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

London, 14 September 2000
EMEA/CVMP/610/00

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

58th MEETING

Under the Chairmanship of Professor R. Kroker the fifty-eighth meeting of the Committee for Veterinary Medicinal Products took place in London on 12 - 14 September 2000.

CVMP Opinions

The Committee adopted a negative opinion for a substance previously having a provisional MRL due to an inadequate response to the list of questions

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**34**	**11**	**5**
New MRL procedures[1]	**89**[2]	**9**	**7**

[1] Applications submitted to the EMEA after 1.1.1995
[2] Including 13 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Guidelines, SOPs and Position Papers

The Committee adopted the following Position Papers:

- Position Paper on how to proceed with specific obligations and follow-up measures for the management of the Marketing Authorisation (EMEA/CVMP/543/00)
- Position Paper on Submission schedule for periodic safety update reports for centrally authorised veterinary medicinal products (EMEA/CVMP/605/00)
- Position Paper on Renewals of Marketing Authorisations for centrally authorised products and Contents of the application dossier for renewals of Marketing Authorisations for centrally authorised medicinal products (EMEA/CVMP/507/00-FINAL)

The Committee adopted the glossary of terms to be appended to the following VICH Note for Guidance that was released for 6 months consultation in July 2000:

- GL23 Safety studies for veterinary drug residues in human food: genotoxicity testing (CVMP/VICH/526/00-CONSULTATION)

Antimicrobial Resistance

The Committee completed its review of the OIE World Wide Public Consultation on Antimicrobial Resistance and confirmed its general support for the approach and proposals in the guideline, and agreed its consolidated response (EMEA/CVMP/707/00).

The next meeting of the CVMP will be held on 10 - 12 October 2000.

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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 December 1999

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) Abamectin (extension)	a) Ovine	a) 23.04.99 b) 18.08.99 c) 115 days d) 0	a) 31.08.99 b) 20.12.99 c) OJ No. L 328 of 22.12.99
a) Doramectin (extension)	a) Reindeer	a) 11.12.97 b) 14.07.99 c) 203 days d) 377 days	a) 12.08.99 b) 20.12.99 c) OJ No. L 328 of 22.12.99
a) Rafoxanide	a) Bovine & Ovine	a) 11.02.97 b) 14.07.99 c) 193 days d) 690 days	a) 12.08.99 b) 20.12.99 c) OJ No. L 328 of 22.12.99
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

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

Status: September 2000

TOTAL 577			
Annex I	Annex II	Annex III	Annex IV
74	440	52	11
Published in the Official Journal of the European Communities: **508**			

Veterinary Medicinal Products that have been granted a Community marketing authorisation since December 1999

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) Stronghold b) UK-124,114 c) Part B	a) Pfizer b) UK	a) Dogs & Cats b) Endectocide	a) Topical solution b) 6%w/v, 12%w/v c) 5	a) 17.11.98 b) 14.07.99 c) 183 days d) 56 days	a) 13.08.99 b) 25.11.99 c) 03.12.99 d) OJ No. C 375 of 24.12.99
a) Oxyglobin b) Haemoglobin c) Part B	a) Biopure Corporation b) USA	a) Dogs b) Anaemia	a) Intravenous infusion b) 130mg/ml c) 1	a) 12.05.98 b) 14.07.99 c) 210 days d) 218 days	a) 13.08.99 b) 29.11.99 c) 01.12.99 d) OJ No. C 375 of 24.12.99
a) Dicural b) Difloxacin c) Part B extension	a) Fort Dodge Animal Health b) NL	a) Dogs b) Urinary tract infections and superficial pyoderma	a) Coated tablets b) 15,50,100 and 150 mg c) 12	a) 03.03.98 b) 14.07.99 c) 183 days c) 316 days	a) 13.08.99 b) 29.11.99 c) 01.12.99 d) OJ No. C 375 of 24.12.99
a) Quadrisol b) Vedaprofen c) Part B extension	a) Intervet b) NL	a) Horses b) Relief of pain associated with colic	a) Solution for injection b) 50 mg/ml c) 1	a) 12.11.97 b) 14.07.99 c) 204 days d) 407 days	a) 13.08.99 b) 29.11.99 c) 01.12.99 d) OJ No. C 375 of 24.12.99
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

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

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