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

London, 25 July 2003
EMEA/CVMP/689/03

PRESS RELEASE
COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Meeting of 22 to 24 July 2003

CVMP Opinions on Veterinary Medicinal Products

The Committee adopted by majority a positive opinion on the granting of a Community marketing authorisation for **Draxxin** (***Tulathromycin***) from Pfizer Limited. The product is an antimicrobial indicated for treatment and prevention of bovine respiratory disease and treatment of swine respiratory disease. The application procedure was initiated on 16 October 2002 and the opinion was adopted on 23 July 2003 with an active review time of 182 days.

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

The Committee adopted by consensus a positive opinion for a Type I variation following a Type II procedure for **Eurican Herpes 205** relating to a change in test procedures of the vaccine. The Committee also adopted by consensus a Type II variation for **Eurifel RCP FeLV** relating to a reduction in the minimum titre of the vaccine.

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 **imidocarb** for sheep. The application procedure was initiated on 25 April 2003 and the opinion was adopted on 23 July 2003 with an active review time of 90 days.

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 **cefquinome** for horses. The application procedure was initiated on 25 April 2003 and the opinion was adopted on 23 July 2003 with an active review time of 90 days.

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

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Community Referrals

The Committee considered a referral from a Member State under article 34 of Council Directive 2001/82/EC regarding withdrawal periods established for one product authorised nationally in 14 Member States and appointed a rapporteur and a co-rapporteur for the procedure. A list of questions to be sent to the Marketing Authorisation Holders to be responded to within 4 months was agreed.

Pharmacovigilance

The Committee reviewed a Periodic Safety Update Report (PSUR) for **Eurifel FeLV** and concluded that no changes to the product literature or other regulatory actions was required.

Upon a request for clarification, the Committee confirmed that the warning regarding **mineral-oil containing products** as included in the revised guideline on preparation of Summary of Product Characteristics SPC – Immunologicals (Volume 6c of The Rules Governing Medicinal Products in the European Union) would in principle also apply to pharmaceutical products containing mineral oils.

The Committee adopted the guideline **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-FINAL) having considered the comments received during the consultation period. This guideline is an important step for the implementation of electronic adverse reaction reporting in veterinary medicine and is a major step forward in the development of **Eudravigilance** (EU electronic data management system for pharmacovigilance) for veterinary medicinal products.

In this context the Committee noted the release for testing of EudraVigilance Veterinary version 2.0. The website (http://erstest.emea.eu.int/vet/) consists of an introductory section that is open to everyone and a restricted section for registered users only, which at present is only available to National Competent Authorities after registration.

The Committee also adopted the **List of Species and Breeds** for electronic reporting of adverse reactions in veterinary pharmacovigilance, prepared by the Pharmacovigilance Working Party (EMEA/CVMP/553/03-CONSULTATION). The list is being released for a 6-month consultation period.

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

Efficacy

The Committee adopted a new guideline on **Specific Efficacy Requirements for Ectoparasiticides in cattle** prepared by the Efficacy Working Party (EMEA/CVMP/625/03-CONSULTATION). The guideline is now being released for consultation until January 2004.

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

Quality

The Committee adopted a new guideline on the **Declaration of Storage Conditions**: A) in the product information of pharmaceutical veterinary medicinal products, B) for active substances (Annex to Notes for Guidance on Stability Testing of New Veterinary Drug Substances and Medicinal Products, and Stability Testing of Existing Active Substances and Related Finished Products) prepared by the Quality Working Party (EMEA/CVMP/422/99-Rev.1-FINAL). The Human version was adopted at the April 2003 CPMP meeting with the same implementation date of October 2003.

The Committee adopted a new guideline on the **Quality of Modified Release Dosage Forms for Veterinary Use** prepared by the Quality Working Party (EMEA/CVMP/680/02-FINAL) with an implementation date of 1 February 2004.

The Committee adopted for release for a 6-month period of consultation, a new guideline on the **Quality Aspects of Pharmaceutical Veterinary Medicines for Administration via Drinking Water** prepared by the Quality Working Party (EMEA/CVMP/540/03-CONSULTATION). The guideline is now being released for consultation until the end of January 2004.

The Committee adopted for release for a 6-month period of consultation, a new guideline on the **Chemistry of New Active Substances** prepared by the Quality Working Party (EMEA/CVMP/541/03-CONSULTATION). The Human version was adopted at the February 2003 CPMP meeting. The guideline is now being released for consultation until the end of January 2004.

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

International harmonisation

The Committee were informed on the **Safety Workshop** which took place on 23-24 June 2003 in London in the context of PERF III activities in preparation of the EU enlargement. The workshop focussed on remaining issues regarding consumer safety of veterinary medicines and environmental risk assessment. The Committee were also informed about the preparations for the **PERF III Veterinary Conference** to be held in **Warsaw** from **24-26 September** (http://perf.eudra.org/perf3/PDFs/confrnce/Flyer-Vets.pdf). Topics to be covered will include the process of accession, effects of the single market, compliance with the *Acquis communautaire*, procedures and phasing-in, progress reports with recommendations from Priority Action Areas (Quality, Safety, Efficacy and Pharmacovigilance), pan-european as well as global issues facing the EU and finally availability of veterinary medicines.

The Committee revised a **Concept Paper** for the proposed new **VICH** priority topic on metabolism and residue kinetics further to comments received from other regions in VICH for discussion at the next VICH Steering Committee meeting.

The Committee received a report from Prof. E. Marques Fontes, Chairman of the 9th Conference of the European Association of Veterinary Pharmacology and Toxicology held in Lisbon 13-18 July 2003 and welcomed the EMEA's invitation to this learned society to join the Interested Parties of the CVMP.

The next meeting of the CVMP will be held on 16-18 September 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 July 2003

Marketing Authorisations

	1995-2002	2003	Overall Total
Applications submitted	50	3	53
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	26	124
Variations type II	37	5	42

Extensions

	1995-2002	2003	Overall Total
Extensions (Annex II applications) submitted	33	1	34
Withdrawals	1	0	1
Positive opinions	15	3	18
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	0	4	4	127
Withdrawals	5	4	9	0	0	0	9
Positive opinions*	36	79	115	0	4	5	119
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