European Medicines Agency
Veterinary Medicines and Inspections

London, 8 September 2004
EMEA/CVMP/834/04

PRESS RELEASE

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Meeting of 6 to 7 September 2004

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for a type II variation for Nobivac Bb regarding the addition of a production site for the active substance.

The Committee adopted by consensus a positive opinion for a type II variation for Nobilis IB4/91 regarding the waiving of the routine application of the batch safety test.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the modification of the current Annex II entry of Council Regulation (EEC) No. 2377/90 for ammonium and sodium salts of bituminosulfonates. The recommendation is to remove the exemption of use in animals producing milk for human consumption so that the Annex II entry applies now to all mammalian food producing species, without restrictions. The application procedure was initiated on 11 June 2004 and an opinion recommending the modification of the Annex II entry was adopted on 7 September 2004 with an active review time of 88 days.

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

Renewals of Marketing Authorisations

The Committee adopted by consensus three positive opinions for the renewals of the marketing authorisations for Halocur, Oxyglobin and Stronghold. The Committee concluded that the quality, safety and efficacy of the products continued to be appropriately demonstrated and, therefore, recommended the renewals of the marketing authorisations.

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Community Referrals

The Committee concluded the evaluation of the referral initiated by the United Kingdom under Article 34 of Council Directive 2001/82/EC regarding the nationally authorised product Dectomax 1% injectable solution (doramectin). The referral had been initiated in order to harmonise the different withdrawal periods established by Member States for the product and the Committee adopted by consensus an opinion recommending a withdrawal period of 70 days following intramuscular administration. With regard to subcutaneous administration the Committee concluded that the data available did not allow for a withdrawal period to be established following that route of administration and therefore references to administration by this route should be removed from the product literature.

An appeal against this opinion may be launched by the companies concerned within the deadlines provided by legislation.

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) for Nobivac Bb, Rabigen SAG2 and Zubrin, and concluded that no further action or changes to the product literature of the products were required.

Availability of veterinary medicines

Further to the request from the European Commission to propose a draft in order to establish a list of substances essential for the treatment of horses in accordance with Article 10(3) of Directive 2001/82/EC, as amended, the Committee agreed on a working document comprising a first draft list of essential substances. This document is intended to be further discussed with experts from FVE and EAVPT during a meeting that will be convened for that purpose in the margins of the October CVMP meeting.

Organisational issues

Following the discussions at the June and July 2004 meetings on the specific additional scientific expertise required the Committee concluded during the July 2004 meeting that 5 co-opted members would be appointed in order to complement the existing expertise of the CVMP. Now the Committee agreed the preferable profile of the co-opted members. The required expertise is as follows:

- one expert in quality aspects of biotechnology products;
- two experts in clinical medicine: one for companion animals and one for large animals, at least one of whom should ideally have experience in statistics;
- one expert in clinical medicine in intensive production;
- one expert on safety and risk assessment.

The next meeting of the CVMP will be held on 12-14 October 2004

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This press release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

Marketing Authorisations

	1995-2003	2004	Overall Total
Applications submitted	60	7	67
Withdrawals	9	1	10
Positive CVMP opinions	42	4	46
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2003	2004	Overall Total
Variations type I	146	13	159
Variations type II	49	6	55
Transfers	4	1	5

Extensions

	1995-2003	2004	Overall Total
Extensions (Annex II applications) submitted	35	5	40
Withdrawals	1	0	1
Positive opinions	21	1	22
Negative opinions	0	0	0

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

Renewals of marketing authorisations

	1995-2003	2004	Overall Total
Renewal applications submitted	11	3	14
Renewal positive opinions	9	5	14
Renewal negative opinions	0	0	0

Scientific advice

	1995-2003	2004	Overall Total
Applications submitted	22	4	26

Establishment of maximum residue limits

	1995-2003			2004			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	52	81	133	4	6	10	143
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	37	86	123	7	4	11	134
Negative opinions**	5	5	10	1	0	1	11

*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

	1995-2003	2004	Overall Total
Referrals	8	2	10