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

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PRESS RELEASE

8th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

Under the Chairmanship of Prof. R. Kroker, the eigth meeting of the Committee for Veterinary Medicinal Products (CVMP) took place in London on 13-15 December 1995.

The Committee observed a one minute silence in memory of Dr. N. Gyrd-Hansen who died recently after a long illness. Dr. C. Willadsen has been nominated as new member of the Committee.

The Committee appointed a rapporteur and a co-rapporteur for a new centralised application for the granting of a Community marketing authorisation for a NSAID; and agreed the timetable for the assessment of another application for a fluoroquinolone antibiotic. Both applications are for products to be used in food-producing animals.

A total of 2 applications (one list A and one list B) has now been received in 1995 by the EMEA for the granting of a Community marketing authorisation. In addition, 1 intention of submission (list B) has been notified for early 1996.

The Committee agreed on and adopted a procedure for co-ordinating foreign and community pre-authorisation inspections during assessment of applications submitted to the EMEA.

The Committee discussed and agreed to release for a 6-month consultation period the two following guidelines:

- Quality of prolonged and controlled release dosage forms for veterinary use (EMEA/CVMP/094/95)
- Additional quality requirements for products intended for incorporation into animal feedingstuffs (medicated premixes) (EMEA/CVMP/080/95)

In addition the Committee adopted a guideline on the manufacture of finished dosage form (EMEA/CVMP/126/95).

Regarding the establishment of maximum residue limits and the inclusion of substance used in food-producing animals in one of the annexes of Council Regulation (EEC) No 2377/90, the Committee made the following recommendations:

	Annex I	Annex II	Annex III	Annex IV
Article 6	1		1	
Article 7		6	1+1 extension of provisional MRL	1

Rapporteurs and co-rapporteurs were appointed for the establishment of MRLs for 4 new substances.

A total of 10 new applications was received in 1995 by the EMEA for the establishment or extension of MRLs. In addition, 10 intentions of submission have been notified for early 1996.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel: (+44-171) 418 84 00 Fax: (+44-171) 418 84 16

The Committee held an additional session to review its procedures relating to the business of the Committee and its working parties

The next meeting of the Committee will be held on 6-7 February 1996.

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

- E-mail: mail@emea.eudra.org;
- Internet: www.eudra.org.

LIST OF PARTICIPANTS

Chairman :	KROKER Reinhard
Belgium	FALIZE Francoise
Danmark :	KRISTENSEN Birgitte WILLADSEN Claus PEDERSEN Anita (European expert)
Deutschland :	MOOS Manfred EGLIT Sabine
Ellas :	ELEZOGLOU Vassilios MIGOS Dimitrios
Espana :	CORBALAN Luis SOBRINO Odon
France :	BOISSEAU Jacques
Ireland :	BEECHINOR Gabriel O'SULLIVAN Cyril
Italia :	CONTI Gabriella MACRI Agostino
Nederland :	HEKMAN Peter LENSING Herman
Luxembourg	WIRTOR Marc
Osterreich :	DICHTL Johannes OBERMAYR Eugen
Portugal :	PRATAS Margarida BELO Jose
Suomi :	KAARTINEN Liisa
Sverige :	LUTHMAN Jan MALMQUIST Margareta
United Kingdom :	WOODWARD Kevin RUTTER Michael OLIVER Heather (European expert) RENSHAW Derek (European expert)

EMEA :	SAUER Fernand JONES Peter CHORAINE Pierre DUARTE Isaura FAIRCHILD Steve McFFATT Anna
European Commission :	ROSTEL-PETERS Barbara