



PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
60th MEETING

Under the Chairmanship of Professor R. Kroker the sixtieth meeting of the Committee for Veterinary Medicinal Products took place in London on 7 – 9 November 2000.

CVMP Opinions

The Committee unanimously adopted positive opinions and CVMP assessment reports for two products falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93; one being a vaccine and indicated for the active immunisation of bitches to prevent mortality, clinical signs and lesions in puppies resulting from herpes canine virus infections and the other for the reduction of inflammation and relief of pain caused by acute musculoskeletal disorders or acute exacerbation of chronic musculoskeletal disorders in dogs.

The Committee unanimously adopted positive opinions and CVMP assessment reports for two Type II variations for a product previously authorised under the centralised procedure.

MRLs	Full Applications	Extensions to further species/ modifications
Opinions adopted at this meeting	1¹	1²

¹ Negative opinion

² Recommending the extension of the provisional MRL

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	37	8	5
New MRL procedures³	91⁴	11	7

³ Applications submitted to the EMEA after 1.1.1995

⁴ Including 13 Opinions recommending definitive MRLs for substances with previously provisional MRLs

Guidelines, SOPs and Position Papers

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

- Note for Guidance: Stability testing of existing active substances and related finished products (EMA/CVMP/846/99 - FINAL).
- Note for Guidance: Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats (EMA/CVMP/005/00 - FINAL).

The Committee adopted the following Note for Guidance for release for 6 months consultation:

- Note for Guidance: Statistical principles for veterinary clinical trials (EMA/CVMP/816/00 - CONSULTATION).

VICH

The Committee reviewed its position on a number of priority topics currently under consideration at VICH prior to the forthcoming Steering Committee meeting in Washington.

The next meeting of the CVMP will be held on 5 - 7 December 2000.

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.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
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) Dicyclanil (modification)	a) Ovine	a) 23.02.00 b) 17.05.00 c) 84 days d) 0	a) 16.06.00 b) 15.09.00 c) OJ No. L234 of 16.09.00

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

Status: November 2000

TOTAL 577			
Annex I	Annex II	Annex III	Annex IV
74	440	52	11
Published in the Official Journal of the European Communities: 514			

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 leukaemias	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

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>