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

London, 15 February 2002
EMEA/CVMP/205/02

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
74th MEETING

Under the Chairmanship of Mr S. P. Dean the seventy fourth meeting of the Committee for Veterinary Medicinal Products took place in London on 12 – 14 February 2002.

CVMP Opinions on Medicinal Products

The Committee unanimously adopted a positive opinion and CVMP assessment report for an extension to an immunological product, namely Porcilis Porcoli, with a change in adjuvant.

Establishment of Maximum Residue Limits

The Committee unanimously adopted 2 positive opinions and summary reports recommending the inclusion of deslorelin acetate and azagly-nafarelin in Annex II of Council Regulation (EEC) No. 2377/90.

The Committee considered appeals in respect to MRL opinions for dihydrostreptomycin and streptomycin following the assessment of the responses to the list of questions further to the establishment of provisional MRLs for these substances. The Committee agreed to amend the previous opinions in light of the grounds for appeal provided and adopted opinions and summary reports recommending the inclusion of dihydrostrepromycin and streptomycin in Annex I of Council Regulation (EEC) No. 2377/90 for all the animal species for which provisional MRLs currently exist.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**41**	**18**	**2**
New MRL procedures[1]	**112**[2]	**9**	**5**

[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 the processing of renewals in the centralised procedure (EMEA/CVMP/695/01-FINAL)
- Guideline on In-Use stability testing of veterinary medicinal products (excluding immunological veterinary products (EMEA/CVMP/424/01-FINAL)

The Committee adopted the following guideline for release for consultation:

- Revised Guideline on the European Drug Master file procedure (EMEA/CVMP/134/02-CONSULTATION)
  This Guideline is scheduled to be adopted by the CPMP at its meeting of 19-21 February 2002. Following the adoption of the guideline by the CPMP, it will be made available on the Website of the EMEA.

The Committee adopted the following Points to Consider for release for consultation:

- Points to consider regarding efficacy requirements for minor species and minor indications (EMEA/CVMP/610/01-CONSULTATION).
  The Committee welcomed this document which is intended to precede a guidance note on a minimal acceptable data package for efficacy of medicines identified for minor species / minor use in pursuance of initiatives on Availability of Medicines.

The Committee adopted the following SOP:

- Revised SOP on Procedure for Management of Periodic Safety Update Reports (PSURs) (CVMP/SOP/692/99-Rev.1)

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).

Regarding another centrally authorised product, the Committee recommended additional precaution statements to be included in the SPC as a result of PSUR and ADR reports, which gave rise to concerns about the safety of the product in one of the target species.

Following requests from certain Member States concerning safety of a nationally authorised product, Baytril, that the CVMP Pharmacovigilance Working Party consider the necessity for a precautionary statement highlighting concerns regarding ocular toxicity at high doses in cats, the Committee recommended that additional precautionary statements be added to the SPC.

The Committee endorsed the publication of a CVMP document describing the procedure on PSURs submission and evaluation for non-marketed products (EMEA/CVMP/227/01-FINAL).

Community Referrals

The CVMP was informed that in regard to the Community Referral concerning long-acting formulations of benzathine penicillin, a number of concerned companies are pursuing a lawsuit against the Commission and the EMEA at the European Court of First Instance.

Organisational Issues

The CVMP agreed the agenda for its next meeting with Interested Parties which is scheduled to be held at the EMEA on Wednesday 13 March 2002 (agenda attached).

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

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) Bovine	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

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

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) 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
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

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) 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
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.

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

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CVMP INTERESTED PARTIES MEETING

AGENDA

Wednesday 13 March 2002
17:00 – 19:00

Room 4B

1. Welcome and Introduction

2. The Work Programme of EMEA for 2002 – Veterinary Unit

3. Availability of Medicines – where are we?

   - Extrapolation of MRLs
   - Reinstatement of claims
   - The cascade renewed or reborn
   - The need for the Task Force again
   - Orphan drug policy

4. Code of Good Veterinary Practice

5. Update on VICH (time permitting)

6. Any Other Business

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