

London, 17 June 2005

## **REPORT OF THE VMRFG MEETING – FOR RELEASE**

**Meeting of 16-17 June 2005**

<b>AGENDA ITEM</b>	<b>DECISIONS</b>
<b>ASSESSMENT ISSUES</b>	
<b>Outcome of Veterinary Mutual Recognition Procedures</b>	Six pharmaceutical applications had reached day 78 at the May 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 seven pharmaceutical products and five immunological products had reached Day 78 at this meeting.
<b>ORGANISATIONAL ISSUES</b>	
<b>IT issues</b>	Training for Member States in the use of the Communication and Tracking System (CTS) for Mutual Recognition was provided at this meeting.
<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>• Abridged (generic) application for an antibiotic injection</li> <li>• Question from Industry – Choice of a Reference product for a clinical trial</li> <li>• Question related to a line extension under MRP</li> <li>• Question related to combined renewal and review procedure</li> </ul> <p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> <li>• Premixes and rate of incorporation in feed;</li> <li>• Question regarding item 4 of the guideline for the Conduct of Bioequivalence Studies;</li> <li>• Question related to Duplicate applications</li> <li>• A question regarding Extrapolation of Stability data-Request for interpretation of Guidelines applied was forwarded to CVMP and subsequently to the QWP.</li> </ul>

<b>AGENDA ITEM</b>	<b>DECISIONS</b>
<b>New Decentralised Procedure</b>	The latest draft of the veterinary flow chart for the decentralised procedure was circulated for information.
<b>Coordination Group Rules of Procedures</b>	The rules of procedures for the Coordination group were updated and proposals for harmonisation between both the human and vet documents discussed. A joint working group with the human MRFG group was endorsed.
<b>CMD(V) SOP – Disagreement in procedures – referral to CMD(V)</b>	The VMRFG continued to discuss a SOP regarding the disagreement in procedures – referral to CMD(V).
<b>Transitional Arrangement</b>	VMRFG agreed to progress a document on transitional arrangements taking into account the MRFG document.
<b>Labelling/package leaflet</b>	VMRFG agreed to use the QRD template for product information and will produce an annotated version with MRP/DCP specific guidance.
<b>BPG – For production of publicly available Assessment Reports</b>	The draft BPG is still under discussion.
<b>ORGANISATIONAL ISSUES</b>	
<b>Date of next Meeting</b>	The next VMRFG meeting is scheduled to take place in London on 14 – 15 July 2005, starting at 13:00. The chair of the VMRFG meetings under the UK presidency will be Dr. Gavin Hall.