

London, 16 April 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 07 April 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of five new products (three pharmaceuticals and two immunologicals) had reached Day 80 at the March meeting.</p> <p>The Marketing Authorisations for three of these applications has been recognised by all of the individual CMS with no withdrawals.</p> <p>One Marketing Authorisation was recognised by eleven CMS and withdrawn in two CMS. One Marketing Authorisation was recognised by seven CMS and withdrawn in eight CMS.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 seven applications (six pharmaceuticals and one immunological) had reached Day 80 at this meeting. Six 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	
Questions from industry and / or MS	<p>Questions were discussed regarding: a vaccine for canine distemper currently marketed in two MS; a question on the criteria for well-established use; the classification (for dispensing) of veterinary medicinal products in the MS; the provision of a confirmatory study as a piece of information/notification; the requirement for accelerated stability studies where long-term stability is shown.</p>
Classification of Teat Dips	<p>In view of the Biocides Directive 98/8/EC and the borderline with Directive 2001/82/EC many MS have reviewed the classification of teat dips. VMRFG has produced a revised document on the classification of these products in the MS, to update the guidance document from 1997. This document is now available on the HEVRA website.</p>

AGENDA ITEM	DECISIONS
ORGANISATIONAL ISSUES	
Participation of Candidate Countries at VMRFG	VMRFG at the April meeting agreed to invite the ten candidate countries to send an observer to the meetings from May 2003 onwards.
VMRFG Liaison Meeting	A VMRFG liaison meeting with interested parties (IFAH-Europe –formerly FEDESA and EGGVP) will take place on 13 May 2003.
Date of next Meeting	The next VMRFG meeting is scheduled to take place in London on 12 May 2003, starting at 10:00 h under the Greek Presidency, chaired by Mr Ioannis Malemis.