

London, 17 September 2004

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 9-10 September 2004

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of two pharmaceutical applications and four immunological applications had reached day 78 at the July meeting. A total of two pharmaceutical applications and two immunological applications had reached day 78 in August. The Marketing Authorisations for six of these applications have been recognised by all of the individual CMS with no withdrawals. The Marketing Authorisation for one of these applications has been recognised by twelve CMS and not validated in one CMS. The Marketing Authorisation for one of these applications has been recognised by two CMS and withdrawn in eleven CMS. The Marketing Authorisation for one of these applications has been recognised by three CMS and withdrawn in four CMS. The Marketing Authorisation for one of these applications has been recognised by four CMS and withdrawn in two CMS
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for two pharmaceutical had reached Day 78 at this meeting.
ORGANISATIONAL ISSUES	
Questions from industry and / or MS	<p>During this meeting the following questions were discussed:</p> <ul style="list-style-type: none"> • Data requirements regarding generic applications; • Interpretation of the bioequivalence guideline EMEA/CVMP/016/00-corr-Final; • Implementation of guidelines which were recently adopted; • Data requirements regarding the informed consent applications; • Two legal bases for the same product; • Proposal for a reference product; • Implementation of revised Ph. Eur. Monographs; • Query regarding generic applications relating to the recent update of the Chapter 2 - Volume 6A – NtA; • Queries regarding procedures which were discussed at the VMRFG meetings.

AGENDA ITEM	DECISIONS
	<p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> • The submission of stability data following a change of manufacturer; • MRP when two national authorisations exist. • Interpretation of Article 28 of Directive 2004/28/EC; • The running of variation procedures; • Tolerance data required for essential similar Veterinary Medicinal Products.
New Decentralised Procedure	The group rediscussed the issue regarding the new Decentralised Procedure.
Co-Ordination Group – Rules of Procedures	Member States comments on the document regarding Rules of procedure of the Future Co-Ordination Group were discussed.
Best Practice Guide for RMS	The Best Practice Guide for RMS was adopted and the final version will be placed on the HEVRA website.
Best Practice Guide For Veterinary MRP	The VMRFG discussed comments received on the draft Best Practice Guide (BPG) for Veterinary MRP. This BPG was adopted and the final version will be placed on the HEVRA website.
ORGANISATIONAL ISSUES	
Date of next Meeting	The next VMRFG meeting (over two days) is scheduled to take place in London on 14-15 October 2004, starting at 13:00 h under the Dutch Presidency, chaired by Dr. Inge Sandberg.