The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE

20th MEETING OF THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Prof. R. Kroker the twentieth meeting of the Committee for Veterinary Medicinal Products took place in London on 8-10 April 1997.

CENTRALISED PROCEDURES

2. The Committee discussed the draft assessment report prepared by the rapporteur and the co-rapporteur on an application received by the Agency for the granting of a Community marketing authorisation for a veterinary medicinal product intended for food-producing animals and containing a new active substance. The Committee agreed on a list of questions to be sent to the applicant.

SCIENTIFIC ADVICE

3. The Committee appointed a co-ordinator to review the request from a company for scientific advice on the design of specific metabolism studies to be carried out in fish and for which no guidance was available.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

4. The Committee adopted a status report and list of questions in consideration of two applications for the establishment of MRLs for new substances.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	2	10	3
MRL procedures*	13	25	9

* Applications submitted to the EMEA after 1.1.1995

5. The Committee appointed rapporteurs and co-rapporteurs for two new applications for the establishment of maximum residue limits, for which a letter of intent had been received.

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6. Regarding the establishment of maximum residue limits for applications received prior to 1 January 1995 by the European Commission and transferred to the Agency, the Committee made the following recommendations:

	Annex I	Annex II	Annex III	Annex IV
New Substances (Article 6)	2	-	-	-
Old Substances (Article 7)	1	2	1	-

Two of the recommendations for inclusion into Annex I concern substances for which provisional MRLs had been previously established.

7. In addition, the status reports and the accompanying consolidated lists of questions to the applicant were adopted for 4 old substances.

8. The Committee considered a request for a fee waiver for an application for the establishment of MRLs for an antibiotic substance intended for use in bees. As the substance is to be used in a minor species for which there is no other substance available for the indication proposed, the Committee agreed to recommend to the EMEA Executive Director the granting of a fee waiver.

9. In its on-going review of data requirements for the establishment of MRLs in minor species, the Committee received advice on drug metabolism and residue depletion in fish from a European expert invited to the meeting.

10. In response to a request from the European Commission, the Committee finalised the list of data requirements to establish clinical MRLs.

NOTES FOR GUIDANCE AND SOPs

11. Liisa Kaartinen was unanimously elected chairperson of the newly constituted Efficacy working party. The working party will undertake the revision of certain guidelines in light of technical advances and experience of use, and also the development of new guidelines on subjects yet to be addressed.

12. The Committee adopted a position paper on *the definition of substances capable of pharmacological action in the context of Council Directive 81/851/EEC with particular reference to excipients* (EMEA/CVMP/072/97)

13. The Committee adopted a position paper on *Selection of target tissues for the establishment of MRLs* (EMEA/CVMP/029/97).

14. The next meeting of the Committee will be held on 6-7 May 1997.

15. The Committee took note of the first meeting of the Veterinary Mutual Recognition Facilitation (VMRF) group chaired by Mr. S. Dean. Future meetings will take place around CVMP meetings.

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: April 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) 18.03.97[1] c) to be published
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) 18.03.97[1] c) to be published
a) Difloxacin (modification)	a) Chicken, Turkeys	a) 10.07.96 b) 23.10.96 c) 104 days d) 0	a) 19.11.96 b) 18.03.97[1] c) to be published
a) Ivermectin (extension)	a) Deer	a) 20.08.96 b) 11.12.96 c) 86 days d) 0	a) 09.01.97 b) 18.03.97[1] c) to be published

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

(Status: April 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

[1] Date of the meeting of the Standing Committee on Veterinary Medicinal Products on which the decision was taken.