The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

EMEA/CVMP/021/96
London, 7 February 1996

PRESS RELEASE

9th MEETING OF THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Under the Chairmanship of Prof. R. Kroker, the ninth meeting of the Committee for Veterinary Medicinal Products (CVMP) took place in London on 6-7 February 1996.

The Committee welcomed a new member from Finland Mrs. Satu Pyörälä, who is associate professor at the University of Helsinki in the Department of Clinical Sciences. She will replace Mrs. E. Koskinen.

The Committee appointed a rapporteur and a co-rapporteur for two new centralised applications for the granting of a Community marketing authorisation: one for an adjuvanted bacterial vaccine containing recombinant strains and falling within the scope of part A of the Annex to Council Regulation (EEC) No 2309/93, and one for a non-steroidal anti-inflammatory drug to be used in food-producing animals falling within the scope of part B of the Annex to Council Regulation (EEC) No 2309/93.

The Committee reviewed and accepted the scientific advice regarding the specific genomic stability of a recombinant virus vector for a particular product which is to be the subject of a future application through the centralised procedure.

The Committee discussed draft phase I and phase II guidelines on environmental risk assessment for veterinary medicinal products. Review of the phase I guideline was completed and it will be released for consultation within three months in conjunction with the phase II guideline which is to undergo further review.

Regarding the establishment of maximum residue limits and the inclusion of substances used in food-producing animals in one of the annexes of Council Regulation (EEC) No 2377/90, the Committee made the following recommendations for applications received before 1.1.95 and transfered from the European Commission to the Agency:

	Annex I	Annex II	Annex III	Annex IV
New substances (Article 6)			1	
Old substances (Article 7)		5	1	

The Committee also considered two assessment reports on applications for new substances (Article 6) received by the Agency since 1.1.95 for the establishment of Maximum Residue Limits (MRLs). In both cases, the Committee adopted a list of questions to be addressed by the applicants.

Rapporteurs and co-rapporteurs were appointed for the establishment of MRLs for 2 new substances.

The Committee also agreeed that immunoglobulines and lipoic acid should be included in the list of those substances not falling within the scope of Council Regulation (EEC) No 2377/90.

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In response to various enquiries from industry, the Committee decided that the route of administration and the therapeutic dose are considered important in the establishment of an MRL and are therefore to be retained as an integral item in the summary of the assessment report.

The Committee supported the Commission's agreement to the participation of the European Union with Japan, and the USA, in the Veterinary International Conference on Harmonisation (VICH) initiative.

The Multilingual Glossary of Technical and Medical Popular Terms prepared by the Heymans Institute of Pharmacology of the University of Ghent for the European Commission was presented to the members. For companies preparing applications to the EMEA under the centralised procedure, this glossary can be consulted on Internet at the following address:

http://allserv.rug.ac.be/~rvdstich/eugloss/welcome.html

The next meeting of the Committee will be held on 20-21 March 1996.

General information about EMEA and EPAR (European Public Assessment Report) for centrally approved human products are now available on Internet at the following address:

WWW.EUDRA.ORG