

**National Organisation
For Medicines**



HoA/HEVRA meeting, 27 May 2003

Press release

The second meeting of HoA/HEVRA under the Greek Presidency took place on 27th May 2003 in Athens. Representatives of fourteen Member States, the European Commission and EMEA attended the meeting. Observers from EEA (Norway), CADREAC and CAVDRI were also present.

The joint HoA/HEVRA meeting focused on enhancing co-operation in telematics, pharmacovigilance and the phasing-in of Candidate Countries in the EU.

The results achieved so far confirm the good co-operation between the regulatory agencies. The planning of resources of the regulatory authorities in the context of the running projects was also discussed.

The need of careful assessment of the public health benefit versus resource implications was emphasized.

EudraVigilance was discussed in detail.

The EudraVigilance database and dataprocessing network has been recognized by Heads of Agencies as an important pillar of the European Risk Management Strategy since it should facilitate the rapid exchange of Individual Case Safety Reports (ICSRs) and the integration of automated tools of signal detection.

In addition, EudraVigilance provides the possibility of the appropriate structuring of spontaneous case report information and the use of a harmonized medical terminology as agreed at international level.

An updated status report was presented by the EMEA describing the current status of implementation of EudraVigilance in Human and Veterinary sectors. In addition, for EudraVigilance Human, the consequences of the implementation in relation to the establishment of a European Risk Management Strategy and, in a broader perspective, the contribution to the protection of public health have been highlighted.

Practical issues such as ICSR e-reporting, the 15 day reporting requirement and the quality of pharmacovigilance data were discussed.

The Heads reaffirmed their agreement to accept the parallel e-reporting by pharmaceutical companies of the EU cases to EMEA.

They also reaffirmed their commitment to investigate how difficulties can be efficiently addressed.

The Chairman of the ad hoc working group for the CTS-EudraTrack re-engineering procedure, presented a comprehensive report for this project. The reengineering proposal is the first phase of an upgrading project that has to be undertaken in the short term in order to guarantee that the system responds to incoming demands (Enlargement, Variations Regulation) and fulfils state-of-the-art standards.

The Heads were appreciative of the report. Practical issues will be carefully followed.

HoA/HEVRA were informed on the Europharm database project. The work performed up to now, the future activities and the responsibilities according to the implementation plan were presented by INFARMED. The Heads were appreciative of the progress report and recognised the importance to further discuss the issue and address strategy to progress the project at the next TSC meeting and at the HoA/HEVRA meeting in November.

Issues related to the Enlargement were followed up. Candidate Countries have started joining CPMP, CVMP, MRFG and VMRFG . The Heads were informed about the recent developments to prepare both Candidate Countries and EU Member States for the new situation after the Enlargement. The importance of PERF in resolving phasing-in issues and proposing regulatory issues was acknowledged.

The Heads will keep the Enlargement as a permanent item in their meetings.

A paper entitled “ Guidelines outlining the purpose and working method for HoA, HEVRA and joint HoA/HEVRA ” was endorsed by the Heads.

Given the increasing number of meetings at EU level, the Heads were updated on video conferencing and other new meeting technologies as alternatives to traveling.

The next joint HoA/HEVRA meeting will be held on 26-28 November 2003 in Rome.