The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

18th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Prof. R. Kroker the eighteenth meeting of the Committee for Veterinary Medicinal Products took place in London on 11-12 February 1997.

CENTRALISED PROCEDURES

2. The Committee noted that a second Community marketing authorisation for a veterinary medicinal product had been granted by the European Commission on 5 February 1997. This marketing authorisation has been granted to Fort Dodge Laboratories for Pentofel, a pentavalent vaccine for cats, which stimulates the development of active immunity against Feline Panleukopenia Virus, Feline Rhinotracheitis Virus, Feline Calicivirus, Feline *Chlamydia psittaci* and Feline Leukaemia Virus.

3. The Committee discussed the draft assessment reports prepared by the rapporteurs and the co-rapporteurs on applications received by the Agency for the granting of marketing authorisations for three vaccines for food-producing animals falling under the scope of part A and B to the Annex of Council Regulation (EEC) No 2309/93. The Committee agreed on lists of questions to be sent to the applicants.

4. The Committee appointed a rapporteur and a co-rapporteur for one new application for the granting of a Community marketing authorisation for an immunological product developed by biotechnological means as listed under part A of the Annex of Council Regulation (EEC) No 2309/93.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	2	10	3
MRL procedures*	12	24	9

* Applications submitted to the EMEA after 1.1.1995

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee recommended that the MRLs of two substances already classified in Annex I be extended to additional species.

6. The Committee adopted a status report and a list of questions in consideration of an other application for the establishment of MRLs for a new substance.

7. The Committee adopted two recommendations concerning two substances for which provisional MRLs are due to expire shortly.

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8. In response to a request from the European Commission, the Committee re-affirmed its agreement to the criteria previously established for entering substances in Annex II of Council Regulation (EEC) No 2377/90.

NOTES FOR GUIDANCE AND SOPs

9. The Committee endorsed a Note for Guidance on the Variation Assessment Report (VAR) for veterinary medicinal products in the centralised and mutual recognition procedures (EMEA/CVMP/014/97).

10. The Committee adopted two SOPs (EMEA/CVMP/036/97 and EMEA/CVMP/037/93) on the procedures to be followed by applicants for fulfilling their obligations under Council Directive 90/220/EEC on the deliberate release into the environment of products containing or consisting of genetically modified organisms.

11. The Committee agreed that its Efficacy WP should be re-convened to review existing efficacy guidelines with a view to updating them in the light of scientific progress and where necessary to prepare new ones.

12. The Committee having considered the matter in-depth, agreed to appoint an ad hoc group of experts to assess the impact of antimicrobial use in veterinary medicine on the possible development of antimicrobial resistance in animals and the potential for transfer of resistance to man. Subsequently, the Committee will consider a risk management policy to address whatever problems are identified by the ad hoc group.

13. The next meeting of the Committee will be held on 11-13 March 1997.

General information about EMEA, Guidelines, SOPs, EPAR (European Public Assessment Report) of veterinary medicinal products which have been granted a Community marketing authorisation and summary reports of substances for which Maximum Residue Limits have been established by the Community are available on Internet and E-mail at the following addresses:

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