

London, 16 February 2004

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 12–13 February 2004

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	There were no applications for discussion at the January meeting.
Evaluation of Veterinary Mutual Recognition Procedures	The Mutual Recognition procedures for fifteen applications (twelve pharmaceuticals and three immunologicals) had reached Day 78 at this meeting. Nine of these products were for discussion at the meeting.
PROCEDURAL ISSUES	
Questions from industry and / or MS	<p>During this meeting the following questions were discussed: interpretation of the Guideline on Requirements for Concurrent Administration of Immunological Veterinary Medicinal Products EMEA/CVMP/550/02; acceptability of an updated Part IA during a variation procedure; clarification of a warning on packaging and SPC; the submission of stability data following a change of manufacturer; change of MAH and the product name simultaneously; multiple applications in MRP.</p> <p>The following questions were re-discussed: the extension of a veterinary medicinal product to a new species; Mineral Oil Warnings in SPCs for immunologicals; change of the name of MAH; change of address of the holder of the manufacturing authorisation.</p> <p>The EC pointed out that according to Commission Regulation EC no 1084/2003 the change of the name of the product or MAH even if the change only concerns one CMS will have to proceed using the MR variation procedure. Therefore VMRF decided that the document VMRF/171/01, which was published on the HEVRA website (Change of Name of the MAH) is no longer valid and it will be removed. This change would now be a MR variation procedure.</p> <p>The VMRFG decided that it cannot accept an update of Part IA during a variation procedure.</p> <p>The VMRFG reached a harmonised position in that residue data in udder tissue is not required at this time.</p>
France change policy regarding generic applications	France stated that from this date they are now able to validate generic applications for which the proposed SPC is not harmonised with the reference product.

AGENDA ITEM	DECISIONS
New Co-ordination Group	The VMRFG continued discussions regarding the future Mutual Recognition Co-ordination Group under the review process of Pharmaceutical Legislation.
The Repeat Use of the MRP	The VMRFG re-discussed amendments which were proposed by the MSs regarding the draft Best Practice Guide on the Repeat Use of the MRP.
Well Established Use	The VMRFG re-discussed the issue on 'well established use' in the context of bibliographical applications.
ORGANISATIONAL ISSUES	
Date of next Meeting	The next VMRFG meeting (over two days) is scheduled to take place in London on 18-19 March 2004, starting at 13:00 h under the Irish Presidency, chaired by Ms Maggie Gething.