

London, 22 April 2004

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 15-16 April 2004

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of one pharmaceutical and two immunologicals had reached day 78 at the March meeting. The Marketing Authorisations for all three of these applications have been recognised by all of the individual CMS with no withdrawals.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for seven pharmaceutical applications had reached Day 78 at this meeting.
PROCEDURAL ISSUES	
Questions from industry and / or MS	<p>During this meeting the following questions were discussed: dosing recommendations for a premix for medicated feeding stuff; change of address of MAH; the variation that the Applicant should submit regarding a change of the scoring of tablets; a possible line extension application with different RMS.</p> <p>The following questions were re-discussed: interpretation of the Guideline on Requirements for Concurrent Administration of Immunological Veterinary Medicinal Products EMEA/CVMP/550/02; the submission of stability data following a change of manufacturer; interpretation of the new variation Regulation concerning the variation number 7 for sterile products.</p>
New Co-ordination Group	The VMRFG discussed a document regarding the future Mutual Recognition Co-ordination Group under the review process of Pharmaceutical Legislation.
The Repeat Use of the MRP	The VMRFG discussed comments received on the draft Best Practice Guide(BPG) on the Repeat Use of the MRP. This BPG was adopted in principle and the final version would be placed on the HEVRA website as soon as possible.
Definition of Risk	The VMRFG discussed the next stages of preparing a concept paper for a definition of serious risk to human or animal health or the environment.

AGENDA ITEM	DECISIONS
ORGANISATIONAL ISSUES	
Meeting Dates and Clock Start Dates in 2005	The VMRFG adopted two documents regarding the Meeting dates and clock start dates and they would be placed on the HEVRA website.
Participation of New Countries at VMRFG	VMRFG will invite the ten new countries to send a delegate to the meetings from May 2004 onwards.
Date of next Meeting	The next VMRFG meeting (over two days) is scheduled to take place in London on 13-14 May 2004, starting at 13:00 h under the Irish Presidency, chaired by Ms Maggie Gething.