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

London, 7 December 2001
EMEA/CVMP/1121/01-CORRIGENDUM

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
72nd MEETING

Under the Chairmanship of Mr S. P. Dean the seventy second meeting of the Committee for Veterinary Medicinal Products took place in London on 4 – 6 December 2001.

CVMP Opinions on Medicinal Products

The Committee unanimously adopted a positive opinion and CVMP assessment report for a vaccine against feline rhinotracheitis, feline calicivirus, feline panleucopenia and feline leukaemia, falling under Part A of Annex to Council Regulation EEC No. 2309/93. The Summary of the Opinion will be published forthwith.

The Committee unanimously adopted an opinion and CVMP assessment report recommending the lifting of the suspension of the marketing authorisation for Econor.

The Committee unanimously adopted a positive opinion and CVMP assessment report for the renewal of the marketing authorisation of an immunological product falling under Part A of Annex to Council Regulation EEC No. 2309/93.

Establishment of Maximum Residue Limits

The Committee unanimously adopted a positive opinion and summary report on the inclusion of a substance, 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**	**4**
New MRL procedures[1]	**110**[2]	**7**	**8**

[1] Applications submitted to the EMEA after 01.01.1995
[2] Including 17 Opinions recommending definitive MRLs for substances with previously provisional MRLs

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Guidelines, SOPs and Position Papers

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

- Guideline on Statistical Principles for Veterinary Clinical Trials (EMEA/CVMP/816/00-FINAL)
- Guideline for the Conduct of Efficacy Studies for Non-steroidal Anti-inflammatory Drugs (EMEA/CVMP/237/01-FINAL)

Pharmacovigilance issues

A Periodic Safety Update Report (PSURs) on a centrally authorised product was 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 adopted the CVMP comments on the VICH guidelines currently under consultation regarding:

- Pharmacovigilance of Veterinary Medicinal Product (GL29:Step 4): Management of Periodic Summary Update Reports (PSUs)
- Pharmacovigilance of Veterinary Medicinal Products (GL 30): Controlled list of terms

The comments will be forward to the VICH Secretariat.

The next meeting of the CVMP will be held on 8-10 January 2002

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.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) Tilmicosin (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) 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

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) Tilmicosin (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

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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 leukaemis	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) Ibafloxacin 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) Sterlie 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 parvovirosis	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.