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

London, 18 May 2000
EMEA/CVMP/373/00

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

55th MEETING

Under the Chairmanship of Professor R. Kroker the fifty-fifth meeting of the Committee for Veterinary Medicinal Products took place in London on 16 – 18 May 2000.

CVMP Opinions

The Committee unanimously adopted a positive opinion and CVMP assessment report for a vaccine falling under Part A of the Annex to Council Regulation (EEC) No. 2309/93 against Classical Swine Fever.

The Committee considered two appeals in respect of MRL Opinions. For 1 substance the Committee upheld the previous decision and for 1 other substance the Committee amended its conclusions considering the explanations provided by the applicant.

MRLs	New Substances	New Substances: Extensions to further species/ Modifications	"Old" Substances
Opinions adopted at this meeting	**--**	**1**	**--**

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**30**	**13**	**5**
New MRL procedures*	**82****	**12**	**7**

* Applications submitted to the EMEA after 1.1.1995
** including 12 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Classification of oral immunological products

At the request of the Commission, the classification of products containing immunological substances given orally to animals was considered. The Committee's opinion was that such products are medicinal products in accordance with the definition provided in Article 1 of Council Directive 65/65/EEC. However, the Committee also agreed that natural colostrum would not be considered a medicinal product.

Availability of Medicines - Risk Assessment for MRLs

The Committee adopted the following Note for Guidance:

- Risk analysis approach for residues of veterinary medicinal products in food of animal origin (EMEA/CVMP/187/00-CONSULTATION) with a consultation period until 1 October 2000.

The next meeting of the CVMP will be held on 20 – 22 June 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 1.1.1995

(Status: May 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) 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

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

(Status: May 2000)

TOTAL 563			
Annex I	Annex II	Annex III	Annex IV
68	432	52	11
Published in the Official Journal of the European Communities: **496**			

Veterinary Medicinal Products that have been granted a Community marketing authorisation under the centralised procedure

(Status: May 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) 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 c) 316	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 d) 407	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 d) 176	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 d) 302	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 d) 428	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 d) 120	a) 07.01.00 b) 13.04.00 c) 18.04.00 d) OJ No. C 120 of 28.04.00

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