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

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PRESS RELEASE

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 16 to 17 September 2003

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus a positive opinion for an extension to **Ibaflin** tablets for dogs. This extension concerns the addition of two new tablet strengths, 30mg and 900mg tablets, to the previously authorised 150mg and 300mg tablets. Ibaflin tablets, which were first authorised on 13 June 2000, contain ibafloxacin, a fluorinated 4-quinolone, which is a broad spectrum antibiotic with bactericidal action against Gram-positive and Gram-negative bacteria.

Renewals of Marketing Authorisations

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Suvaxyn Aujeszky 783 O/W** (EU/2/98/009/001-006). The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisation.

Maximum Residue Limits

The Committee adopted by consensus a positive opinion recommending the establishment of maximum residue limits in accordance with Council Regulation (EEC) No 2377/90, as amended for **diclofenac** (cattle and pigs). The application procedure was initiated on 5 July 2002 and the opinion was adopted on 17 September 2003 with an active review time of 119 days.

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

International Harmonisation

The Committee welcomed the progress made by the VICH Expert Working Group on Ecotoxicity/Environmental Impact assessment. The draft VICH guideline on environmental impact assessment-Phase II is now scheduled for adoption for public consultation at the forthcoming VICH Steering Committee meeting in October.

Public

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Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSUR) for **Ibaflin**, **Eurifel RCP FeLV , Porcilis Pesti, Vibragen Omega, Sevoflo,** and **Econor** and concluded that no changes to the product literature or other regulatory actions were required.

The Committee also revised the Periodic Safety Update Report (PSUR) for **Zubrin** and concluded that, in view of the pharmacovigilance data available, the current warning under section 5.4 (Undesirable effects) of the Summary of Product Characteristics (SPC) should be amended in order to provide more information on the occurrence of adverse reactions, in an attempt to reduce their incidence.

Organisational issues

The Committee endorsed the work programmes 2004-2005 for the CVMP Efficacy, Safety, Immunological and Pharmacovigilance Working Parties, having previously adopted the work programme for the Quality Working Party at the July 2003 CVMP meeting. The work programmes will be summarised in the EMEA Work Programme to be published later this year and will be the subject of a Focus Group meeting with the Interested Parties of the CVMP in February 2004 at the Agency.

The Committee's Strategic Planning Group held one of its quarterly meetings at which a number of key issues were discussed, including future CVMP strategy concerning antimicrobial resistance, future actions concerning the evaluation of the resistance to fluoroquinolones, involvement/contribution of Members to CVMP business, review of the timetable for scientific advice and preparation of the informal CVMP meeting to be held in Rome on 24-25 November 2003.

The next meeting of the CVMP will be held on 14-16 October 2003

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

Annex I to CVMP Press Release September 2003

Marketing Authorisations

	1995-2002	2003	Overall Total
Applications submitted	50	5	55
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	41	139
Variations type II	37	10	47

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	1	34
Withdrawals	1	0	1
Positive opinions	15	4	19
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	5	10
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	6	7	130
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	1	4	5	120
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