

**Draft Stakeholders' Information****57th meeting of Heads of Medicines Agencies  
18 – 19 May 2009  
Marienbad, Czech Republic****The Heads of Medicines Agencies – Human Session on 18 May 2009**

- HMA and the European Commission discussed the pharmaceutical package currently under discussion by the Council Working Party, specifically the legal proposals on counterfeit, information to patients and pharmacovigilance.
- Information on the outcome of the public consultation on the draft Eudravigilance access policy for medicines for human use was provided. The Eudravigilance Access Policy shall be further discussed and submitted for approval in autumn 2009 at both EMEA Management Board and HMA levels.

**The Heads of Medicines Agencies – Joint Session on 18 May 2009**

- HMA discussed the 2005 HMA Strategy Paper and agreed to start working on its update in order to respond appropriately to the challenges the European Medicines Regulatory Network is faced under an ever changing nature of the pharmaceutical sector.
- HMA welcomed the publication of the uniform requests form for NCAs to act as Reference Member States under the Decentralised Procedure. HMA also agreed on the next steps on the current work on MRP and DCP, focused on improving the quality of dossiers and assessment reports.
- HMA also discussed a proposal for a more consistent and regular interactions with stakeholders. Following the discussion, the proposal will be reviewed and further discussed at a future HMA meeting.
- The HMA/EMEA Training Project Team Report presented a draft Strategy for Regulatory and Scientific Training within the European Regulatory Network which was endorsed for internal consultation within HMA. The document will be further discussed and submitted for adoption at the next HMA meeting.
- HMA agreed to carry out an evaluation study on the EudraPharm Project in 2009 in order to redefine implementation priorities.
- Agreement was also achieved by HMA in carrying out an analysis to determine the feasibility of the concept of a single business support system to regulatory activities between agencies and stakeholders.

## **The Heads of Medicines Agencies – Veterinary Session on 19 May 2009**

- HMA decided to publish the Reflection Paper on the Improvement of the Veterinary Pharmaceutical Legislation for external consultation on the HMA website until mid August 2009. The document includes ideas and reflection on the different issues of the current veterinary pharmaceutical legislation.
- HMA discussed with the European Commission the views related to the area of antimicrobial resistance.
- HMA endorsed the Draft HMA Strategic Plan on Antimicrobial Issues. HMA will consider further steps with respect to the external consultation of the document.
- HMA discussed the draft HMA-v Action Plan on antimicrobial resistance which aims to bring together different actions in this area at the HMA level.
- HMA discussed the results of the pilot phase for the PSUR worksharing project and how to handle this project in the future.
- HMA adopted a revised mandate for the PhVWP(v) and a proposal for the EMEA training programme in veterinary pharmacovigilance.
- HMA discussed the development of e-submissions in the veterinary area and its future perspective.
- HMA discussed the impact of the new variations regulations on the workload for NCAs.