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

London, 14 November 2003
EMEA/CVMP/1042/03

PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 11 to 13 November 2003

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus the following opinions:

- A positive opinion for a Type II variation for **Econor** concerning a change in the particle size of the finished product for the 50 % presentation.
- A positive opinion for a Type II variation for **Nobilis IB4-91** concerning the removal of the contra-indication for layers and breeder chickens.
- A positive opinion for a Type II variation for **Nobivac Bb** concerning an increase in the maximum release titre of the product.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the extension of the existing maximum residue limits for **nafcillin** to all ruminants. The application procedure was initiated on 10 June 2002 and the opinion was adopted on 13 November 2003 with an active review time of 115 days.

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

International Harmonisation

The Committee was informed of the recent meeting of VICH Pharmacovigilance EWG, which took place in Washington DC on 13-17 October 2003 and expressed its disappointment at the outcome of the meeting as not much progress was achieved towards harmonisation of pharmacovigilance for veterinary medicines.

The Committee will, together with the Commission, review the possibilities remaining for such harmonisation in preparation of the next Steering Committee meeting at which a decision on future activities of few Experts Working Groups are anticipated.

The Committee discussed the draft VICH guideline GL27 on Pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to Antimicrobial resistance, which has been presented to the VICH Steering Committee for sign-off. The CVMP decision on this draft guideline is envisaged for the December 2003 meeting.

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

Quality

The Committee adopted a concept paper on the revision of the guideline on plastic primary packaging materials (EMEA/CVMP/1028/03).

The document is available on the EMEA web site: http://www.emea.eu.int

Training of Assessors

The Committee was informed of the final preparations for two training sessions for assessors organised by the EMEA in collaboration with the competent national authorities. Training on Safety and Residue Testing and Establishment of MRLs will take place on 26 and 27 November and will focus on assessment of consumer safety, establishment of MRLs, determination of withdrawal periods and evaluation of analytical methods. Training on Efficacy will take place on 8 December 2003 and will address dossier evaluation, use and interpretation of guidelines with particular focus on the statistical guideline, dose determination studies and case studies on bioequivalence and dose determination.

Organisational issues

The Committee agreed the meeting dates for 2006 (*See attachment*).

EMEA-IFAH Europe Info day

Following the CVMP meeting an Info day was held to address with Interested Parties the minor uses minor species (MUMS) policy and the implementation of the guidelines on antimicrobial resistance.

The next meeting of the CVMP will be held on 9-11 December 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

CVMP MEETING DATES FOR 2006

January	**17 – 19**
February	**14 – 16**
March	**14 – 16**
April	**18 – 20**
May	**16 – 18**
June	**20 – 22**
July	**18 – 20**
August	**15 – 17**
September	**12 – 14**
October	**10 – 12**
November	**7 – 9**
December	**12 – 14**

Marketing Authorisations

	1995-2002	2003	Overall Total
Applications submitted	50	8	58
Withdrawals	8	1	9
Positive CVMP opinions	38	2	40
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2002	2003	Overall Total
Variations type I	98	47	145
Variations type II	37	10	47

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	2	35
Withdrawals	1	0	1
Positive opinions	15	5	20
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	2	9
Renewal positive opinions	5	4	9
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	1	7	8	131
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	1	5	6	121
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	7	1	8