

London, 19 January 2005

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 13-14 January 2005

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of two immunological and four pharmaceutical applications had reached day 78 at the November meeting. The Marketing Authorisations for four 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 The Marketing Authorisation for one of these applications has been recognised by eighteen CMS and withdrawn in two CMS. The Marketing Authorisation for one of these applications has been recognised by seven CMS and withdrawn in two CMS.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for one pharmaceutical 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"> • Validation of a specific variation procedure; • National application already authorised in some MSs; • National application already authorised in some New MSs; • Veterinary application register under article 7 of Directive 2001/82; • Generic application according the new Directive 2004/28/EC. <p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> • MRP when two national authorisations exist; • Implementation of revised Ph. Eur. Monographs; • Clinical Studies performed in accordance with GLP standards;
Coordination Group – Rules of Procedure	A new version of the document of Rules of procedure of the Future Coordination Group and MSs comments were discussed.

AGENDA ITEM	DECISIONS
New Decentralised Procedure	A new version of the veterinary flow chart for decentralised procedure was discussed and adopted.
Authorisation of colourants in veterinary medicinal products in the EU (VMRF/069/98-Rev.1-Final)	The public document regarding Authorisation of colourants in veterinary medicinal products in the EU was revised and it will be published on the HEVRA website
ORGANISATIONAL ISSUES	
Date of next Meeting	<p>The next VMRFG meeting is scheduled to take place in London on 10-11 February 2005, starting at 13:00. The Netherlands will continue to chair the VMRFG meetings for the next five months (Dr. Inge Sandberg) during the Luxembourg presidency of the European Union.</p> <p>The next meeting of interested parties will be held on 11 February at 8.15 at EMEA and will be chaired by Dr. Inge Sandberg.</p>