

London, 19 June 2004

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 17-18 June 2004

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of three pharmaceutical applications had reached day 78 at the May meeting. The Marketing Authorisations for two 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 The Marketing Authorisation for one of these applications has been recognised by ten CMS and withdrawn in three CMS.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for two pharmaceutical and two immunological applications 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"> • MRP when two National Authorisations exist; • Validation of a variation for a product approved on day 90 but not yet authorised; • Definition of the term ‘same medicinal product’; • Issues regarding variation procedures due to acquisition of a Veterinary Medicinal Product by a new Applicant; • Issues regarding National Applications; • Removal of one active substance from a Veterinary Medicinal Product.
New Decentralised Procedure	The group started to discuss issues regarding the new Decentralised Procedure.
Definition of Risk	The VMRFG discussed and revised a draft document regarding a definition of serious risk to human or animal health or the environment.
Procedure for collection of data and handling of replies to the VMRFG/IFAH MRP questionnaire	The document regarding Procedure for collection of data and handling of replies to the VMRFG/IFAH MRP questionnaire was revised and the new version will be placed on the HEVRA website.

AGENDA ITEM	DECISIONS
Best Practice Guide For Veterinary MRP	The VMRFG started to revise the Best Practice Guide for veterinary MRP.
ORGANISATIONAL ISSUES	
Meeting Dates and Clock Start Dates in 2005	The VMRFG adopted amendments on two documents regarding the Meeting dates and clock start dates for 2005 and they would be placed on the HEVRA website.
Contact Points	The VMRFG adopted amendments on documents regarding the Contact Points for Procedures and the Current List of Contact Points for VMRF Group Meetings and Eudratrack. The updated document regarding the Contact Points – Procedures will be placed on the HEVRA website.
Date of next Meeting	The next VMRFG meeting (over two days) is scheduled to take place in London on 15-16 July 2004, starting at 13:00 h under the Dutch Presidency, chaired by Dr. Inge Sandberg