

Press release

Meeting of the Heads of Agencies

27th and 28th February, Uppsala

At their first meeting under the Swedish Presidency the Heads of Agencies met on 27th and 28th February 2001 in Uppsala. In addition to delegates from Member States, representatives from the European Commission and the EMEA attended the meeting. Observers from Iceland, Norway and Slovakia, the latter as a representative from CADREAC, were also present.

The Heads of Agencies endorsed a Joint Audit Programme for GMP (Good Manufacturing Practices) inspections with a view to evaluate their inspection systems, with the mission, wherever necessary, to implement corrective actions likely to guarantee the quality equivalence of these systems throughout all Member States. The programme includes audits, training and supervision of the programme.

In the follow-up of the December Paris meeting held under the French Presidency, discussions focused on the review of the European system for evaluation and control of medicinal products. The discussion was based on the Commission discussion document dated 22 January, 2001. The Heads of Agencies endorsed two new objectives that had been introduced in the document, namely to strengthen the pharmacovigilance procedures and to increase the number of veterinary products available. The Heads also accepted the option for generic versions of centrally authorised products to go either through the centralised procedure or the mutual recognition procedure.

The Director of EMEA, Mr Thomas Lönngren, presented the work programme for EMEA for the year 2001, which had been discussed at the EMEA Management Board meeting last week. The EMEA could foresee an increase in workload, partly due to the success of the new system for orphan drugs. Mr Lönngren requested that the heads discuss priorities in the future.

There was an update of activities of the Mutual Recognition Facilitation Group (MRFG) and of the EudraTrack Subgroup. The results of the monitoring programme on withdrawals were also presented. The figures showed a slight decrease in the percentage of withdrawals. A decision was made to publish the statistics and that the exercise will be continued, at least until the next meeting of the Heads of Agencies group.

IT was discussed in depth. It was decided that a workshop should be organised in May 2001 on IT strategy and the implementation thereof. The Swedish Presidency and the EMEA took on this task. The workshop should be open to delegates from Member States, the EMEA and the Commission; both from DG Enterprise and the JRC. The IT strategy and implementation plan should be decided at the next meeting of the Telematic Steering Committee in June.

The group discussed TSE and how to handle the current situation with difficulties for companies to conform to the administrative actions needed with respect to the new Directive. The Heads of Agencies endorsed the regulatory actions, e.g. for products for which companies have failed to present the necessary TSE-data, proposed by MRFG.