

Press release

## ***Meeting of the Heads of the European Drug Regulatory Authorities (HoA),***

13 and 14 June 2000

The last meeting of the Heads of the European Drug Regulatory Authorities under the Portuguese Presidency took place on the 13 and 14 June 2000, in Sintra. Twelve Member States were present at the meeting. Apologies were received from Italy, Spain and Luxembourg. The Executive Director of the EMEA and representatives of the European Commission (DG Enterprise) also took part, as well as observers from Norway, Iceland and the Slovak Republic, the latter as a representative from the CADREAC.

The Review of the European System of Authorisation and Supervision of Medicinal Products was the main point of the discussions held in the meeting. The HoA agreed on some specific issues which will be the object of further elaboration by the Member States, aiming at presenting the conclusions at the next HoA meeting, during the French Presidency. These conclusions will serve as a contribution from the HoA group to the European Commission's reflections in anticipation of the legislative proposals. Information was provided on the decisions made in the Telematics Steering Committee meeting, which was held on the 12th June, in Sintra. The new IT management structure was presented.

A recommendation that the PERF programme shall be continued was issued. The new programme may start already in October 2000, providing that enough funding is available.

The organisation and support given to the HoA website were also discussed.

There was an update of the 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 exercise will be continued and the importance of the participation of all Member States was stressed.

It was decided that the Group should elaborate a list of areas to be addressed in the frame of future junior and senior assessors training programmes.

The Group was given information on the difficulties found by the new members of the Mutual Recognition System (Iceland and Norway) and solutions will try to be found within the MRFG. The next meeting of the Group will be held in St. Denis, France, on the 12th and 13th October 2000.

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