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

London, 22 June 2000
EMEA/CVMP/461/00

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

56th MEETING

Under the Chairmanship of Professor R. Kroker the fifty-sixth meeting of the Committee for Veterinary Medicinal Products took place in London on 20 – 22 June 2000.

CVMP Opinions

The Committee unanimously adopted two positive opinions and CVMP assessment reports both falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93; one for an antibacterial product indicated for oral use in poultry and the other for an extension to an antibacterial product authorised under the centralised procedure indicated for systemic use in cattle and dogs.

MRLs	Full Applications	Extensions to further species/ Modifications
Opinions adopted at this meeting	**1**	**4**[1]

[1] One of which was a negative opinion

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**32**	**11**	**5**
New MRL procedures[2]	**87**[3]	**6**	**7**

[2] Applications submitted to the EMEA after 1.1.1995
[3] including 12 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Guidelines, SOPs

The Committee adopted the following Notes for Guidance following the close of the consultation period:

- Note for Guidance on stability testing of biotechnological/biological veterinary medicinal products (CVMP/VICH/501/99)
- Note for Guidance on impurities: residual solvents (CVMP/VICH/502/99)

The next meeting of the CVMP will be held on 18 – 20 July 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

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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: June 2000

TOTAL 572			
Annex I	Annex II	Annex III	Annex IV
69	440	52	11
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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
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) 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

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