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

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EMEA/CVMP/298/00

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

54th MEETING

Under the Chairmanship of Professor R. Kroker the fifty-fourth meeting of the Committee for Veterinary Medicinal Products took place in London on 18-19 April 2000.

CVMP Opinions

The Committee unanimously adopted positive opinions and CVMP assessment reports for two extensions to products authorised under the centralised procedure falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93; one being an antibiotic indicated for treatment and prevention of swine dysentery in pigs; the other indicated for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and the reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery in dogs.

MRLs	New Substances	New Substances: Extensions to further species/ Modifications	"Old" Substances
Opinions adopted at this meeting	**--**	**4**	**--**

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	**29**	**14**	**6**
New MRL procedures*	**81****	**11**	**6**

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

Guidelines, SOPs

The Committee adopted the following Guideline following the close of the consultation period:

- Guideline for the conduct of post-marketing surveillance studies of veterinary medicinal products (EMEA/CVMP/044/99-FINAL).

The next meeting of the CVMP will be held on 16 - 18 May 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 1.1.1995

(Status: April 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: April 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: April 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) 09.03.2000 c) 10.03.2000 d) OJ No. C 95 of 04.04.2000

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