

London, 27 June 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 19-20 June 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of six new products (all pharmaceuticals) had reached Day 80 at the May meeting.</p> <p>The Marketing Authorisations for all six of these applications has been recognised by all of the individual CMS with no withdrawals.</p>
Evaluation of Veterinary Mutual Recognition Procedures	<p>The Mutual Recognition procedures for nine applications (eight pharmaceuticals and one immunological) had reached Day 78 at this meeting. Seven 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 withdrawal period set for a particular product on different national markets; a request for clarification on the issue of harmonisation of SPCs; a request regarding the proposed invented name for a product; a proposal to amend the MR timetable for procedures starting in September 2003 to avoid having D90 on 23 December.</p>
Variations	<p>The VMRFG have started work on Best Practice Guides for Type IA, Type IB and Type II variations, to be finalised before the implementation of the new variation regulations in October 2003.</p>
ORGANISATIONAL ISSUES	
Participation of Candidate Countries at VMRFG	<p>Observers from the candidate countries currently participate at the VMRFG meetings and the VMRF group have decided to keep enlargement issues on the agenda as a permanent item.</p>
Contact points	<p>An updated list of contact points has been published on the HEVRA website and now includes contact points for the Candidate Countries where these are available.</p>
Date of next Meeting	<p>The next VMRFG meeting (over two days) is scheduled to take place in London on 24-25 July 2003, starting at 13:00 h under the Italian Presidency, chaired by Mr Virgilio Donini.</p>