

Meeting of the Heads of Regulatory Authorities

17/18 May 1998, Rome

1. At the meeting of the Heads of Regulatory Authorities which concluded today, the Group expressed their warm thanks and congratulations to IMS HEALTH for organizing the 5th Conference of Medicines Agencies.

2. The Heads of Agencies Meeting considered a very full agenda of business and a number of important decisions were taken. In particular, the Group approved plans to set up its own web site. The site was launched today at the Conference and contains information about the activities of the Heads of Agencies Group, the Mutual Recognition Facilitation Group (MRGF) and information from individual agencies. It would also include a link to web sites of individual member states, and of EMEA and European Commission.

3. The Heads of Agencies reviewed progress with the Mutual Recognition Procedure. They noted a number of encouraging developments. More than 300 procedures representing some 400 products, had been successfully considered with more than 500 variations. The introduction of automatic validation from 1 May has "at a stroke" resolved major concern. There has been a marked reduction in the number of withdrawals from 1 January 1998 about 50 %. The Heads of agencies reaffirmed their personal commitment to the further development of the Mutual Recognition System as their highest priority to complete the Single Community System. It was agreed to hold a workshop on Transparency and Visibility on the Mutual Recognition System in London later in the year.

4. The Group also agreed to pursue further measure to strengthen collaboration in the training of assessors and professional experts.

Ends

18 May 1998

Notes.

Adress of the Heads of Agencies Web Site is:
<http://heads.medagencies.org>