

**The 65th meeting of the Head of Medicines Agencies, (HMA)
28-29 April 2011 Visegrád**

STAKEHOLDERS' INFORMATION

28 April 2011 – Human Session

- **PHARMACOVIGILANCE** - The Chair of the European Risk Management Strategy Facilitation Group (ERMS FG) and EMA gave a status report about the implementation of the new legislation on pharmacovigilance. After discussion HMA agreed that an update on the implementation of the legislation will be given at each HMA meeting in order to provide information on progress made and to identify any major issues which require resolution.
- **GOOD CLINICAL PRACTICE** - The Chair of CMDh gave a progress report. Based on that report HMA endorsed the mandate of CMDh GCP IWP to coordinate and monitor an annual risk based programme of routine inspections to CRO's often used in the conduct of bioequivalence trials.
- **CLINICAL TRIALS** - HMA discussed the future revision of the Clinical Trials Directive and agreed on a common position to the European Commission consultation paper.
- **MEDICINES AND MEDICAL DEVICES** - HMA received feedback on a first joint workshop between HMA and Competent Authorities on Medical Devices held in Budapest on 27 April. This was considered a positive interaction for the discussion of the main challenges to both sectors and to seek for issues for further cooperation. A second meeting will take place in the second semester of 2011.

28 April 2011 – Joint Session

- **TRANSPARENCY** - HMA agreed on the HMA/EMA Working Group on Transparency guidance document on the identification of commercially confidential information and protection of personal data within the structure of the marketing authorisation (MA) dossier and the release of information after the granting of a marketing authorisation. The document was endorsed and supported for public consultation to stakeholders during the next 3 months.
- **EFFICIENT USE OF RESOURCES** – HMA endorsed the use of the harmonised technical validation criteria as proposed by the Chair of the Task Force on Resources in MRP/DCP. HMA also endorsed that the Reference Member State (RMS) is to do the technical validation.
- **TRAINING** - HMA endorsed the report of the first year of operation of the Office of Training Steering Group (OTSG) and took note of a list of available scientific and regulatory training events for use by the European Regulatory Network during 2011.
- **BENCHMARKING** - HMA adopted the interim report of the Benchmarking of European Medicines Agencies Steering Group (BEMA SG) based on the first half of the BEMA II visit schedule containing the key interim findings of the benchmarking visits from June 2008 up to

November 2009. The executive summary of the document will be publicly available on the HMA website.

HMA also approved the draft list of KPIs and SPIs for the BEMA III questionnaire and re-confirmed the scope of the benchmarking programme. The BEMA Steering Group will further develop proposals for the BEMA III programme.

- **TELEMATICS** - The Telematics Support Group (TSG) presented an updated report on the Common EU Submission Platform (CESP), which aims to provide a single EU submission platform that can be used both by industry and the EMA. The TSG will take forward the Proof of Concept Study and report back at the second HMA meeting during the Polish Presidency.

29 April 2011 - Veterinary Session

- **PSUR WORKSHARING** - HMA agreed on the measures for further improvement on the PSUR worksharing in the framework of European Surveillance Strategy (ESS). There was an agreement that all MSs should act at least once a year as P-RMS. HMA was asked to promote the existence of the work sharing system to Marketing Authorisation Holders nationally.
- **BORDERLINE WORKING GROUP** - HMA endorsed the mandate of the CMDv Borderline Working Group.
- **AVAILABILITY** - HMA noted the report on the survey of implementation of legal provisions to improve availability of veterinary medicines. The written report will be published on the HMA website.