

London, 27 May 2005

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 19-20 May 2005

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of one immunological and eleven pharmaceutical applications had reached day 78 at the April meeting. The Marketing Authorisations for these applications have been recognised by all of the individual CMS with no withdrawals.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for six pharmaceutical products 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"> • Microbiological quality of premixes; • Duplicate application; • Application in the CTD format. <p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> • Premixes and rate of incorporation in feed; • Question regarding the item 4 of the guideline for the Conduct of Bioequivalence Studies; • Extrapolation of Stability Data.
New Decentralised Procedure	A new draft of the veterinary flow chart for decentralised procedure was circulated for information the VMRFG comments on this new version will be sent to the Ad - hoc group of HMA on DCP.
Coordination Group Rules of Procedures	The document regarding the Rules of procedures for the Coordination group was rediscussed.
CMD(V) SOP – Disagreement in procedures – referral to CMD(V)	The VMRFG started to discuss a SOP regarding the Disagreement in procedures – referral to CMD(V).

AGENDA ITEM	DECISIONS
BPG – For production of publicly available Assessment Reports	The VMRFG adopted a draft BPG – For production of publicly available Assessment Reports and requested comments to IFAH and EGGVP.
ORGANISATIONAL ISSUES	
Date of next Meeting	The next VMRFG meeting is scheduled to take place in London on 16 – 17 June 2005, starting at 13:00. The Netherlands will continue to chair the VMRFG meetings for one month (Dr. Inge Sandberg) during the Luxembourg presidency of the European Union.