

London, 24 January 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 13 January 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of four new products (three pharmaceuticals and one immunological) had reached Day 80 at the December meeting.</p> <p>The Marketing Authorisations for three of these applications have been recognised by all of the individual CMS with no withdrawals. One product was withdrawn in two CMS.</p> <p>Two CMS have referred a procedure to CVMP for arbitration under Article 33 of Directive 2001/82/EC involving a pharmaceutical with three strengths (Day 90 of MRP 12.09.02). The arbitration concerns a mutual recognition procedure for a “line extension” and was initiated due to concerns on the risk benefit of the higher dose proposed.</p>
Evaluation of Veterinary Mutual Recognition Procedures	<p>The Mutual Recognition procedures for two applications (both immunologicals) had reached Day 80 at this meeting. One of these products was for discussion at the meeting. One product had a single CMS and was not for discussion.</p>
Mineral Oil Warnings	<p>The VMRFG have agreed to compile a list of mutually recognised products which contain mineral oils with a view to reviewing the warnings currently present on the SPC, in light of the recent guidance adopted by CVMP.</p>
PROCEDURAL ISSUES	
New Meeting Schedule for 2003	<p>The group agreed to amend the meeting days for the VMRF group meeting from June 2003 onwards to Thursday afternoon/Friday of the same week (D77/78) as they currently meet. This was agreed in order to allow for more meeting time due to the increasing workload of the group.</p>
Questions from industry and / or MS	<p>Questions were discussed regarding: where to find a directory or list of products authorised via the MRP; submission of an informed consent application in a CMS by the different MAH after a mutual recognition procedure; the acceptability of a DMF in CTD-format for a veterinary product authorisation.</p>
Best Practice Guide	<p>The group adopted proposed revisions to the Best Practice Guide and will re-adopt a revised document in February in light of the changes to the meeting dates agreed at the January meeting.</p>

AGENDA ITEM	DECISIONS
ORGANISATIONAL ISSUES	
Meeting dates and Clock Starts in 2003	The list of meeting dates and clock start dates for veterinary MR procedures in 2003 has been updated in light of the new meeting schedule and is now available on the HEVRA website. The VMRFG will meet on Day 77/78 of the procedure and the comments on the initial assessment report will be sent by CMS on Day 54 instead of Day 55 as at present. The clock start dates have been amended for procedures starting from April 2003 onwards and the meeting dates from June 2003 onwards.
VMRFG Liaison Meeting	A VMRFG liaison meeting with interested parties (IFAH-Europe –formerly FEDESA and EGGVP) took place on 14 January 2003.
Date of next Meeting	The next VMRFG meeting is scheduled to take place in London on 10 and 11 (morning only) February 2003, starting at 09:00 h under the Greek Presidency, chaired by Mr Ioannis Malemis.