

London, 27 October 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 16-17 October 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of two new pharmaceutical products had reached Day 78 at the September meeting. The Marketing Authorisation for one of these applications was recognised by ten CMS and withdrawn in one CMS. The other was recognised by nine CMS and withdrawn in one CMS.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for seven applications (six pharmaceuticals and one immunological) had reached Day 78 at this meeting. Five of these products were for discussion at the meeting.
PROCEDURAL ISSUES	
Questions from industry and / or MS	Questions were discussed regarding: if a Regulatory Affairs Consultant could apply for a Marketing Authorisation on behalf of a Company outside the EEA; Request to CVMP on interpretation of VICH Guideline GL 11: Impurities in New Veterinary Medicinal Products; Transfer of marketing authorisation for a product through MRP; Requirements for provision of mutagenicity data; Florfenicol per os in pigs, chickens and turkeys, Withdrawal of an application during the validation, Submission of three vaccines in parallel.
Best Practice Guide For Veterinary MRP Including CAVDRI Additions	The VMRFG has started work on The Best Practice Guide for veterinary MRP including CAVDRI additions, this new document is an updated of the previous Best Practice Guides for veterinary MRP (VMRF/033/03).
Numbering System for Identification of the Procedures	The VMRFG discussed and adopted the new document on Numbering System for Identification of the Procedures.
Automatic validation of MRP	The VMRFG discussed and adopted the amendments which were made on the document VMRF/171/98 regarding Procedure for Automatic Validation of Mutual Recognition Procedures. This new document does not include the validation of procedures regarding variations, since this issue is included in the Best Practice Guide for the Processing of Type IA (VMRF/116/03), Type IB (VMRF/117/03) and Type II (VMRF/118/03).
ORGANISATIONAL ISSUES	
Date of next Meeting	The next VMRFG meeting (over two days) is scheduled to take place in London on 13-14 November 2003, starting at 13:00 h under the Italian Presidency, chaired by Mr Virgilio Donini.

