

London, 18 February 2005

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 10-11 February

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	One pharmaceutical application had reached day 78 at the January meeting. The Marketing Authorisations for this application has been recognised by twenty one CMS and withdrawn in two CMS.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for nine pharmaceutical and five 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"> • Fixed combination product submitted as a bibliographical application; • Submission of a single Part III for all strengths; • Residues depletion studies for certain types of generic product; • Original primary packaging supplied by the manufacturer; • Change of the name of a material use in a closure of semisolid product; <p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> • Article 7 of Directive 2001/82; • MRP when two national authorisations exist; • Implementation of revised Ph. Eur. Monographs; <p>The VMRFG decided that for a period of 3 months they will stop answering questions from the Industry due the increased workload with the implementation of the new Directive 2004/28/EC</p>
Coordination Group – Rules of Procedure	A new version of the document of Rules of procedure of the Future Coordination Group was discussed and a final draft was agreed. The new Coordination Group (VCMD) will rediscuss this document.

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ORGANISATIONAL ISSUES	
Date of next Meeting	The next VMRFG meeting is scheduled to take place in London on 10-11 March 2005, starting at 13:00. The Netherlands will continue to chair the VMRFG meetings for the next four months (Dr. Inge Sandberg) during the Luxembourg presidency of the European Union.