

London, 15 July 2005

## REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 14-15 July 2005

AGENDA ITEM	DECISIONS
<b>ASSESSMENT ISSUES</b>	
<b>Outcome of Veterinary Mutual Recognition Procedures</b>	Six pharmaceutical and five immunological applications had reached day 78 at the June 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 ten pharmaceutical products and two immunological products had reached Day 78 at this meeting.
<b>ORGANISATIONAL ISSUES</b>	
<b>Questions from industry and / or MS</b>	<p>The following questions were rediscussed:</p> <ul style="list-style-type: none"> <li>• Question from Industry – Choice of a Reference product for a clinical trial (response is not made available to public)</li> <li>• Question from industry – Regarding item 4 of the Guideline for the Conduct of Bioequivalence Studies.</li> <li>• Question from MS – Related to combined renewal and review procedure.</li> </ul>

<b>AGENDA ITEM</b>	<b>DECISIONS</b>
<b>New Decentralised Procedure</b>	The latest draft of the flow chart for the decentralised procedure submitted to the Head of Agencies (HMA) for discussion at their July meeting was circulated for information.
<b>Coordination Group Rules of Procedures</b>	<p>A joint VMRFG / MRFG sub-group has been proposed to carry this work forward.</p> <p>A first draft Best Practice Guide outlining the role of the Chair and Vice Chair was discussed.</p>
<b>Transitional Arrangement</b>	VMRFG continued to discuss the document on transitional arrangements taking into account the MRFG document.
<b>Labelling/package leaflet</b>	The latest draft Best Practice Guide was agreed. An annotated version of the QRD template with specific national requirements will be added as an annex.
<b>The Best Practice Guide – For production of publicly available Assessment Reports</b>	The draft Best Practice Guide was adopted in principle. It will be publicly available in September/ October this year.
<b>The Variation Best Practice Guides</b>	Work on updating the Type IA, IB and Type II variation Best Practice Guides is nearing completion. It was agreed to include a flow chart within these documents. These are up for adoption at the September meeting.
<b>General</b>	A number of other Best Practice Guides requiring an update in light of the new legislation were discussed. Also a number of other items and documents were presented to the group for information.
<b>ORGANISATIONAL ISSUES</b>	
<b>Date of next Meeting</b>	The next VMRFG meeting is scheduled to take place in London on 8-9 September, 2005. Gavin Hall will chair the meeting under the UK presidency.