

**National Organisation
For Medicines**



HoA meeting, 28 May 2003

Press release

The second meeting of Heads of Agencies under the Greek Presidency took place on 28 May 2003 in Athens. Representatives of fourteen Member States, the European Commission and EMEA attended the meeting. Observers from EEA (Norway) and Candidate Countries (Czech Republic and Hungary) were also present.

An update of relevant developments and the model for “excellence in pharmacovigilance” a stocktake of progress in taking forward the European Risk Management Strategy (ERMS), proposals for decision and future priorities were extensively discussed.

The draft mandate of the PhVWP, as agreed by the CPMP and the PhVWP, was accepted by the Heads. The practical consequences of the mandate in terms of human and financial resources were also discussed. The ERMS working group was asked to take forward the activities needed for the wider developments in the context of pharmacovigilance. It was also agreed that as it concerns the MRP, the MRFG will liaise with PhVWP to undertake a programme of recommendations for best practice to ensure effective co-ordination of decision making and rapid implementation on risk management issues. Once finished this Best Practice Guide will be sent to HoA for endorsement.

The recent developments on the Review were presented by the Commission. It was mentioned that the Greek Presidency is speeding up its efforts to reach a political agreement. Despite the fact that the Member States on some issues do not follow the Commission’ proposal, there is a strong possibility of a balanced compromise.

The Chair of the MRFG gave an overview of the progress in the activities of the Mutual Recognition Facilitation Group including recent statistics, an overview of new and updated MRFG documents and a first approach on the Patient Information Leaflet in the context of the Review.

The importance of the future Co-ordination group in MRP was emphasized as well as the need for careful planning of the relevant future activities.

HoA were informed that Candidate Countries participate in the MRFG as observers since their May meeting. HoA agreed to maintain Romania and Bulgaria as observers to the MRFG meetings.

The Chair of the EMACOLEX presented a report of the work of the group. The issues discussed included: Harmonization of SmPCs, Usage Patents, Enlargement issues, Well Established Use Directive, Parallel Trade, Shortage of Medicines. The way forward for some of them was also proposed.

HoA have been informed about the recent work of the joint CPMP/MRFG Working Group on Harmonisation of SPCs. After discussion a decision for the future of the SPC Harmonisation Project was left to the next HoA meeting in Verona.

The next HoA meeting will be held on 8-9th July 2003 in Verona, Italy.