

## STAKEHOLDERS' INFORMATION

### 61<sup>st</sup> meeting of Heads of Medicines Agencies (HMA)

12-13 April, 2010  
Sevilla, Spain

#### Heads of Medicines Agencies – Veterinary Session on 12 April, 2010

- HMA discussed several issues related to the development of antimicrobial resistance:
  - o The results of the questionnaire on the legal status of antimicrobial veterinary medicines were discussed and HMA decided to further investigate the differences within Member States so as to understand the different practices to control the use of antimicrobials and make use of those results in the HMA Action Plan on Antimicrobials Resistance (AMR).
  - o Comments received during public consultation of the HMA Strategic Plan on Antimicrobials were analysed. In general, the comments fully support the HMA vision for antimicrobials and include valuable suggestions. HMA discussed and adopted in principle a revised HMA Strategic Plan and agreed to revise the HMA Action Plan about AMR under the Belgian Presidency.
  - o The EMA gave an update report on the progress of the European Surveillance of Veterinary Antimicrobial Agent Consumption - the ESVAC project. HMA supported ongoing activities with respect to the collection and analysis of data on sales of veterinary antimicrobials and HMA encouraged all Member States to join this project.
- The future of veterinary pharmacovigilance was discussed during the meeting and general support for the Pharmacovigilance Working Party views on the review of the current legislation and proposals for change was expressed by HMA. There was agreement on the convenience of discussing these proposals in the context of the European Surveillance Strategy and the ongoing work to review veterinary medicines legislation.
- The results of the survey on the availability of vaccines against the priority diseases listed within the DISCONTTOOLS project were presented and the publication of the results on the HMA website was approved.

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## **Heads of Medicines Agencies – Joint Session on 12 -13 April, 2010**

- A status report on the progress made by the Task Force on the Availability of Resources at National Competent Authorities (NCAs) for Mutual Recognition Procedures (MRP) and Decentralised Procedures (DCP) was presented. HMA endorsed the development of further operational improvements such as the proposal to establish those conditions under which the Reference Member State can start the procedure after validation which will be further discussed with the CMDh.
- In relation to the evaluation made by the HMA/EMA Task Force on Transparency, HMA noted that the publication of only INN information of ongoing applications for generic and biosimilar products is not considered commercially confidential information.
- An update report on the work carried out by the Coordination Group for Mutual Recognition and Decentralised Procedure for human medicines (CMDh) and for veterinary medicines (CMDv) was presented.
- HMA made important progress setting the strategy for training assessors and regulatory staff within the European Regulatory network. The Terms of Reference for the HMA/EMA Office of Training and the mandate of the HMA/EMA Office of Training Steering Group were adopted. The draft Work Programme for the Office for the first year was also endorsed and Quality of Medicines will be the subject for the pilot study run by the Office.
- HMA noted the good progress made with the legislative proposals on pharmacovigilance and falsified products at the Working Party on Pharmaceuticals and Medical Devices of the Council of the European Union.
- The conclusions of the Strategic Workshop on e-readiness that was held during the HMA meeting were approved as well as the publication of the updated maps reflecting by when all NCA will be ready to accept electronic-only dossiers (see separate stakeholders' information).
- A report prepared by EMACOLEX (European Medicines Agencies Coordination Group on Legal and Legislative Questions) with regard to the implications that articles 290 and 291 of the Lisbon Treaty may have on the European Medicines Regulatory Network was presented to HMA.



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## Heads of Medicines Agencies – Human Session on 13 April, 2010

- There is agreement on the need to improve the liaison between HMA and Medical Devices Competent Authorities (CAMD). HMA decided to constitute an HMA subgroup to liaise with the CAMD, both to support the constitution of a permanent group of medical devices competent authorities (Central Management Committee) and to facilitate joint strategic discussions between persons responsible for medicines and for MDs. The HMA subgroup will report to the July HMA meeting and a general discussion will be held on these proposals, including the decision on a first joint meeting.

- A report was presented on the workshop on “Lessons Learnt during the pandemic flu a/H1N1v vaccination”, which took place in Brussels on March 22. This workshop was organised by FAMHP and the “Belgian inter-ministerial commissariat”, and brought together experts and stakeholders involved in the pandemic influenza vaccination in 7 European countries and also representatives from the EMA, WHO (Europe) and ECDC. The objectives were to draw conclusions on lessons learnt, prioritize issues and identify solutions for future pandemics. After agreement on the scientific and technical reliability of the work carried out by the European Medicines Regulatory Network, some operational improvements were identified for further occasions: 1) exchange of information between National Competent Authorities and communication area; 2) recommendation to allow regulatory procedures to be run and changed independently from WHO decisions on pandemic phases; 3) need to identify criteria to return from accelerated to normal procedures and the need to identify which procedures and variations really need accelerated timetables and which do not.

- The Clinical Trials Facilitation Group (CTFG) Action Plan for 2010 and 2011 was approved and HMA expressed its strong commitment to the Voluntary Harmonisation Procedure. The CTFG will prepare a more detailed analysis of the resources needed to run the VHP and its proposed strengthening.

- A policy document related to the EMA on (Emerging) Safety Related Issues for Medicines for Human Use was presented. The scope of this Policy is limited to (emerging) safety related issues for medicines for human use. This also includes quality defects resulting in safety concerns. However, quality defects that do not lead to safety concerns are outside the scope of this Policy. HMA acknowledged and supported the Policy.

- EMA informed about the Action Plan for Herbal Medicines 2010-2011. Said Action Plan, which was reviewed by the Herbal Medicinal Products Committee (HMPC), addresses the key trends and new issues for this period of time and some objectives



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and activities are included. HMA endorsed the Action Plan for Herbal Medicines 2010-2011, with some wording amendments being suggested to the document. EMA and HMA will publish the Action plan on their website.