

London, 19 May 2004

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 13-14 May 2004

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of seven pharmaceutical applications had reached day 78 at the April meeting. 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 The Marketing Authorisation for one of these applications has been recognised by four CMS and withdrawn in one CMS.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for three pharmaceutical applications had reached Day 78 at this meeting.
ORGANISATIONAL ISSUES	
Questions from industry and / or MS	During this meeting 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 manufacturing site; interpretation of the new variation Regulation concerning the variation number 7 for sterile products; a possible line extension application with different RMS.
New Co-ordination Group	The draft joint human and veterinary document on the future Mutual Recognition Co-ordination Group under the review process of Pharmaceutical Legislation was circulated for information.
Definition of Risk	The VMRFG re-discussed the issue regarding a concept paper for a definition of serious risk to human or animal health or the environment.
Parallel Applications MS-SOP	VMRFG adopted amended document regarding the Parallel Applications – MS – SOP (VMRF/038/99-Rev.1-Final) and it would 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 17-18 June 2004, starting at 13:00 h under the Irish Presidency, chaired by Ms Maggie Gething.