

London, 26 March 2004

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

**Meeting of 18 March 2004**

<b>AGENDA ITEM</b>	<b>DECISIONS</b>
<b>ASSESSMENT ISSUES</b>	
<b>Outcome of Veterinary Mutual Recognition Procedures</b>	A total of twelve pharmaceuticals and three immunologicals had reached day 78 at the February meeting. The Marketing Authorisations for seven of these applications have been recognised by all of the individual CMS with no withdrawals. The Marketing Authorisation for one of these applications has been recognised by twelve CMS and by six Acceding Countries and withdrawn in one CMS. The Marketing Authorisation for one of these applications has been recognised by four CMS and by three Acceding Countries and withdrawn in six CMS. The Marketing Authorisation for two of these applications have been recognised by twelve CMS and withdrawn in two CMS. The Marketing Authorisation for two of these applications have been recognised by six CMS and withdrawn in two CMS. The Marketing Authorisation for two of these applications have been recognised by ten CMS and withdrawn in one CMS.
<b>Evaluation of Veterinary Mutual Recognition Procedures</b>	The Mutual Recognition procedures for three applications (one pharmaceutical and two immunological) had reached Day 78 at this meeting.
<b>PROCEDURAL ISSUES</b>	
<b>Questions from industry and / or MS</b>	<p>During this meeting the following questions were discussed: when a new Acceding Country can be included in a MRP; procedure required to extend an orally administered poultry vaccine to include administration by coarse spray; requirements for a generic Mutual Recognition application for a product containing hyaluronic acid; interpretation of the new variation Regulation concerning the variation number 7 for sterile products; ectoparasiticide for goats producing milk for human consumption; possible modification of the clock start date for MRP for 29<sup>th</sup> April.</p> <p>The following questions were re-discussed: change of the name of Manufacturing Licence Holder; interpretation of the Guideline on Requirements for Concurrent Administration of Immunological Veterinary Medicinal Products EMEA/CVMP/550/02; multiple applications in MRP; the submission of stability data following a change of manufacturer; change of MAH and the product name simultaneously; implementation of warning regarding accidental self injection of products containing mineral oils.</p> <p>The group noted that Acceding Countries could choose to take part in MRP before 1<sup>st</sup> May, and the MR authorisations would be recognised if the date</p>

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	of issue was after accession. However Acceding countries were not obliged to take part until after 1 <sup>st</sup> May. In view of this there will be no change of the April 29 <sup>th</sup> clock start.
<b>New Co-ordination Group</b>	The VMRFG re-discussed the issue regarding the future Mutual Recognition Co-ordination Group under the review process of Pharmaceutical Legislation.
<b>The Repeat Use of the MRP</b>	The VMRFG discussed the last revision regarding the draft Best Practice Guide on the Repeat Use of the MRP. This BPG will be adopted by the next VMRFG meeting.
<b>Standardisation of Section headings for the SPC</b>	The VMRFG agreed that the SPC Headings for the day 90 SPC would be the same headings as the Centralised products, any changes necessary would be made at the next renewal or type II variation affecting the SPC.
<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 15-16 April 2004, starting at 13:00 h under the Irish Presidency, chaired by Ms Maggie Gething.