

# Press release

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## Heads of Medicines Agencies (Human and Veterinary) meeting

The Heads of Medicines Agencies (Human and Veterinary) (HMA) of the EEA held its second meeting under the UK Presidency at Wotton House, Dorking, on 24 and 25 November 2005.

HMA (Joint Veterinary and Human) formally adopted the HMA Strategy Paper on European Medicines Regulatory Network (EMRN), which was drafted by the UK Presidency on behalf of the HMA. The HMA (Joint) agreed to the formation of an Implementation Group, which Jean Marimbert, Director General of the French medicines agency (AfSSAPS) agreed to chair. The Group will be responsible for taking forward the work set out in the Strategy Paper. A consultation process will be launched in the New Year and a stakeholder meeting held under the auspices of the Austrian presidency.

HMA (Joint) examined proposals to develop a strategy designed to address the counterfeiting of medicines in the supply chain, having commissioned a survey into the extent of the problem at its Edinburgh meeting. The strategy will concentrate on the public health issues arising out of counterfeiting and examine regulatory and enforcement solutions to the problem, and will dovetail with actions taken in other international fora. This work will be taken forward under the Austrian presidency.

Good progress on the benchmarking of veterinary and human national competent authorities was also noted by HMA (Joint). The project, designed to identify best practice and encourage learning from one another, is an important aspect of the long term development of the European Medicines Regulatory Network of agencies. The Co-Rapporteurs are the UK and Germany. HMA (Joint) endorsed the outline of the report, to be made in the summer of 2006, which will mark the end of the first benchmarking cycle.

HMA (Joint) welcomed the setting up of the new human and veterinary Co-ordination groups for mutual recognition and decentralised procedures following the introduction of the new pharmaceutical legislation, and recognised the opportunities these new streamlined procedures bring for the authorisation of new medicines by the national competent authorities.

At the HMA (Veterinary) meeting delegates received an update on progress made in defining a Strategic Research Agenda (SRA) under the European Technology Platform for Global Animal Health. The SRA is planned for stakeholder consultation early in 2006 and the Vision document, previously endorsed by the HMA-V, is due to be formally published in early December.

It went on to discuss progress made by the European Surveillance Strategy group. It was agreed that the work of the group should continue with a revision to the mandate to bring it up to date. Dr Cornelia Ibrahim, Head of Pharmacovigilance in the BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit), who is currently the chair of the veterinary Pharmacovigilance Working Party, agreed to lead the group.

The HMA (Veterinary) delegates also met with the veterinary pharmaceutical industry and discussed a range of issues relating to the implementation of the new medicines legislation and the improved availability of veterinary medicines.

At their meeting the Heads of Medicines Agencies (Human) discussed the work of the Clinical Trials Facilitation Group, endorsing the approach to be taken in ensuring that there was a harmonised approach to the implementation of the Clinical Trials Directive.

HMA (Human) also received a further update on the European Risk Management Strategy from the Chair of the Steering Group and from the EMEA, and adopted the rolling 2-year work programme implementing the action plan published in May. HMA (Human) considered further its own involvement in European pharmacovigilance, agreeing that the pharmacovigilance Working Party of the EMEA should provide updates on a regular basis to HMA (Human). It also discussed how it, or the HMA (Joint) sub group on communications, could play a more active role in the communication of European pharmacovigilance issues to key players at national level.

HMA (Human) also had an interesting discussion with a representative of DG Research who gave them an update on the Joint Technology Initiative for Innovative Medicines.

On 24 November, the UK Presidency also hosted an IT exhibition at Wotton House for HMA delegates entitled 'Moving to an Electronic World'.

ENDS

**Notes to Editor:**

1. The Heads of Medicines Agencies (HMA) is the network of regulatory agencies for human and veterinary medicines of the European Economic Area (EEA). This network provides a forum for the co-ordination and the exchange of views and proposals on issues concerning the European System of Medicines Regulations and the role of the HMA within that system. They meet four times a year usually under the chairmanship of the Member State that holds the Presidency of the EU. There are normally separate meetings of the heads of veterinary medicines agencies and the human medicines agencies, and one joint meeting where common issues are discussed.
2. The previous HMA meeting was held in Edinburgh from 14-15 July 2005.
3. The aim of the European Technology Platform for Global Animal Health is to facilitate and accelerate the development and distribution of the most effective tools for controlling animal diseases globally, thereby improving human and animal health, animal welfare and food safety and quality.
4. The European Surveillance Strategy Group was established to explore the actions needed for co-ordination of veterinary pharmacovigilance throughout the European regulatory network.
5. The next meeting of Heads of Medicines Agencies will take place under the Austrian Presidency in Vienna from 22nd-23rd February 2006.