

STAKEHOLDERS' INFORMATION

62nd meeting of Heads of Medicines Agencies (HMA)

5-6 July, 2010, La Hulpe, Belgium

Heads of Medicines Agencies – Veterinary Session on 5 July 2010

- HMA discussed the way forward on how to revise the Action Plan on Antimicrobials Resistance (AMR) in application of the adopted HMA Strategic Plan on AMR at the April 2009 meeting. A proposal will be sent out for comments from HMA by the Belgian Presidency and an updated Draft Revised Action Plan will be submitted for adoption at the October meeting.
- The European Medicines Agency (EMA) presented the draft Eudravigilance Veterinary Access Policy. HMA discussed the draft and general support was given with some proposals for adaptation. EMA will reexamine the draft Eudravigilance Veterinary Access Policy on these points and will submit the draft for adoption at the October Management Board.
- HMA endorsed the initiative of Periodic Safety Update Report (PSUR) evaluation worksharing in the veterinary field.

Heads of Medicines Agencies – Joint Session on 5 – 6 July 2010

- The HMA management group was enlarged with Guido Rasi (IT) and Martina Cvelbar (SI).
- In relation to the October meeting, HMA discussed and supported the idea to have a meeting with the European Generics Association (EGA) in the margins of that meeting on 26 October. The Belgian Presidency will undertake to organize this meeting.
- EMA presented the revised Transparency Policy and the actions envisaged with regard to access to pharmaceutical company data. HMA discussed and supported the draft which will be submitted for adoption at the October Management Board. At the October meeting the HMA/EMA Transparency Group will present an update report on the Transparency Recommendations.
- A status report was given by the Task Force Resources in Mutual Recognition Procedures (MRP) and Decentralized Procedures (DCP). HMA endorsed different proposals for operational improvements such as the list with validation criteria and the conditions under which the Reference Member State (RMS) can start the procedure after the validation phase. HMA supported the elaboration of further proposals for operational improvements by the Task Force.
- HMA endorsed the draft Memorandum of Understanding on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities (NCA's) for services to the Agency. EMA will submit the draft for adoption at the October Management Board.

- HMA noted the update given by the former Spanish Presidency on the Intersectoral Conference on Veterinary Medicines.
- The Working Group on Product Testing (WG PT) gave an update report and HMA supported the next steps as proposed by the WG PT such as the publication of the document on Principles for the Mutual Recognition of Testing Results and further collaboration with the Coordination Group for Mutual Recognition and Decentralized Procedures for Medicinal Products for Human Use (CMDh) in order to elaborate proposals for implementation of risk analysis for MRP/DCP products.
- HMA discussed and adopted the draft Strategy Paper II 2011-2015. The draft Strategy Paper II will go for public consultation until the end of July.
- In order to prepare the elaboration of an action plan of the Strategy Paper II 2011-2015, 4 break-out sessions were held on the following items: Best Practices, Resources, External Communication and Working Methods.
- HMA discussed the third cycle of BEMA (HMA Benchmarking exercise) and endorsed its continuation as well as some proposals for improvement such as increased transparency and the revision of the questionnaire. The BEMA Steering Group will elaborate further on those proposals by the first half of 2011.

Heads of Medicines Agencies – Human Session on 5 – 6 July 2010

- HMA took note of the first reading agreement concerning the legislative proposal on pharmacovigilance between the European Parliament and the Council of the European Union. HMA took also note of the good progress made on the legislative proposal on falsified medicines in the Working Party on Pharmaceuticals and Medical Devices.
- Concerning the Incident Review Network, an update report was given on the Incident Management Plan and HMA agreed with the identified areas for improvement. HMA decided to extend the pilot phase with 12 additional months. HMA also endorsed the proposal to progress in the preparation of the implementation of the revised Access Policy. Furthermore, HMA noted the progress made in the PSUR worksharing initiative.
- EMA informed HMA of the Workshop on clinical trials in 3rd countries on 6 September. The Belgian Presidency informed HMA of the Ministerial Conference on ‘Innovation and Solidarity in Pharmaceuticals’ on 23-24 September.