The European Agency for the Evaluation of Medicinal Products

London, 13 June 1997
EMEA/CVMP/203/97

# PRESS RELEASE

## 22nd MEETING
## OF
## THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Prof. R. Kroker the twenty-second meeting of the Committee for Veterinary Medicinal Products took place in London on 10-12 June 1997.

### CENTRALISED PROCEDURES

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

3. 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.

4. The Committee also discussed the joint assessment report prepared by the rapporteur and the co-rapporteur on the answers provided by the applicant to the Committee's list of questions concerning an other application for the granting of a Community marketing authorisation.

5. The Committee took note of the first variation accepted by the Agency in respect of the marketing authorisation granted to Pentofel, a feline pentavalent inactivated vaccine authorised by the Community on 5 February 1997.

### ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

6. The Committee recommended the inclusion of one new substances into Annex III of Council Regulation (EEC) No 2377/90 on the establishment of MRLs and adopted a status report and a list of questions for an other new substances under evaluation.

| | Opinions delivered since 1.1.1995 | Applications under evaluation | Applications anticipated within the next 4 months |
|---|---|---|---|
| Centralised procedures | 3 | 10 | 1 |
| MRL procedures* | 16 | 25 | 5 |

* Applications submitted to the EMEA after 1.1.1995

7. 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 twelve other old substances.

8. A rapporteur was appointed for an application for the extension of existing MRLs to include a new target species.

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**NOTES FOR GUIDANCE AND SOPs**

9. The Committee agreed to release for consultation two new Notes for Guidance on *the establishment of MRLs in minor species* and on *the establishment of MRLs in Salmonidae*.

10. Having reviewed comments received from interested parties, the Committee adopted a new Note for Guidance on the *Investigation of Chiral Substances* (EMEA/CVMP/128/95) to come into operation on 1 January 1998.

**ANY OTHER BUSINESS**

11. The Committee took note of the proposed 3rd EMEA/FEDESA InfoDay to be held at the EMEA on 12 September 1997.

12. The Committee adopted its meeting dates for 1998 (see attached).

13. The next meeting of the Committee will be held on 15-17 July 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: June 1997)

| **Substance**<br>a) INN | **Therapeutic area**<br>a) Target species | **EMEA/CVMP**<br>a) Validation<br>b) Opinion<br>c) Active time<br>d) Clockstop | **Commission**<br>a) Sent to Commission<br>b) Date of the regulation<br>c) OJ No. |
|---|---|---|---|
| a) Eprinomectin | a) Bovine | a) 22.02.96<br>b) 25.06.96<br>c) 108 days<br>d) 0 | a) 26.07.96<br>b) 08.01.97<br>c) OJ No. L 5 of 09.01.97 |
| a) Doramectin (modification) | a) Bovine | a) 14.05.96<br>b) 24.07.96<br>c) 70 days<br>d) 0 | a) 23.08.96<br>b) 14.02.97<br>c) OJ No. L 45 of 15.02.97 |
| a) Praziquantel | a) Ovine | a) 03.08.95<br>b) 18.09.96<br>c) 187 days<br>d) 152 days | a) 16.10.96<br>b) 18.03.97[1]<br>c) OJ No. L 110 of 26.04.97 |
| a) Moxidectin (modification) | a) Bovine and Ovine | a) 12.06.96<br>b) 18.09.96<br>c) 97 days<br>d) 0 | a) 16.10.96<br>b) 18.03.97[1]<br>c) OJ No. L 110 of 26.04.97 |
| a) Difloxacin (modification) | a) Chicken, Turkeys | a) 10.07.96<br>b) 23.10.96<br>c) 104 days<br>d) 0 | a) 19.11.96<br>b) 18.03.97[1]<br>c) OJ No. L 110 of 26.04.97 |
| a) Ivermectin (extension) | a) Deer | a) 20.08.96<br>b) 11.12.96<br>c) 86 days<br>d) 0 | a) 09.01.97<br>b) 18.03.97[1]<br>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: June 1997)

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

EMEA/CVMP/187/97-**FINAL**

# COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

## 1998 Meeting Dates

| | |
|---|---|
| **January** | 13-14-15 |
| **February** | 10-11-12 |
| **March** | 10-11-12 |
| **April** | 7-8 |
| **May** | 5-6-7 |
| **June** | 9-10-11 |
| **July** | 7-8-9 |
| **August** | ---- |
| **September** | 8-9-10 |
| **October** | 13-14-15 |
| **November** | 10-11-12 |
| **December** | 8-9-10 |