

## **Stakeholders' Information**

### **56th meeting of Heads of Medicines Agencies 26 – 27 January 2009 Prague, Czech Republic**

#### **The Heads of Medicines Agencies – Human Session on 26 January 2009**

- The participants of the meeting were informed on the activities of the European Risk Management System Facilitation Group. Furthermore to the ERMS issues, the HMA consented to the publication of the 2008 Public Status Report on the Implementation of the European Risk Management Strategy.
- Regarding the proposal for involvement and participation of patients and consumers representatives in the meetings of the CHMP and PhVWP(h), start of the pilot phase in 3 consecutive meetings of PhVWP(h) was consented.
- The representatives of the European Commission presented an update on EU pharmaceutical legislation. The presentation included all three legislative proposals as well as the communication to the European Parliament and the Council, adopted on December 10, 2008 within the so called “Pharmaceutical Package”.

#### **The Heads of Medicines Agencies – Joint Session on 26 January 2009**

- The Chair of the Task Force on Availability of Resources for MRP and DCP dealing therewith reported the HMA on its activities, especially the Request Form for DCP which will be published at the HMA website. This Form is intended to be a simple document, short and easy to fill in and bring most important details in order for a RMS to estimate the work load and prevent double booking and simplify slot management. The message from report was avoiding Parallel assessment by the CMS.
- HMA was also informed on the outcomes of a EMEA/HMA Workshop on Transparency issues.
- HMA was given a presentation on the issue of antimicrobial resistance in the human areas, highlighting the current challenges, complexity of the problem and the need for intersectorial attitude. An update of the activities and progress made in the area of veterinary medicine was given as well.

### **The Heads of Medicines Agencies – Veterinary Session on 27 January 2009**

- The HMA Action Plan on antimicrobial issues was introduced.
- EMEA informed the HMA about the areas and needs for future co-operation between HMA and EMEA. It was proposed to organise a co-ordination meeting in May 2009 to improve co-ordination of different activities. Participation of stakeholders was proposed.
- HMA were informed about the progress concerning the veterinary pharmaceutical and residues legislation, namely revision of Annex I to Directive 2001/82/EC, as amended and the new MRL regulation.
- Update on the Task Force Working Group on Veterinary Legislation was given by the chair of that group – the following updated documents were presented to the HMA meeting, namely the Report of the Task Force, last updated Draft of the Reflection Paper and the Draft Work Plan and a Draft List of Action.
- The format of meetings between HMA and stakeholders was discussed.