



Athens, March 6, 2003

HoA/HEVRA meeting, 25 February 2003

Press release

A meeting of HoA/HEVRA took place on 25th February 2003 in Athens under the Greek Presidency. Representatives of thirteen Member States, the European Commission and EMEA attended the meeting. Observers from EEA (Norway and Iceland), CADREAC and CAVDRI were also present.

The joint HoA/HEVRA meeting focused on enhancing co-operation among the Regulatory Authorities for Medicinal Products of member and candidate countries.

Information technology was discussed in detail. The evolution of Eudratrack to the Communication Tracking System (CTS) was presented, including a CTS training program for candidate countries. The Heads decided to create an ad-hoc working group on CTS reengineering. A timetable and the resources required for CTS reengineering will be investigated by this group. The CTS reengineering group (CTS-RG) should liaise with the CTS user group. The involvement of the candidate countries in the CTS user group, depending on feasibility, was also proposed.

Issues related to the Enlargement were followed up. The importance of close co-operation with the candidate countries on the procedures of EU legislation and especially MRP phasing in was emphasized. It was decided to invite candidate countries to join VMFRG and MRFG as soon as feasible. In the context of co-operation and discussions/dialogue within MRFG the creation of an enlargement task force was proposed by their representative and will be further elaborated. Enlargement issues will also be on the agenda of the next HoA/HEVRA meeting in Greece.

Concerning the Review of the pharmaceutical legislation the Heads were informed that the plan of the Greek Presidency is to achieve a common position on the Regulation and complete the first reading of the Directives.

The Heads of Agencies were also informed about the progress on training of assessors, an item that is considered of great importance.



The Heads were appreciative of the report on the optimal use and mutual recognition of the Official Medicines Control Laboratories (OMCLs) presented by EDQM, especially as it concerns the achievements and perspectives of a common quality system within the OMCL network.

The next joint HoA/HEVRA meeting will be held on 27th May 2003 in Athens.