

London, 19 January 2004

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 15 January 2004

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of ten new pharmaceutical products and four immunologicals had reached day 78 at the December meeting.</p> <p>The Marketing Authorisations for eight of these applications have been recognised by all of the individual CMS with no withdrawals. One of these applications was recognised by fourteen CMS and withdrawn in eight CMS. Four Marketing Authorisations were recognised by sixteen CMS and withdrawn in two CMS. One Marketing Authorisation was recognised by four CMS and withdrawn in two CMS.</p>
Evaluation of Veterinary Mutual Recognition Procedures	<p>There were no applications for discussion at the meeting.</p>
PROCEDURAL ISSUES	
Questions from industry and / or MS	<p>During this meeting the following questions were discussed: Mineral Oil Warnings in SPCs for immunologicals; Change of address of the holder of the manufacturing authorisation; Change of name of the marketing authorisation holder. The following questions were re-discussed: withdrawal of a product from the national market during a variation procedure and extension of a veterinary medicinal product to a new species.</p>
New Co-ordination Group	<p>A document regarding the setting up of the proposed new Co-ordination Group was adopted and will be presented to HEVRA on 21st January 2004.</p>
The Repeat Use of the MRP	<p>The VMRFG discussed amendments which were proposed by the MSs regarding the draft Best Practice Guide on the Repeat Use of the MRP.</p>
Well Established Use	<p>Documents were discussed regarding ‘well established use’ in the context of bibliographical applications.</p>
The Retest of Veterinary Medicinal Products Manufactured in third Countries	<p>The issue regarding the retesting of veterinary medicinal products manufactured in the third countries was re-discussed.</p>

AGENDA ITEM	DECISIONS
ORGANISATIONAL ISSUES	
Contact Points	The VMRFG adopted amendments on documents regarding the Contact Points for Procedures and the Current List of Contact Points for VMRF Group Meetings and Eudratrack. The updated document regarding the Contact Points – Procedures will be placed on the HEVRA website.
Date of next Meeting	The next VMRFG meeting (over two days) is scheduled to take place in London on 12-13 February 2004, starting at 13:00 h under the Irish Presidency, chaired by Ms Maggie Gething.