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PRESS RELEASE

15th MEETING
OF
THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. Under the chairmanship of Professor R. Kroker the fifteenth meeting of the Committee for Veterinary Medicinal Products took place in London on 22-23 October 1996.

CENTRALISED PROCEDURES

2. The Committee discussed the draft assessment reports prepared by the rapporteur and the co-rapporteur on an application received by the Agency for the granting of a marketing authorisation for a non-steroidal anti-inflammatory drug for food-producing animals falling under the scope of part B to the Annex. The Committee agreed on a list of questions to be sent to the applicant.

3. Having previously confirmed eligibility under the criteria in part B of the Annex, the Committee appointed a rapporteur and a co-rapporteur for two new applications for which a letter of intent had been received.

4. The Committee also considered as eligible for the granting of a Community marketing authorisation an ectoparasiticide for companion animals to be administered via a new delivery system (part B) and an immunoglobulin based product for calves (part A).

	Opinions delivered	Applications under evaluation	Applications under validation	Applications anticipated within the next 4 months
Centralised procedures	2	8	0	5
MRL procedures*	9	15	4	10

* Applications submitted to the EMEA after 1.1.1996

SCIENTIFIC ADVICE

5. The Committee considered three requests for scientific advice and appointed, for two of them, co-ordinators to review the data provided by the companies and prepare answers, whilst the third request could not be addressed by the Committee in the absence of further data.

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ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

6. The Committee recommended the modification of MRLs of a substance already classified into Annex I.

7. The Committee adopted status reports and lists of questions in consideration of other applications for new substances: one for the establishment of MRLs, two for the extension to another species of existing MRLs.

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

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

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

10. In addition, the status reports and the consolidated list of questions to the applicant were adopted for 9 old substances currently under evaluation.

11. The Committee considered a paper on sensitivity requirements of analytical methods for the purpose of residue monitoring and agreed to the proposal that the limits of quantification (LOQ) of analytical methods should be set at minimally half the value of the respective MRLs established by the Committee.

NOTES FOR GUIDANCE AND SOPs

12. The Committee discussed with representatives from FEDESA comments from the veterinary pharmaceutical industry on the CVMP draft Note for Guidance on *Environmental Risk Assessment for Veterinary Medicinal Products* which had been released for a 6-month consultation period.

13. The Committee agreed to release for a 6-month consultation period a Note for Guidance on *Harmonisation of Requirements for Equine Influenza* : *specific requirements for substitution of a strain* (EMEA/CVMP/116/96).

14. The next meeting of the Committee will be held on 10-11 December 1996.

General information about EMEA, Guidelines, SOPs and EPAR (European Public Assessment Report) for centrally approved veterinary products are available on Internet and E-mail at the following addresses:

- E-mail: mail@emea.eudra.org;
- Internet: www.eudra.org.