

London, 20 March 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 10 March 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of twelve new products (ten pharmaceuticals and two immunologicals) had reached Day 80 at the February meeting.</p> <p>The Marketing Authorisations for eight of these applications has been recognised by all of the individual CMS with no withdrawals.</p> <p>One Marketing Authorisation was recognised by six CMS and withdrawn in five CMS. One Marketing Authorisation was recognised by seven CMS and withdrawn in one CMS. One Marketing Authorisation was withdrawn in both CMS. One Marketing Authorisation was recognised by fourteen CMS and withdrawn in one CMS.</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 five applications (three pharmaceuticals and two immunologicals) had reached Day 80 at this meeting. All of these products were for discussion at the meeting.</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 Clock Start Dates for 2004	<p>At the February 2003 meeting, 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 along with the clock start dates for procedures commencing in 2004 which were agreed at the March 2003 meeting.</p>

AGENDA ITEM	DECISIONS
Questions from industry and / or MS	Questions were discussed regarding: a vaccine for canine distemper currently marketed in some MS; the use of the informed consent procedure in a CMS where the Applicant is different to that for the original MRP; a question on the criteria for well-established use; the use of a new working cell seed, whether this would be a variation or a notification; Article 55(2) of Directive 2001/82/EC concerning the use of GMP certificates where no MRA is in force.
Best Practice Guide Procedure for the Automatic validation of MRP Document Management	The revised Best Practice Guide is now available on the HEVRA website. In light of the changes introduced to the BPG, a number of linked documents (procedure for the automatic validation of MRP, document management - guidance on the use of emails during MRP and standardisation of headings) have been revised and are now available on the HEVRA website.
Classification of Teat Dips	In view of the Biocides Directive 98/8/EC and the borderline with Directive 2001/82/EC many MS are reviewing the classification of teat dips. The guidance document from 1997 currently on the HEVRA website has now included a statement to that effect. It is the intention of VMRFG to produce a revised document of the position regarding the classification of these products in the MS shortly.
ORGANISATIONAL ISSUES	
Date of next Meeting	The next VMRFG meeting is scheduled to take place in London on 07 April 2003, starting at 09:00 h under the Greek Presidency, chaired by Mr Ioannis Malemis.