

London, 23 May 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 12 May 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of seven new products (six pharmaceuticals and one immunological) had reached Day 80 at the April meeting.</p> <p>The Marketing Authorisations for four of these applications has been recognised by all of the individual CMS with no withdrawals.</p> <p>One Marketing Authorisation was recognised by seven CMS and withdrawn in three CMS. One Marketing Authorisation was recognised by seven CMS and withdrawn in eight CMS. One Marketing Authorisation was recognised by nine CMS and withdrawn in two CMS.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. The Commission Decision was issued on 16 April 2003 which supports the view of the RMS.</p>
Evaluation of Veterinary Mutual Recognition Procedures	<p>The Mutual Recognition procedures for six applications (six pharmaceuticals) had reached Day 80 at this meeting. Two of these products were for discussion at the meeting.</p>
Mineral Oil Warnings	<p>The VMRFG has agreed to write to all Marketing Authorisation holders of licences for 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. This warning may be included on the SPC at the next variation/renewal or by a Type II variation.</p>
PROCEDURAL ISSUES	
Questions from industry and / or MS	<p>Questions were discussed regarding: the need for a variation/notification where there is a change in a working seed and where the specifications remain unchanged; the provision of a confirmatory study as a piece of information/notification; the addition of species of the same family to a fish product and whether a Type II/line extension is required; and withdrawal times for a product licensed nationally in different Member States.</p>
Reasons for Withdrawals in 2002	<p>The group adopted a restricted document on the reasons for withdrawals in 2002 and this will be presented to HEVRA at their next meeting.</p>

AGENDA ITEM	DECISIONS
ORGANISATIONAL ISSUES	
Participation of Candidate Countries at VMRFG	Some of the candidate countries (Czech Republic, Hungary, Slovak Republic) have already responded to the invitation from VMRFG to send observers to the meetings.
VMRFG Liaison Meeting	A VMRFG liaison meeting with interested parties (IFAH-Europe –formerly FEDESA and EGGVP) took place on 13 May 2003.
Date of next Meeting	The next VMRFG meeting (over two days) is scheduled to take place in London on 19-20 June 2003, starting at 13:00 h under the Greek Presidency, chaired by Mr Ioannis Malemis.