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

London, 15 November 2002
EMEA/CVMP/1111/02

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 12 to 14 November 2002

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by consensus two positive opinions on initial marketing authorisation applications for **PROTEQFLU** and **PROTEQFLU-Te, *recombinant Canarypox virus vaccines*** from Mérial. The products are intended respectively to provide active immunisation against equine influenza and equine influenza together with tetanus in horses. Review of the applications was initiated on 14 November 2001 and the opinions adopted on 13 November 2002 with an active review time of 210 days.

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

The Committee adopted by consensus five positive opinions for five type II variations for **Suvaxyn Aujeszky**, **Fevaxyn Pentofel**, **Eurican Herpes 205**, **Eurifel RCP FeLV** and **Ibraxion** regarding compliance with the required standardised safety warning for veterinary medicinal products containing mineral oils with regard to the operator safety.

Renewals of Marketing Authorisations

The Committee adopted by consensus two positive opinions for the renewal of the marketing authorisations for **Dicural (*Difloxacin*)** and **Metacam (*Meloxicam*)**. 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.

Scientific Advice

The Committee agreed scientific advice for two procedures. The first concerned preclinical and clinical development for a diuretic product intended for treatment of aldosterone effects in dogs with congestive heart failure and the second concerned injection site residue studies for a long–acting endectocidal product.

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Maximum Residue Limits

The Committee adopted by consensus a positive opinion and summary report recommending the inclusion in Annex I of Council Regulation (EEC) No. 2377/90 for **bacitracin *in rabbits***. The evaluation of the application was submitted on 19 August 2002 and the opinion adopted on 13 October 2002 with an active review time of 87 days.

Considering the review of the risk assessment approach for the establishment of maximum residue limits with a view to establishing a more pragmatic approach in securing the provision of medicines for treating animals especially to those classed as minor species, whilst at the same time guaranteeing consumer safety and further to the recommendation for extrapolation of existing maximum residues limits to all food producing species for 12 substances in January 2002, the Committee adopted an opinion and summary report recommending the extension of the current Annex II entry for **sulphur** to **all food producing species** further to a company request.

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

Community Referrals

Referral under Article 20 of Directive 81/851/EEC (now Article 35 of Directive 2001/82/EEC)

The Committee noted the notifications for appeal against the opinion regarding long acting injectable veterinary medicinal products containing **benzathine benzylpenicillin**, adopted by the Committee during the October 2002 meeting and appointed a rapporteur for the appeal. The decision on the appeal procedure is foreseen for the January 2002 meeting.

Guidelines, SOPs and Position Papers

The Committee adopted a Position Paper on **Establishment of MRLs for milk in relation to the daily intake by children** (EMEA/CVMP/391/02-FINAL).

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

The Committee adopted a concept paper for the development of a guideline by the Quality Working Party on the quality aspects of pharmaceutical veterinary medicines administered via drinking water (EMEA/CVMP/1055/02).

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

Pharmacovigilance issues

The Committee reviewed Periodic Safety Update Reports (PSURs) on **Nobilis IB-4 91**, **Porcilis AR-T DF**, **Porcilis Pesti**, **Econor** and **Pirsue** 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 agreed CVMP proposals to promote and improve pharmacovigilance reporting and to strengthen the EU pharmacovigilance system for veterinary medicinal products based on the recommendations of the Joint EMEA/FEDESA/FVE Workshop on the EU Pharmacovigilance system meeting in Madrid, Spain, on 27-28 May 2002. The proposals will be submitted to the Heads of European Veterinary Regulatory Authorities (HEVRA) for agreement and implementation.

International Harmonisation

The Committee adopted the following VICH guidelines following the close of the consultation period:

- VICH GL28: Safety of Veterinary Drugs in Human Food: **Carcinogenicity Testing** (CVMP/VICH/645/01-FINAL)
- VICH GL31: Safety of Veterinary Drugs in Human Food: **Repeat-Dose (90 days) Toxicity Testing** (CVMP/VICH/484/02-FINAL)
- VICH GL32: Safety of Veterinary Drugs in Human Food: **Developmental Toxicity Testing** (CVMP/VICH/485/02-FINAL)
- VICH GL33: Safety of Veterinary Drugs in Human Food: **General approach to testing** (CVMP/VICH/486/02-FINAL)

The guidelines will come into effect by 1 October 2003

The documents are available on the EMEA web site: http://www.emea.eu.int

The next meeting of the CVMP will be held on 10-12 December 2002

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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

	1995-2001	2002	Overall Total
Applications submitted	47	3	50
Withdrawals	7	1	8
Positive CVMP opinions	30	7	37
Negative CVMP opinions[1]	0	0	0

Variations

	1995-2001	2002	Overall Total
Variations type I	84	14	98
Variations type II	25	8	33

Extensions

	1995-2001	2002	Overall Total
Extensions (Annex II applications) submitted	26	7	33
Withdrawals	0	1	1
Positive opinions	11	3	14
Negative opinions	0	0	0

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

Renewals of marketing authorisations

	1995-2001	2002	Overall Total
Renewal applications submitted	2	3	5
Renewal positive opinions	2	3	5
Renewal negative opinions	0	0	0

Scientific advice

	1995-2001	2002	Overall Total
Applications submitted	16	4	20

Establishment of maximum residue limits

	1995-2001			2002			Overall Total
	Full	Extension/ Modification	Total	Full	Extension/ Modification	Total	
Applications submitted	47	66	113	3	7	10	123
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	31	73	114	5	6	11	125
Negative opinions**	5	5	10	0	0	0	10

*Including 15 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

	1995-2001	2002	Overall Total
Referrals	5	3	8