



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

London, 21 April, 1999

**SIXTH EMEA/FEDESA JOINT INFO DAY
AT THE EUROPEAN AGENCY IN LONDON**

On 16th April 1999 the sixth joint EMEA/FEDESA Info Day was held at the Agency in London to address latest developments on the centralised and mutual recognition systems and to provide updates on progress achieved in setting MRLs for old substances.

In his welcome address Peter Jones drew attention to some of the key issues currently being addressed at EMEA and reminded participants that a critical time lay ahead as the time approaches in 2000 for a detailed review of the European Regulatory systems and the need for input by all interested parties.

In the morning session jointly chaired by Susanne Zänker from FEDESA and Kornelia Grein from the Agency, presentations by Jill Ashley-Smith and Melanie Leivers of the EMEA emphasised the importance of pre-submission planning in the centralised procedures and provided updates on important elements such as naming policy and variation procedures. Suggestions on how to avoid potential difficulties were discussed and generally participants agreed that the centralised system was working well.

Neil Craven of FEDESA launched the joint EMEA/FEDESA Performance Indicators Questionnaire which will survey the experiences of Applicants, Rapporteurs/Co-Rapporteurs and the EMEA during the assessment of centralised procedures. The major objective is to highlight trends in the functioning of the procedure and where necessary provide opportunities for improvement.

Isaura Duarte of the EMEA and Kevin Woodward from Industry reviewed the progress made in establishing MRLs for old substances from both an Agency and Industry perspective, respectively as the 1 January 2000 deadline for completion approaches. All agreed that the progress-achieved to-date has been impressive but there is still a concern that there maybe insufficient time for some companies to complete the requisite studies to generate the data requested by CVMP.

Peter Jones summarised the work of EMEA in the Availability of Medicines Initiative pointing out the substances considered essential to veterinary medicine which are likely to be lost from the market if they are not assigned MRLs. The results of these efforts are included in a position paper on the EMEA web page: <http://www.eudra.org/emea.html>, which was demonstrated at the meeting.

During the afternoon Dr Carmen Jungbäck from the Paul Ehrlich Institute in Germany chaired the sessions focussing on the Mutual Recognition system. Several presentations were given on the 'Experiences of Mutual Recognition so far' by the Chairperson, 'The Main Issues for Industry' by Rick Clayton and Jim Bell for FEDESA, 'Current issues of the VMRFG' by Heather Oliver and 'Experience with variations' by Dr Liisa Kaartinen (Finland).

There was also a presentation of the new Heads of the Veterinary Regulatory Authorities (HEVRA)/VMRF Group Web site which was launched on 1 April by Dr Gerard Moulin (France). The Website can be found at <http://www.hevra.org> and contains information on the systems, together with the documents, which have been adopted by VMRFG.

Public

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Following the presentations there was a lively discussion and dialogue. The questions focussed on the procedures for variations and several other points of interest including the new Automatic Validation procedure which is being used for a trial period of 6 months from 1 April; use of arbitration and the possible new systems which may be implemented under the so-called Regulation 2000 review and new legislation. Following the useful results which had been obtained from the survey of procedures which had been carried out by FEDESA it was noted that a further joint FEDESA/VMRF Group survey would be carried out to identify and hopefully address any current weaknesses in the procedures.

Copies of the overheads may be seen and downloaded from the FEDESA Website at <http://www.fedesa.be>