

London, 20 November 2003

REPORT OF THE VMRFG MEETING – FOR RELEASE

Meeting of 13-14 November 2003

| AGENDA ITEM | DECISIONS |
|---|---|
| ASSESSMENT ISSUES | |
| Outcome of Veterinary Mutual Recognition Procedures | <p>A total of six new pharmaceutical products and one immunological had reached Day 78 at the October meeting.</p> <p>The Marketing Authorisations for two of these applications has been recognised by all of the individual CMS with no withdrawals. One of these applications was recognised by thirteen CMS and withdrawn in one CMS. One Marketing Authorisation was recognised by nine CMS and withdrawn in three CMS. One Marketing Authorisation was recognised by five CMS and withdrawn in one CMS. One Marketing Authorisation was recognised by two CMS and withdrawn in three CMS. One Marketing Authorisation was recognised by two CMS and not validated in two CMS.</p> |
| Evaluation of Veterinary Mutual Recognition Procedures | <p>The Mutual Recognition procedures for ten applications (six pharmaceuticals and four immunological) had reached Day 78 at this meeting. Seven of these products were for discussion at the meeting.</p> |
| PROCEDURAL ISSUES | |
| Questions from industry and / or MS | <p>The question regarding whether a Regulatory Affairs Consultant could apply for a Marketing Authorisation on behalf of a Company outside the EEA was re-discussed. Additionally the group discussed the following questions: what type of variation could be applied on the deletion of a route of administration; withdrawal of a product from a national market during a variation procedure; requirement for residue data (udder tissue); assessment reports in CTD format; batch release ('retesting') of products imported to the EU from 3rd countries with a focus on vaccines.</p> |
| Best Practice Guide For Veterinary MRP Including CAVDRI Additions | <p>The VMRFG finalised the discussion on The Best Practice Guide for veterinary MRP including CAVDRI additions; this new document was adopted and will be placed on the Hevra website.</p> |
| Revision of Volume 6 A – Chapter 2 and Chapter 5 of the Notice to Applicants | <p>The VMRFG discussed the comments from MSs and the amendments which were made on both chapters of the Notice to Applicants.</p> |
| ORGANISATIONAL ISSUES | |
| Date of next Meeting | <p>The next VMRFG meeting (over two days) is scheduled to take place in London on 11-12 December 2003, starting at 13:00 h under the Italian Presidency, chaired by Mr Virgilio Donini.</p> |