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

London, 14 March 2003
EMEA/CVMP/272/03

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 11 to 13 March 2003

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a type II variation for **Eurifel FeLV** regarding reduction of minimum vaccine titre.

Maximum Residue Limits

The Committee adopted by consensus a negative opinion for the establishment of final maximum residue limits for morantel. The maximum residue limits previously established for the substance have provisional status, which will expire on 1 July 2003. The applicant may appeal against the CVMP opinion.

For further details please see the Summary opinion available on the EMEA web site: http://www.emea.eu.int

Post-authorisations issues

The Committee discussed issues related to the Sampling and Testing programme for centralised products and supported the organisation of a seminar in September 2003 involving assessors, OMCL laboratories, inspectors and members of the EMEA scientific committees.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) on several products and concluded that no further action or changes to the product literature of the products were required.

In the context of the discussion on the PSURs the Committee confirmed that sales figures from third countries are required where adverse reactions (ADRs) are reported.

International harmonisation

The Committee undertook an in depth review of draft VICH guidelines on consumer safety and environmental risk assessment (Phase II) and consolidated the EU position in preparation for input into the forthcoming Expert Working Group meetings on these two topics.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eu.int http://www.emea.eu.int

Organisational Issues

The Committee was informed of the progress made in the organisation of the first DIA international veterinary conference to be held in Nice from 22 to 24 October 2003 (see attached).

The next meeting of the CVMP will be held on 8-10 April 2003

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.emea.eu.int

Marketing Authorisations

	1995-2002	2003	Overall Total
Applications submitted	50	1	51
Withdrawals	8	1	9
Positive CVMP opinions	38	0	38
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2002	2003	Overall Total
Variations type I	98	11	109
Variations type II	37	3	40

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	1	34
Withdrawals	1	0	1
Positive opinions	15	2	17
Negative opinions	0	0	0

[1] In case of appeal the opinion will not be counted twice

Renewals of marketing authorisations

	1995-2002	2003	Overall Total
Renewal applications submitted	7	1	8
Renewal positive opinions	5	2	7
Renewal negative opinions	0	0	0

Scientific advice

	1995-2002	2003	Overall Total
Applications submitted	20	1	21

Establishment of maximum residue limits

	1995-2002			2003			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	50	73	123	0	1	0	124
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	0	1	0	116
Negative opinions**	5	5	10	0	0	0	10

*Including 16 opinions recommending definitive MRLs for substances with previously provisional maximum residue limits

**Including 2 opinions (1 full, 1 extension) concluding that final maximum residue limits could not be established for substances with provisional maximum residue limits previously established

Referrals

	1995-2002	2003	Overall Total
Referrals	8	0	8