

London, 20 February 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 10-11 February 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of two new products (both immunologicals) had reached Day 80 at the January meeting.</p> <p>The Marketing Authorisations for both of these applications has been recognised by all of the individual CMS with no withdrawals.</p> <p>Two CMS 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. At its January meeting CVMP overruled the objections of the CMS who had initiated the referral. The opinion of CVMP has been forwarded to the Commission and the formal Commission Decision is now awaited.</p>
Evaluation of Veterinary Mutual Recognition Procedures	<p>The Mutual Recognition procedures for twelve applications (ten pharmaceuticals and two immunologicals) had reached Day 80 at this meeting. Ten of these products were for discussion at the meeting. Two procedures had a single CMS and were not for discussion.</p>
Mineral Oil Warnings	<p>The VMRFG has started 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. The meeting dates of the VMRF group for 2003 and 2004 are now available on the HEVRA website.</p>
Questions from industry and / or MS	<p>Questions were discussed regarding: the use of a new working cell seed, whether this would be a variation or a notification; the type of variation required where a MAH requests the use of an additional supplier of fetal bovine calf serum.</p>

AGENDA ITEM	DECISIONS
Best Practice Guide	The group adopted proposed revisions to the Best Practice Guide in light of the proposed changes to the meeting timetable and this document is now available on the HEVRA website.
ORGANISATIONAL ISSUES	
Date of next Meeting	The next VMRFG meeting is scheduled to take place in London on 10 March 2003, starting at 09:00 h under the Greek Presidency, chaired by Mr Ioannis Malemis.