

London, 19 December 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 11-12 December 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of six new pharmaceutical products and four immunologicals had reached day 78 at the November meeting.</p> <p>The Marketing Authorisations for six of these applications have been recognised by all of the individual CMS with no withdrawals. One of these applications was recognised by one CMS and withdrawn in one CMS. One Marketing Authorisation was recognised by eight CMS and withdrawn in three CMS. One Marketing Authorisation was recognised by one CMS and withdrawn in four CMS. One Marketing Authorisation was recognised by one CMS and withdrawn in two CMS.</p>
Evaluation of Veterinary Mutual Recognition Procedures	<p>The Mutual Recognition procedures for fourteen applications (ten pharmaceuticals and four immunologicals) had reached Day 78 at this meeting. Nine of these products were for discussion at the meeting.</p>
PROCEDURAL ISSUES	
Questions from industry and / or MS	<p>During this meeting were discussed the following questions: withdrawal of a product from national market during a variation procedure; extension of a veterinary medicinal product to a new species; the reasons for a recent withdrawal of a product during the MRP; problems which have come up with the new variation regulation; multiple applications in MRP and the requirement for residue data (udder tissue) was re-discussed.</p>
New Co-ordination Group	<p>The VMRFG have started to discuss the new Co-ordination Group, because the revision of the directive (2001/82/EC) gives provision for establishment of a Co-ordination Group within the new system of Mutual Recognition and Decentralised Procedures.</p>
Best Practice Guide for RMS	<p>The VMRFG have started to work on Best Practice Guide for RMS.</p>
The repeat use of the MRP	<p>The VMRFG started to discuss the amendments regarding the document on the Repeat Use of the MRP.</p>
Template for the Exchange of Information on a MRP	<p>The VMRFG discussed the new amendments which were made on the template for exchange of information on a MRP, according to the Best Practice Guide for veterinary MRP including CAVDRI additions; which was adopted and published on the HEVRA website in November.</p>

AGENDA ITEM	DECISIONS
Revision of Volume 6 A – Chapter 2 and Chapter 5 of the Notice to Applicants	The VMRFG finalised the discussion regarding the amendments which were made on both chapters of the Notice to Applicants.
ORGANISATIONAL ISSUES	
Date of next Meeting	The next VMRFG meeting (over one day) is scheduled to take place in London on 15 January 2004, starting at 13.00 h under the Irish Presidency, chaired by Ms Maggie Gething.