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

London, 14 February 2003
EMEA/CVMP/195/03

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 11 to 13 February 2003

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus two positive opinions for two type II variations for **Oxyglobin** and **Clomicalm**, both regarding several quality aspects. The Committee also adopted by consensus a positive opinion for a type I variation following a type II procedure for **Nobivac Bb** for a change in the manufacturer of the product.

Maximum Residue Limits

The Committee adopted an opinion recommending the extrapolation of the current MRL for **emamectin** in **Salmonidae** to **fin fish** further to a request from a company. This recommendation was made in accordance with the review of the risk assessment approach for the establishment of maximum residue limits with the aim of establishing a more pragmatic approach in securing the provision of medicines for treating animals, especially those classed as minor species.

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 two positive opinions for the renewal of the marketing authorisations for **Clomicalm (*clomipramine*)** and **Neocolipor (*E. coli inactivated vaccine*)**. The Committee concluded that the quality, safety and efficacy of the products continued to be appropriately demonstrated and, therefore, recommended the renewal of the marketing authorisations.

Guidelines, SOPs and Position Papers

The Committee adopted a revised guideline for the **conduct of efficacy studies for intramammary products for use in cattle**, prepared by the Efficacy working Party, in order to provide further clarification to point 5.4 of the guideline with respect to dry cow treatment (EMEA/CVMP/344/99-FINAL-Rev.1)

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

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The Committee adopted the following guidelines prepared by the Joint CPMP/CVMP Quality Working Party, following the close of the consultation period:

- Note for Guidance on the **Use of Near InfraRed Spectroscopy by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations**
- Note for Guidance on the **Declaration of Storage Conditions**

The publication of the documents on the EMEA web site (http://www.emea.eu.int) will follow their final adoption by the CPMP at the February meeting (18-20 February 2003).

The Committee adopted for release for a 3-month period of consultation a guideline on **Data elements for the electronic submission of adverse reaction reports related to veterinary medicinal products authorised in the EEA, including message and transmission specifications** (EMEA/CVMP/065/03) prepared by the EudraVigilance Telematics Implementation Group (TIG). This guideline is required for the transition from reporting of adverse reactions to veterinary medicinal products on paper forms to electronic transmission of this information. It defines how the data should be structured to transmit information that can be analysed and it describes the technical requirements for electronic transmission.

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

Pharmacovigilance

The Committee reviewed Periodic Safety Update Reports (PSURs) on **Suvaxyn Aujeszky 783 + O/W**, **Virbagen Omega**, **Halocur**, **Oxyglobin** and **Zubrin** and concluded that the information available did not create a need for further action or changes to the product literature of the products.

The Committee endorsed a **common EU pharmacovigilance reporting form for Marketing Authorisation Holders**, following the close of the consultation period (EMEA/CVMP/601/02-FINAL). This form will serve as the standardised paper reporting form for Marketing Authorisation Holders as mentioned in Volume 9 in 'Pharmacovigilance of Veterinary Medicinal Products – Notice to Marketing Authorisation Holders' (based on the CVMP Note for Guidance Pharmacovigilance of Veterinary Medicinal Products – EMEA/CVMP/183/96-FINAL) point 5.3.10.

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

The next meeting of the CVMP will be held on 11-13 March 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 February 2003

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	10	108
Variations type II	37	1	38

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	0	33
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	0	7
Renewal positive opinions	5	2	7
Renewal negative opinions	0	0	0

Scientific advice

	1995-2002	2003	Overall Total
Applications submitted	20	0	20

Establishment of maximum residue limits

	1995-2002			2003			Overall Total
	Full	**Extension/ Modification**	**Total**	**Full**	**Extension/ Modification**	**Total**	
Applications submitted	50	73	123	0	0	0	123
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