

Press Release

Heads of Medicines Agencies (Human and Veterinary) meeting in Helsinki 6 -7 September 2006

The Heads of Medicines Agencies (human and veterinary medicines) held their first meetings under Finland's EU Presidency in Helsinki on 6 and 7 September 2006. An additional IT-session took place in the morning of the second day. Presentations were made by the UK and Belgian regulatory agencies on their respective IT systems now being implemented.

HMA-v (Veterinary medicines)

The Heads of Medicines Agencies for veterinary medicines met on 6 September 2006.

The main discussion points and decisions:

The long standing problem with the authorisation of diluents for veterinary medicinal products in the decentralised procedure or mutual recognition procedure (DCP/MRP) was discussed on the basis of a status report describing the Member States' positions in this issue. The HMA-v meeting reached a common understanding. It recommends that all Member States would also accept the option of a simple diluent to be authorised as part of one or more products and that the diluent could be packaged and sold separately, where appropriate.

Progress reports of the European Surveillance Strategy (ESS) and HMA Task Force on the Availability of Veterinary Medicines were given. Drafts for action plan and final report will be presented at November HMA-v meeting.

The HMA-v welcomed the publication "Simple Guide to Veterinary Pharmacovigilance in the EU", and encouraged national agencies to print and distribute it to all veterinary practitioners in Member States.

HMA-j (Joint meeting)

The Heads of Medicines Agencies for human and veterinary medicines held their joint meeting on 6 September 2006.

The main discussion points and decisions:

The Heads of Medicines Agencies Strategy Paper on the European Medicines Regulatory Network was discussed having the focus on the consultation with HMA's Partners and Stakeholders. Summary report on the meeting with Stakeholders in Vienna on 12 May was presented and this will shortly be placed on the HMA website. A further publication analysing the written consultation responses from stakeholders is likely to be published after the November HMA meeting.

The HMA Management Group gave a progress report with an update on current issues under preparation. New policy for working group consultation on the website was adopted. The HMA-j endorsed a new guideline for minutes of the HMA meetings.

Negotiations with the European Directorate for the Quality of Medicines (EDQM) had resulted into an agreement about a Memorandum of Understanding (MoU) on the conditions for EDQM's access to Communication and Tracking System for the Mutual Recognition Procedure (CTS). The MoU will be signed by the Chair of HMA Management Group.

HMA-j agreed upon a new logo for the HMA-organisation. The Working Group on Visibility will continue to develop a new website for HMA.

A policy discussion about the strategy of product testing in the European network took place aiming at a solution in coordination and management in MRP/DCP product testing.

Chairpersons of CMD-h and CMD-v presented the regular update reports on the activities of the coordination groups.

HMA-h (Human medicines)

The Heads of Agencies for human medicines met on 7 September 2006.

The main discussion points:

The European Commission gave a progress report on the assessment of the Community system of human Pharmacovigilance.

Finnish (National Agency for Medicines) proposal to create a temporary Working Group for planning an EMEA data bank for paediatric medicines available in Europe was discussed. HMA agreed that there is a need for information on paediatric medicines authorised in Europe. HMA discussed the issue and pointed out that such a proposal has to be linked to on going initiatives on other databases. EMEA will consider the practical possibilities for the data bank in relation to the implementation of the paediatric legislation.

Concerning the PSUR work-sharing initiative, the HMA-h agreed to publish the list of harmonised birthdates (dates on licensing) on HMA website.

The next meeting of Heads of Medicines Agencies will be held in Helsinki from 29 to 30 November 2006.

Additional information:

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The Heads of Medicines Agencies (HMA) is a network of both human and veterinary medicines agencies of the 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. The Agencies usually meet four times a year under the chairmanship of the Member State that holds the Presidency of the EU.