

## **Meeting of the Heads of Agencies**

7 and 8 March 1999 – Berlin

On the occasion of their second meeting under German Presidency the Heads of Regulatory Authorities met on 7 March 1999 in Potsdam and on 8 March 1999 in Berlin. The European Commission, DG III, and the Executive Director of the EMEA took part. Present were also observers from Norway and Hungary, the latter as a representative from CADREAC (the group of the Central and Eastern European Countries).

The EU Commission informed the Heads that there will be an audit concerning centralised and decentralised procedures. Final results are awaited by the beginning of 2000. The Heads of Agencies acknowledged the paper on the "Conduct of Pharmacovigilance for Medicinal Products authorised through the Mutual Recognition Procedure". It was finalised by the CPMP Pharmacovigilance working party in February 1999.

The Heads took notice of the report from the ad hoc Working Group on Herbal Medicinal Products. It deals with regulatory aspects, quality, safety, and efficacy of herbal medicinal products. The need was raised to further discuss quality matters and legal perspectives of homeopathic products derived from an informal assessors meeting in Berlin as well as to improve the acceptance of these products in the enlarging community.

Information Technology was discussed in detail. Management of IT-projects was one of the main topics. Different proposals for reforming the structure and the management were presented. Heads, Commission and the Executive Director of the EMEA realised the need for common leadership to improve the IT platform. The Commission will be asked to reconsider the mandate of the "telematic Conference" in order to implement stronger the common responsibility for various projects' development. The item will be presented to the Pharmaceutical Committee followed by a discussion of the state of development of the various projects before further discussed at the next meeting of the Heads of Agencies. Strong support for the International Reviewer Forum which harmonises user requirements was given.

The MRP-Index will be launched by 15 April 1999.

The Chairperson of the Mutual Recognition Facilitation Group (MRFG) reported about the last MRFG meeting in February. The issues discussed were line extensions, duplicate application, and second wave. A paper on second wave will soon be finalised. Plasma Master File will be an item on the agenda of the next meeting of the MRFG.

The Heads are invited to join the 9th ICDRA Conference of drug regulators in Berlin (25-29 April 1999) preceded by meetings for African and New independent states in Berlin. The next meeting of the Heads of Agencies will take place in Berlin on 3 and 4 June 1999. The meeting will be partly joined by the MRFG to discuss mainly the functioning of the decentralised procedure.

8 March 1999

### **Postscriptum to the Press Release – Reminder:**

The MRP Index will be launched by 15 April 1999 and presented to a broader audience on the occasion of the ICDRA Conference in Berlin 25-29 April 1999.