

London, 18 October 2004

## REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 14-15 October 2004

AGENDA ITEM	DECISIONS
<b>ASSESSMENT ISSUES</b>	
<b>Outcome of Veterinary Mutual Recognition Procedures</b>	A total of two pharmaceutical applications had reached day 78 at the September meeting. The Marketing Authorisations for 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 one immunological product 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>• Queries regarding the issues relating to the running of Mutual Recognition procedures and the choice of RMS;</li> <li>• The authorisation of colourants as part of veterinary vaccines;</li> <li>• Query regarding the Guideline for the Conduct of Bioequivalence Studies;</li> <li>• Query regarding diluent for vaccines;</li> <li>• Use of Feedgrade antibiotics in veterinary premixes;</li> <li>• The availability of the SPCs to the public on request;</li> <li>• Products intended to kill flies by direct application (pour-on).</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>• MRP when two national authorisations exist;</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>

<b>AGENDA ITEM</b>	<b>DECISIONS</b>
	<ul style="list-style-type: none"> <li>• Proposal for a reference product;</li> <li>• Query regarding generic applications relating to the recent update of the Chapter 2 - Volume 6A – NtA;</li> <li>• Possibility of submission of new studies during a Mutual Recognition Procedure.</li> </ul>
<b>Meeting Dates and Clock Start Dates in 2006</b>	The VMRFG adopted preliminary documents regarding the Meeting dates and clock start dates. These documents could change due to the new legislation.
<b>Co-Ordination Group – Rules of Procedure</b>	The VMRFG discussed a new version of the document regarding Rules of procedure of the Future Co-Ordination Group.
<b>ORGANISATIONAL ISSUES</b>	
<b>Date of next Meeting</b>	The next VMRFG meeting is scheduled to take place in London on 11-12 November 2004, starting at 13:00 h under the Dutch Presidency, chaired by Dr. Inge Sandberg.