

London, 17 November 2004

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 11-12 November 2004

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of one immunological and two pharmaceutical applications had reached day 78 at the October 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 The Marketing Authorisation for one of these applications has been recognised by seventeen CMS and withdrawn in one CMS.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for one pharmaceutical and three immunological products had reached Day 78 at this meeting.
ORGANISATIONAL ISSUES	
Questions from industry and / or MS	<p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> • Query regarding diluent for vaccines; • Products intended to kill flies by direct application (pour-on); • Query regarding generic applications relating to the recent update of the Chapter 2 - Volume 6A – NtA; • Tolerance data required for essential similar Veterinary Medicinal Products; • Queries regarding procedure which were discussed at the VMRFG meetings; • The authorisation of colourants as part of veterinary vaccines; • Extrapolation of stability data;
Co-Ordination Group – Rules of Procedure	The VMRFG discussed MSs comments and a new version of the document regarding Rules of procedure of the Future Co-Ordination Group.
New Decentralised Procedure	The VMRFG discussed the times frames of the new decentralised procedure.
Variations-Best Practice Guides	The VMRFG started to revise the documents regarding on Best Practice Guides for Type IA, Type IB and Type II variations which were adopted in September 2003.

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ORGANISATIONAL ISSUES	
Date of next Meeting	<p>The next VMRFG meeting is scheduled to take place in London on 9-10 December 2004, starting at 13:00 h under the Dutch Presidency, chaired by Dr. Inge Sandberg.</p> <p>The next meeting of interested parties will be held on 10 December 2004 at 8.15 at EMEA and will be chaired by Dr. Inge Sandberg.</p>