) 14.03.01 c) 120 days d) 298 days	a) 06.04.01 b) 22.08.01 c) OJ No. L227 of 23.08.01
a) Bronopol (extension)	a) Salmonidae	a) 15.03.01 b) 13.06.01 c) 90 days d) 0	a) 06.07.01 b) 07.11.01 c) OJ No. L291 of 08.11.01
a) Deltamethrin (extension)	a) Fin fish	a) 09.11.99 b) 13.06.01 c) 177 days d) 404 days	a) 06.07.01 b) 07.11.01 c) OJ No. L291 of 08.11.01

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

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) 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 leukaemia	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

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) 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
a) Bayovac CSF E2 b) Live vaccine c) Part A	a) Bayer b) DE	a) Pigs b) Marker vaccine against classical swine fever	a) Emulsion for injection b) E2 glycoprotein of (CSF) virus c) 4	a) 16.12.98 c) 08.11.00 c) 210 days d) 309 days	a) 29.11.00 b) 02.02.01 c) 06.02.01 d) OJ No. C 53 of 20.02.01
a) Zubrin b) Tepoxalin c) Part B	a) Schering-Plough b) UK	a) Dogs b) Treatment of pain and inflammation	a) Oral lyophilisate b) 30, 50, 100 & 200 mg/ml c) 39	a) 18.05.99 b) 08.11.00 c) 210 days d) 330 days	a) 08.12.00 b) 13.03.01 c) 14.03.01 d) OJ No. C 127 of 27.04.01
a) Eurican Herpes 205 b) Inactivated vaccine c) Part B	a) Merial b) FR	a) Dogs b) Vaccine against canine herpes	a) Powder + solvent for emulsion for injection b) 1 ml c) 2	a) 13.07.99 b) 08.11.00 c) 209 days d) 274 days	a) 08.12.00 b) 26.03.01 c) 29.03.01 d) OJ No. C 127 of 27.04.01
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Cattle b) Diarrhoea / respiratory infections	a) Solution for injection b) 20 mg/ml c) 2	a) 14.09.99 b) 10.01.01 c) 184 days d) 301 days	a) 09.02.01 b) 23.04.01 c) 25.04.01 d) OJ No. C 158 of 31.05.01
a) Virbagen Omega b) Feline interferon c) Part A	a) Virbac S.A. b) FR	a) Dogs b) Reduce mortality and clinical signs of canine parvovirus	a) Solution for injection b) 5MU/ml or 10MU/ml c) 1	a) 21.12.99 b) 11.07.01 c) 210 days d) 358 days	a) 10.08.01 b) 06.11.01 c) 08.11.01 d) OJ No. C 336 of 30.11.01

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 2000 on the Internet at the following address: <http://www.emea.eu.int>.