

London, 18 March 2005

## REPORT OF THE VMRFG MEETING – FOR RELEASE

### Meeting of 10-11 March

AGENDA ITEM	DECISIONS
<b>ASSESSMENT ISSUES</b>	
<p><b>Outcome of Veterinary Mutual Recognition Procedures</b></p>	<p>A total of five immunological and nine pharmaceutical applications had reached day 78 at the February meeting:</p> <ul style="list-style-type: none"> <li>• The Marketing Authorisations for six of these applications have been recognised by all of the individual CMS with no withdrawals.</li> <li>• The Marketing Authorisation for one of these applications has been recognised by eighteen CMS and withdrawn in one CMS.</li> <li>• The Marketing Authorisation for one of these applications has been recognised by eight CMS and not validated in four CMS.</li> <li>• The Marketing Authorisation for one of these applications has been recognised by thirteen CMS and withdrawn in one CMS.</li> <li>• The Marketing Authorisation for four of these applications has been recognised by eight CMS and withdrawn in three CMS.</li> <li>• The Marketing Authorisation for one of these applications has been recognised by seven CMS and withdrawn in four CMS.</li> </ul>
<p><b>Evaluation of Veterinary Mutual Recognition Procedures</b></p>	<p>The Mutual Recognition procedures for two pharmaceutical and five immunological products had reached Day 78 at this meeting.</p>
<b>ORGANISATIONAL ISSUES</b>	
<p><b>Questions from industry and / or MS</b></p>	<p>During this meeting the following questions were discussed:</p> <ul style="list-style-type: none"> <li>• Variation to packaging which cannot be considered as a primary packaging and neither as secondary packaging;</li> <li>• Extension to a Marketing Authorisations within MRP;</li> <li>• Change of the specifications of the active substance to the specifications of the Current Edition of the European Pharmacopoeia.</li> </ul> <p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> <li>• Fixed combination product submitted as a bibliographical</li> </ul>

AGENDA ITEM	DECISIONS
	<p>application;</p> <ul style="list-style-type: none"> <li>• Submission of a single Part III for all strengths;</li> <li>• Residues depletion studies for certain types of generic product;</li> <li>• Interpretation of Article 28 of Directive 2004/28/EC.</li> </ul>
<p><b>The abbreviation for the future Coordination Group</b></p>	<p>The VMRFG was informed of the decision which was made at the Heads of Medicines Agencies (Veterinary Medicines) regarding the name of the new Coordination Group. Therefore the abbreviation for the future Veterinary Coordination Group on Mutual Recognition and Decentralised Procedure would be CMD(V).</p>
<p><b>Proposal for a “guideline on the definition of a serious risk to human or animal health or the environment”</b></p>	<p>The proposal for a “guideline on the definition of a serious risk to human or animal health or the environment” was circulated for information and the VMRFG was informed that this guideline was published in the Commission website (<a href="http://pharmacos.eudra.org">http://pharmacos.eudra.org</a>) for consultation until 31 March 2005.</p>
ORGANISATIONAL ISSUES	
<p><b>Contact Points</b></p>	<p>The VMRFG adopted amendments on documents regarding the Contact Points for Procedures and the List of Contact Points for VMRF Group Meetings and Eudratrack. The updated document regarding the Contact Points – Procedures will be placed on the HEVRA website.</p>
<p><b>Date of next Meeting</b></p>	<p>The next VMRFG meeting is scheduled to take place in London on 14-15 April 2005, starting at 13:00. The Netherlands will continue to chair the VMRFG meetings for the next three months (Dr. Inge Sandberg) during the Luxembourg presidency of the European Union.</p>