

London, 01 August 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 24-25 July 2003

AGENDA ITEM	DECISIONS
ASSESSMENT ISSUES	
Outcome of Veterinary Mutual Recognition Procedures	<p>A total of nine new products (eight pharmaceuticals and one immunological) had reached Day 78 at the June meeting.</p> <p>The Marketing Authorisations for three of these applications has been recognised by all of the individual CMS with no withdrawals. One Marketing Authorisation was recognised by ten CMS and not validated in one CMS. One Marketing Authorisation was recognised by ten CMS and withdrawn in five CMS. One Marketing Authorisation was recognised by ten CMS and withdrawn in one CMS. One Marketing Authorisation was recognised by three CMS and withdrawn in one CMS. One Marketing Authorisation was recognised by three CMS and withdrawn in two CMS. One Marketing Authorisation was recognised by nine CMS and withdrawn in six CMS.</p>
Evaluation of Veterinary Mutual Recognition Procedures	<p>The Mutual Recognition procedures for four applications (all pharmaceuticals) had reached Day 78 at this meeting. Three 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 Directive provisions regarding requirements for mutagenicity data; a teat-dip product; the bioequivalence guideline and the need for bioequivalence data in each target species; variations to be submitted regarding the change in a MAH address.</p>
Variations-Best Practice Guides	<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. These guides will be released for general consultation on the HEVRA website on 04 August for a period of one month</p>

AGENDA ITEM	DECISIONS
ORGANISATIONAL ISSUES	
Enlargement and VMRFG	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. Various issues regarding the phasing in of mutually recognised products were discussed at the July meeting.
Date of next Meeting	The next VMRFG meeting (over two days) is scheduled to take place in London on 18-19 September 2003, starting at 13:00 h under the Italian Presidency, chaired by Mr Virgilio Donini.