

London, 21 July 2004

## REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 15-16 July 2004

AGENDA ITEM	DECISIONS
<b>ASSESSMENT ISSUES</b>	
<b>Outcome of Veterinary Mutual Recognition Procedures</b>	A total of two pharmaceutical applications and two immunological applications had reached day 78 at the June meeting. The Marketing Authorisations for all of these applications have been recognised by all of the individual CMS with no withdrawals.
<b>Evaluation of Veterinary Mutual Recognition Procedures</b>	The Mutual Recognition procedures for two pharmaceutical and four immunological applications had reached Day 78 at this meeting.
<b>ORGANISATIONAL ISSUES</b>	
<b>Questions from industry and / or MS</b>	<p>During this meeting the following questions were discussed:</p> <ul style="list-style-type: none"> <li>• Duration of Withdrawal period for meat;</li> <li>• Interpretation of Article 28 of Directive 2004/28/EC;</li> <li>• The running of variation procedures;</li> <li>• Tolerance data required for essential similar Veterinary Medicinal Products;</li> </ul> <p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> <li>• The submission of stability data following a change of manufacturer;</li> <li>• Issues regarding variation procedures due to acquisition of a Veterinary Medicinal Product by a new Applicant;</li> <li>• MRP when two national authorisations exist.</li> </ul>
<b>New Decentralised Procedure</b>	The group continued the discussion regarding the new Decentralised Procedure.
<b>Co-Ordination Group – Rules of Procedures</b>	The group started to discuss a document regarding Rules of procedure of the Future Co-Ordination Group.
<b>Definition of Risk</b>	The VMRFG discussed the new draft document and the comments from MSs regarding a definition of potential serious risk to human or animal health or the environment.

<b>AGENDA ITEM</b>	<b>DECISIONS</b>
<b>Best Practice Guide for RMS</b>	The VMRFG discussed a new draft and the comments from MSs regarding the Best Practice Guide for RMSs.
<b>Best Practice Guide For Veterinary MRP</b>	The VMRFG discussed the comments which were received from MSs and from IFAH-Europe regarding the Best Practice Guide for veterinary MRP.
<b>ORGANISATIONAL ISSUES</b>	
<b>Date of next Meeting</b>	The next VMRFG meeting (over two days) is scheduled to take place in London on 9-10 September 2004, starting at 13:00 h under the Dutch Presidency, chaired by Dr. Inge Sandberg.