

**Meeting of the Heads of Agencies
3 and 4 June 1999 - Berlin**

At their last meeting under German Presidency the Heads of Regulatory Authorities met on 3 and 4 June 1999 in Berlin. The European Commission and the Executive Director as well as the Head of Human Medicines Evaluation Unit of the EMEA took part. Observers from Iceland Norway and Hungary, the latter as a representative from CADREAC (Collaboration Agreement between Drug Regulatory Authorities in European Union and Associated Countries) were also present.

A part of the meeting was held jointly with the Mutual Recognition Facilitation Group (MRFG) to discuss mainly the functioning of the decentralised procedure. Overall the Mutual Recognition procedure was considered to work well and both groups are currently dealing with improving it.

The Chairperson of the MRFG reported about the results of the MRFG meetings in March, April and May. The issues discussed were line extension, duplicate application, and second wave.

One of the main points of the agenda were reasons for withdrawals. Both groups emphasized the importance of careful analyses of withdrawals and supported the usage of arbitration especially for safety reasons.

The groups discussed in principle the need of a MR-SPC and expected further information in an experimental phase from the MRFG.

The Heads of Agencies and the MRFG agreed that a joint meeting every year would be useful. It was agreed to invite members of the CADREAC countries as regular observers to the MRFG meetings.

Information Technology was discussed in detail. Management of IT-Projects was one of the main topics. Commission, EMEA - Executive Director and Heads agreed on the institution of an IT-Steering and Decision body as responsible IT-management steering board of European Pharmaceutical Regulators supported by a management group acting as an interface and coordinating group. In connection with the initiative to restructure the IT-Management for European Pharmaceutical Regulators a meeting will take place in July to update the current development.

The technical possibilities for establishing Video conferences as a valuable tool were discussed and further actions for achieving a solution were agreed.

Status and planning of next steps of the Pan European Regulatory Forum on Pharmaceuticals (PERF) initiative were presented by the EMEA and discussed.

The Paul-Ehrlich-Institut (PEI) tabled a proposal for the future handling of the so-called Plasma Master File (PMF). The PMF regulates the content and format of the information necessary for the starting material for human blood and plasma derived medicinal products and shall lead to a harmonised approach to this issue in all EU-MS. The initiative of the PEI was fully endorsed by the Heads of Agencies and the Commission. The necessary changes of the legal basis (Directive 75/318/EEC) will be considered by the Commission. The different working parties of the CPMP and the MRFG shall be involved in the development of a concept paper for the relevant variation procedures and the scientific update of the format of the PMF.

The Paul-Ehrlich-Institut presented suggestions how to solve problems emerging from the diverging European vaccination schedules in clinical trials and SPC's for vaccines for primary immunisation of infants. A proposal was made how prototype vaccination schedules could look like in order to overcome obstacles arising from different vaccination policies. The Heads of Agencies took note of this initiative and will re-discuss it at their next meeting.

The next meeting of the Heads of Agencies will take place in Helsinki under the Finnish Presidency in October 1999.

June 1999