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

London, 6 September 2002
EMEA/CVMP/834/02-Rev.1

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
80th MEETING

Under the Chairmanship of Mr S. P. Dean the eightieth meeting of the Committee for Veterinary Medicinal Products took place in London on 3 – 5 September 2002.

CVMP Opinions on Medicinal Products

The Committee unanimously adopted a positive opinion and CVMP assessment report for SevoFlo, a pharmaceutical product for the induction and maintenance of anaesthesia in dogs.

Establishment of Maximum Residue Limits

The Committee considered the assessment of the responses to the lists of questions further to the establishment of provisional MRLs for two old substances. For permethrin the Committee unanimously adopted a positive opinion and summary report recommending the inclusion in Annex I of Council Regulation (EEC) No. 2377/90. The Committee however could not recommend the inclusion in Annex I for oxolinic acid.

The Committee considered an appeal in respect to the MRL opinion for cefalonium, following the assessment of the responses to the list of questions further to the establishment of provisional MRLs. Having reviewed the ground for appeal, the Committee revised the previous negative opinion and recommended the inclusion of an MRL for cefalonium in bovine milk in Annex I.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**48**	**12**	**8**
New MRL procedures[1]	**119**[2]	**4**	**4**

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

Community Referrals

The Committee heard representations from a number of Marketing Authorisation Holders concerned by the Community Referral regarding long acting formulations of benzathine benzylpenicillin following consultation by CVMP on its preliminary findings of data submitted. The Committee reflected further and will conclude its opinion at the October meeting.

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Guidelines, SOPs and Position Papers

The Committee adopted the revised Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMEA/410/01-Rev2). Pending approval by the CPMP at the September meeting, it will be transmitted to the European Commission, which will start consultation on the document. Thereafter, if there are comments, they will be referred back to the Committees for discussion and final adoption. Thereafter, the Commission will publish the guideline after translation in all Community languages.

The Committee welcomed the recent growth in applications for obtaining scientific advice from CVMP for products under development, and the updating of the support given to companies seeking such advice. The Committee endorsed a Standard Operating Procedure on Scientific Advice to be given by the CVMP for veterinary medicinal products (EMEA/CVMP/458/02) as well as an EMEA guidance document for companies requesting Scientific Advice (EMEA/CVMP/854/02). The SOP replaces the previous SOP on scientific advice.

Pharmacovigilance issues

Periodic Safety Update Reports (PSURs) on 4 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 Summary of Product Characteristics (SPC) of the products.

The Committee endorsed the revised VEDDRA terminology (EMEA/CVMP/413/99-FINAL) following the close of the consultation period. Intensive testing and sharing of experience with interested parties, in particular veterinary pharmaceutical industry, had taken place in the review process. VEDDRA is intended for use in electronic reporting of adverse reactions to veterinary medicines and has been chosen as suitable dictionary of clinical terms by VICH.

Availability of Medicines

The CVMP agreed to further support companies in developing products for indications and/or species where no authorised veterinary medicines are available and facilitate MRL extensions. The CVMP is developing a list of most needed substances for specific species. The Committee intends to review the data available with the objective to extend the existing MRLs, where possible.

International Harmonisation

The Committee appointed Dr C. Ibrahim as a new expert to the VICH Pharmacovigilance Expert Working Group, replacing Dr. A. Kamphuis who has resigned from this position.
Recently, Dr J.-C. Rouby was appointed as a new expert to the VICH Expert Working Group on Biologicals Quality Monitoring, replacing Prof P.-P. Pastoret.

Pharmacovigilance Risk Management Strategy

The Committee considered elements on a Risk Management Strategy for optimising pharmacovigilance for veterinary medicines in the EU, and in particular the possible need for further expertise to advise the Committee and its Working Party in specific disciplines related to the safety of veterinary medicinal products.

The next meeting of the CVMP will be held on 1 – 3 October 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** 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
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

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) 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
a) Methylprednisolone	a) Bovine	a) 13.07.99 b) 11.07.01 c) 177 days d) 535 days	a) 02.08.01 b) 17.01.02 c) OJ No. L16 of 18.01.02
a) Acetylisovaleryltylosin (extension)	a) Porcine	a) 12.04.01 b) 11.07.01 c) 84 days d) 0	a) 03.08.01 b) 17.01.02 c) OJ No. L16 of 18.01.02
a) Abamectin (extension)	a) Ovine	a) 23.04.99 b) 05.12.01 c) 283 days d) 674 days	a) 03.01.02 b) 24.05.02 c) OJ No. L137 of 25.05.02
a) Allantoin	b) All food producing species	a) 12.07.01 b) 10.10.01 c) 90 days d) o	a) 08.11.01 b) 24.05.02 c) OJ No. L137 of 25.05.02
a) Benzocaine (extension)	a) Salmonidae	a) 12.10.00 b) 07.11.01 c) 120 days d) 271 days	a) 29.11.01 b) 24.05.02 c) OJ No. L137 of 25.05.02

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 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

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 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) 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

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) 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
a) Eurifel RCP FelV b) Vaccine c) Part A	a) Mérial b) FR	a) Cats b) Vaccine vs. feline infectious rhinotracheitis, calicivirus, panleukopenia & leukaemia	a) Powder & solvent for emulsion for injection	a) 19.12.00 b) 5.12.01 c) 210 d) 141	a) 04.01.02 b) 08.03.02 c) 12.03.02 d) OJ No C 77 of 28.03.02
a) Metacam b) Meloxicam c) Part B extension	a) Boehringer Ingelheim b) DE	a) Cats b) Alleviation of pain and inflammation	a) Solution for injection b) 5 mg/ml c) 1	a) 13.06. 01 b) 17.04.02 c) 210 days d) 99 days	a) 17.05.02 b) 09.08.02 c) 13.08.02 d) OJ No. C206 of 30.08.02
a) Gallivac HVT IBD b) Live vaccine c) Part A	a) Mérial b) FR	a) Chickens b) Infectious Bursal disease/Marek's disease	a) Frozen suspension solvent b) 3.0 log10 PFU c) 2	a) 12.07.00 b) 17.04.02 c) 210 days d) 436 days	a) 17.05.02 b) 09.08.02 c) 13.08.02 d) OJ No. C206 of 30.08.02

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.