

STAKEHOLDERS INFORMATION

60th meeting of Heads of Medicines Agencies (HMA)

28-29 January, 2010
Madrid, Spain

Heads of Medicines Agencies – Veterinary Session on 28 January, 2010

- The preliminary results of the questionnaire on the legal status of veterinary medicines were presented. Final results will be presented in the April HMA.
- A report was given on the Spanish antimicrobial surveillance network (VAV) devoted to monitoring antimicrobial resistance in zoonotic and commensal bacteria isolated from healthy animals at the slaughterhouse level. The main features and results obtained since the beginning of the working-point in 1996 were presented.
- The European Commission gave an update report on the review of veterinary medicines legislation and key issues, policy initiatives for antimicrobials and the implementation of maximum residue limits.
- The European Medicines Agency (EMA) reported on the Task Force created by the Committee for Medicinal Products for Veterinary Use to review strategically how the committee handles referrals relating to veterinary medicinal products in view of the increasing workload in this area. This would also ensure coherence with other activities as regards referrals in other forums, such as the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDv) and HMA.
- EMA gave an update on the progress in a survey on the availability of vaccines against the priority diseases listed within the DISCONTTOOLS project.
- Bearing in mind comments received during the consultation phase, the revised principles for Access to EVVet data (EudraVigilance for Medicines for Veterinary Use) were discussed. A revised policy will be drafted by the EMA and presented in the July HMA.



Presidencia
Española



2010.es

Heads of Medicines Agencies – Joint Session on 28 January 2010

- A report was given by the HMA/CMD-h Task Force on the Availability of Resources at National Competent Authorities (NCA) for Mutual Recognition Procedures (MRP) and Decentralised Procedures (DP). HMA endorsed the proposals made by the Task Force and recommended focusing on further operations for the improvement of DC and MRP.
- The Telematics Support Group gave an update report on its activities and HMA endorsed a proposal to begin with a Feasibility Study on an EU Submission Platform. It was proposed to hold a specific workshop to discuss the long-term IT strategy of the network.
- A progress report on the e-submission readiness was presented by the Telematics Implementation Group and key findings were shown. HMA adopted the e-CTD Survey Report (electronic- Common Technical Document), which will be published.
- A HMA workshop on e-readiness will be organized during the next HMA meeting in order to achieve full e-readiness within the network.
- The HMA/EMA Training Strategy and Action Plan was adopted by HMA. HMA also approved the creation of an office dedicated to training and the setting up of a Steering group which will oversee the implementation of the Strategy and Action Plan.
- HMA supported all the work done by the Working Group of Communication Professionals and noted the relevance of the communication network established within the HMA.
- The experience with the pandemic vaccines assessment procedures and communication strategies was discussed and it was agreed to go on with this in order to identify opportunities for improvement. Continued high regulatory activity is expected in the coming months with regard to the influenza vaccines.
- HMA agreed to use the stakeholder's information document as the main tool for communicating the key issues discussed by HMA.
- HMA adopted the Terms of Reference of a Focus Group on "Improvement of the veterinary medicinal products legislation and regulation". The objective of the focus group is to prepare a report setting out the view of specific groups and their proposals for improvement that may be reflected in future legal framework. The



Presidencia
Española



2010.es

Focus group will consist of stakeholders, heads of agencies or representatives appointed by heads of agencies and members of the Task Force Working Group on Improvement of Legislation.

- The European Commission gave a report on the effects of the Treaty of Lisbon on pharmaceutical *acquis*.

Heads of Medicines Agencies – Human Session on 29 January, 2010

- HMA supported the participation of patient/consumer representatives in the Pharmacovigilance Working Party as well as the proposed procedure for selection.
- The chairpersons of the Council Working Party on Pharmaceuticals and Medical Devices reported on the current situation of the proposals for Pharmacovigilance and falsified medicinal products. The objective of the Spanish Presidency is to work for a first Reading Agreement / Political Agreement.
- A report was presented on the main consequences and new tasks for the NCA when the proposals for pharmacovigilance and falsified products enter into force.
- An update report was given by the Task Force on the Availability of Human Medicinal Products. HMA supported the further work of this Task Force.