

London, 18 April 2005

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 14-15 April

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	A total of five immunological and two pharmaceutical applications had reached day 78 at the March 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 eleven pharmaceutical and one immunological 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"> ?? Interpretation of Article 13 of Directive 2004/28/EC; ?? Question regarding the item 4 of the guideline for the Conduct of Bioequivalence Studies; ?? Same veterinary medicinal product registered by two companies with a different trade names; ?? Premixes and rate of incorporation in feed. <p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> ?? Variation to packaging which cannot be considered as a primary packaging and neither as secondary packaging; ?? Fixed combination product submitted as a bibliographical application.
New Decentralised Procedure	A new version of the veterinary flow chart for decentralised procedure which was adopted at the January meeting was discussed. The VMRFG decided that this subject will be rediscussed in length during the next VMRFG meetings.
Proposal for a “guideline on the definition of a serious risk to human or animal health or the environment”	The individual Member States comments on the proposal for a “guideline on the definition of a serious risk to human or animal health or the environment” were sent to the Commission.

AGENDA ITEM	DECISIONS
ORGANISATIONAL ISSUES	
Date of next Meeting	<p>The next VMRFG meeting is scheduled to take place in London on 19-20 May 2005, starting at 13:00. The Netherlands will continue to chair the VMRFG meetings for the next two months (Dr. Inge Sandberg) during the Luxembourg presidency of the European Union.</p> <p>The next meeting of interested parties will be held on 20 May at 8.15 at EMEA and will be chaired by Dr. Inge Sandberg.</p>