The European Agency for the Evaluation of Medicinal Products

London, 11 September 1997
EMEA/CVMP/301/97

PRESS RELEASE

24th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Prof. R. Kroker the twenty-fourth meeting of the Committee for Veterinary Medicinal Products took place in London on 9 - 11 September 1997.

CENTRALISED PROCEDURES

2. The Committee decided to invite an applicant for the granting of a Community marketing authorisation for a veterinary medicinal product intended for food-producing animals to provide oral explanations to the Committee on outstanding issues before the Committee delivers its opinion.

3. The Committee endorsed two requests for eligibility for the centralised procedure for companion animal products under Part B of the Annex to Council Regulation (EEC) No. 2309/93.

4. A Rapporteur was appointed to co-ordinate the response to a request for scientific advice for a candidate for Part B of the Annex to Council Regulation (EEC) No. 2309/93.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee recommended the inclusion of one new substance into Annex I (for milk) and Annex II (for other tissues) of Council Regulation (EEC) No 2377/90 and adopted status reports and lists of questions for three other new substances under evaluation.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	5	8	2
MRL procedures*	19	23	5

* Applications submitted to the EMEA after 1.1.1995

6. The Committee also recommended the inclusion of two old substances, with previous provisional MRLs, into Annex I and of four old substances into Annex II of Council Regulation (EEC) No 2377/90. The Committee recommended the extension of provisional MRLs for one old substance whilst awaiting further data from the Applicant.

7. Another old substance was considered as not falling within the scope of Council Regulation (EEC) No. 2377/90.

8. A Rapporteur and Co-Rapporteur were appointed for an application for the establishment of MRLs for a new substance.

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NOTES FOR GUIDANCE AND SOPs

9. The Committee adopted a Standard Operating Procedure on the Appeal and Provision of Explanations in Support of Objections to CVMP Recommendations on the Establishment of MRLs and agreed to release it for consultation for a 3 month period.

10. The Committee adopted, prior to release for consultation, a revised Note for Guidance on the Establishment of MRLs for *salmonidae* and other fin fish.

11. The Committee agreed to release for consultation, for 6 months, a position paper on the need for compliance of veterinary vaccines with monographs of the European Pharmacopoeia.

12. The Committee took note of the comments from the CPMP Biotechnological Working Party on Transmissible Spongiform Encephalopathies in the light of the recent Commission Decision (97/534/EEC) and agreed to take these comments into consideration at the end of the consultation period for the CVMP Guideline on BSE (1 October 1997).

ANY OTHER BUSINESS

13. Further to the 2nd VICH Steering Committee meeting held in Paris in August 1997, the Committee nominated a Topic Leader and an Expert for the two topics to be considered by the Pharmacovigilance Expert Working Group

14. The next meeting of the Committee will be held on 14 - 16 October 1997.

15. The Committee agreed the future work plan for the reconvened CVMP Efficacy Working Party to be chaired by Dr L Kaartinen, Member from Finland.

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.

Maximum Residue Limits adopted by the Community since 1.1.1997

(Status: September 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: September 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