The European Agency for the Evaluation of Medicinal Products

London, 8 May 1997
EMEA/CVMP/170/97

PRESS RELEASE

21st MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Prof. R. Kroker the twenty-first meeting of the Committee for Veterinary Medicinal Products took place in London on 6-7 May 1997.

CENTRALISED PROCEDURES

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

3. The Committee also agreed to invite another applicant to provide written or oral explanations and consequently to stop the clock.

SCIENTIFIC ADVICE

4. The Committee adopted its response to 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 (see attached document EMEA/CVMP/159/97).

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

5. The Committee recommended the inclusion of two new substances into Annex II and III of Council Regulation (EEC) No 2377/90 on the establishment of MRLs.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	2	9	3
MRL procedures*	15	25	7

* Applications submitted to the EMEA after 1.1.1995

6. The Committee also adopted the status reports and lists of questions concerning three applications for the modification and extension to additional target species of existing MRLs.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Switchboard: (+44-171) 418 8400 Fax: (+44-171) 418 8551
E_Mail: mail@emea.eudra.org http://www.eudra.org/w3/emea.html

7. At a previous meeting, the Committee had been unable to recommend the establishment of final MRLs for an old substance for which the provisional MRLs were due to expire. At the request of the applicant, the Committee reviewed again the data submitted in support of the application and agreed to revise its previous recommendation and to propose the inclusion of the substance into Annex I.

8. Members also reconsidered another substance, for which the applicant had objected to the Committee's recommendation not to set final MRLs. The Committee concluded that the explanations provided by the company did not justify a change to the previous recommendation and was unable to establish final MRLs on the basis that no physico-chemical residue detection method had been provided by the company in accordance with the requirements of Volume VI of the Rules governing Medicinal Products in the European Union.

NOTES FOR GUIDANCE AND SOPs

9. The Committee agreed the principles of two new Notes for Guidance on *the establishment of MRLs in minor species* and on *the establishment of MRLs in Salmonidae*. These should be adopted at the next meeting of the Committee and then released to interested parties for consultation.

10. The Committee agreed to release for consultation a Revision of its Note for Guidance for *Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Veterinary Medicinal Products* (EMEA/CVMP/145/97).

11. The Committee also agreed that the EMEA Contribution on Chapter IV of the Notice to Applicant on the Centralised Procedure should be sent to the European Commission, which is preparing a revised version of the Notice to Applicants.

12. The next meeting of the Committee will be held on 10-12 June 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.

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) 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) 18.03.97[1] 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) 18.03.97[1] 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) 18.03.97[1] 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: 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.

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

EMEA/CVMP/159/97-**FINAL**

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SCIENTIFIC ADVICE

Conduct of radio-labelled metabolism and residue studies in fish

On 11 February 1997, a company requested scientific advice on the conduct of radio-labelled metabolism and residue studies in salmon, pursuant to article 51 (j) of Council Regulation (EEC) No 2309/93.

The future applicant proposed to carry out a repeated-dose study using unlabelled substance for the first 13 days followed by radio-labelled substance for the 14th day. The tissues would then be analysed using both liquid scintillation counting (to determine total residues) and HPLC (to measure marker residue).

The Committee considered that the proposed study design would not lead to a reliable value for the ratio of total:marker residue, because the HPLC assay, using an UV or fluorescence detection method, would measure not only the amount administered on day 14 but also any substance administered on the previous 13 days which had not been eliminated.

Instead, the Committee recommended a single-dose study to determine the ratio of marker to total residue.

The Committee also recommended that, for the purpose of getting a marketing authorisation, marker residues studies be carried out with the proprietary product, according to the proposed regime, in order to determine the withdrawal period for that product.