The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

23rd MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Prof. R. Kroker the twenty-third meeting of the Committee for Veterinary Medicinal Products took place in London on 15-17 July 1997.

2. The Committee welcomed Professor Christian Friis who replaces Dr. Claus Willadsen. Professor Friis is a veterinarian teaching toxicology at the Royal Veterinary and Agricultural University of Copenhagen. He is also head of the Laboratory of Toxicology of the Department of Pharmacology and Pathobiology.

3. The Committee also welcomed Mr John O'Brien in replacement of Mrs Jill Ashley-Smith. Mr John O'Brien is a pharmacist from the Veterinary Medicines Directorate (UK) where he is licensing manager for pharmaceuticals and feed-additives.

CENTRALISED PROCEDURES

4. The Committee agreed to recommend the granting of a Community marketing authorisation for a new non steroidal anti-inflamatory drug (NSAID) for use in food-producing animals and falling under the scope of part B to the Annex of Council Regulation (EEC) No 2309/93.

5. The Committee also agreed to recommend the granting of a Community marketing authorisation for another NSAID also intended for food-producing animals and falling under the scope of part B to the Annex of Council Regulation (EEC) No 2309/93.

6. An applicant for the granting of a Community marketing authorisation for a veterinary medicinal product intended for companion animals provided oral explanations to the Committee in preparation of its answers to the list of questions adopted by the Committee earlier this year.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	5	8	2
MRL procedures*	18	26	5

* Applications submitted to the EMEA after 1.1.1995

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ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

7. The Committee recommended the inclusion of two new substances into Annex III of Council Regulation (EEC) No 2377/90 on the establishment of MRLs and adopted status reports and lists of questions for two other new substances under evaluation.

8. The Committee also recommended the inclusion of four old substances into Annex II of Council Regulation (EEC) No 2377/90 and adopted the status reports and lists of questions concerning nine other old substances.

9. The Committee recommended the extension of the provisional MRLs expiring at 1.1.1998 for two substances, in order to allow for completion of the studies in progress.

10. Rapporteurs were appointed for two applications for the extension of existing MRLs to include new target species.

11. The Committee finalised the assessment for two old substances and concluded that no MRLs could be recommended on the basis of the data provided.

12. Further to the request of the applicant, the Committee reconsidered its previous recommendation to include an old substance into Annex IV. After consideration of the objections by the applicant, the Committee confirmed however its previous conclusions.

NOTES FOR GUIDANCE AND SOPs

13. The Committee took note that the Secretariat did not release for consultation the Note for Guidance on *the establishment of MRLs in Salmonidae* as the text adopted required further expansion. The Committee consequently agreed to revise the document prior to its release after a future meeting.

14. The Committee agreed to release for consultation two position papers on *Batch potency testing of immunological veterinary medicinal products* (CVMP/IWP/038/97) and on *premixes for medicated feeding stuffs for veterinary use versus powders/granules for oral use in drinking water* (EMEA/CVMP/199/97). There follows a consultation period of 6 months for both papers.

15. Having reviewed comments received from interested parties, the Committee adopted three new Notes for Guidance on *Harmonisation of Requirements for Equine Influenza Vaccines* (EMEA/CVMP/116/96), on the *Inclusion of Antioxidants and Antimicrobial Preservatives in Medicinal Products* (CPMP/QWP/115/95) and on *Pharmacovigilance of Veterinary Medicinal Products* (EMEA/CVMP/183/96). These notes shall come into operation on 1 January 1998.

16. The Committee agreed on a list of Notes for Guidance to be revised/drafted as a priority by its reconvened Efficacy Working Party (EMEA/CVMP/228/97), which is scheduled to meet in September.

ANY OTHER BUSINESS

17. In advance of the VICH 2nd Steering Committee to be held in Paris in August 97, the Committee reviewed the priority topics for the second phase and undertook preparatory discussions.

18. The next meeting of the Committee will be held on 9-11 September 1997.

Maximum Residue Limits adopted by the Community since 1.1.1997

(Status: July 1997)

Substance a) INN	**Therapeutic area** a) Target species	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Sent to Commission b) Date of the regulation c) OJ No.
a) Eprinomectin	a) Bovine	a) 22.02.96 b) 25.06.96 c) 108 days d) 0	a) 26.07.96 b) 08.01.97 c) OJ No. L 5 of 09.01.97
a) Doramectin (modification)	a) Bovine	a) 14.05.96 b) 24.07.96 c) 70 days d) 0	a) 23.08.96 b) 14.02.97 c) OJ No. L 45 of 15.02.97
a) Praziquantel	a) Ovine	a) 03.08.95 b) 18.09.96 c) 187 days d) 152 days	a) 16.10.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Moxidectin (modification)	a) Bovine and Ovine	a) 12.06.96 b) 18.09.96 c) 97 days d) 0	a) 16.10.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Difloxacin (modification)	a) Chicken, Turkeys	a) 10.07.96 b) 23.10.96 c) 104 days d) 0	a) 19.11.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Ivermectin (extension)	a) Deer	a) 20.08.96 b) 11.12.96 c) 86 days d) 0	a) 09.01.97 b) 23.04.97 c) OJ No. L 106 of 24.04.97

Veterinary Medicinal Products which have been granted a Community marketing authorisation under the centralised procedure

(Status: July 1997)

Product a) Brandname b) INN c) List A/B	**Company** a) Name b) Origin	**Therapeutic area** a) Target species b) Indication	**Presentation** a) Form b) Dosage c) No. of presentations	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Opinion received b) Decision c) Notification d) OJ No.
a) Nobi-vac-Porcoli b) Inactivated vaccine c) List A	a) Intervet International b) NL	a) Piglets b) Neonatal colibacillosis	a) Solution for injection b) Multidose c) 2	a) 01.01.95 b) 27.07.95 c) 107 days d) 94 days	a) 24.08.95 b) 29.02.96 c) 04.03.96 d) OJ No. C/96 of 29.03.96
a) Pentofel b) Vaccine c) List A	a) Fort Dodge Laboratories b) IRL	a) Cats b) Rhinotracheitis	a) Solution for injection b) Monodose c) 3	a) 16.06.95 b) 18.09.96 c) 208 days d) 235 days	a) 17.10.96 b) 05.02.97 c) 06.02.97 d) OJ No. C/63 of 28.02.97