



Press release

EU Heads of Medicines Agencies (Human and Veterinary) meeting

The EU Heads of Medicines Agencies (Human and Veterinary) held its first meeting under the Austrian Presidency in Vienna at Hilton Hotel, at 22nd and 23rd February 2006.

HMA – Human Meeting

HMA received a status report of the European Risk Management Strategy Facilitation Group (ERMS) including:

- An update of the action plan link to the 2 year rolling workprogramme for ERMS
- Review and learning of the new tool, Risk management plans
- Recognition of the pharmacovigilance linked sections of the HMA Strategy paper
- Letters to industry linked to the Periodic Safety Update Reports (PSUR) work sharing initiative was adopted to be published on the HMA (HoA) website

An update from the Pharmacovigilance Working Party was provided focusing on the efficiency of the meetings (prioritising of topics), effectiveness of the meetings via strengthening the expertise of the working party by co-opting members for certain areas of expertise and strengthening the communication to CHMP as well as to CMD.

An update on the paediatric initiative was presented. There is currently an ongoing assessment on paediatric data available for products already on the market. This project will further continue.

A report about the background and current activities on Pharmaceutical Forum was presented by the Commission.

The Draft Guidance document on Module 3 of the Homeopathic Medicinal Products Dossier was adopted by the HMA. It will be published for a public consultation period of 2 months at the HoA website. Comments should be sent to the rapporteur of this document Burt Kroes (homeo-nl@cbg-meb.nl) until 15 May 2006.

HMA – Joint Meeting

A report about the ongoing work concerning the implementation about the review 2001 was presented. The work on guidelines is nearly finalised, these guidelines are published or will be published at the EMEA website, DG Enterprise website or HMA (HoA) website.

The chair of the implementation working group of the HMA Strategy Paper (Jean Marimbert, FR) reported about the action plan for consultation of the Strategy Paper. There will be a possibility of written comments and a meeting with interested parties will be organised on the 12th of May in Vienna. The letter to interested parties will go out in first part of March.

Progress report from the HMA management group on issues as



- SOP for Crisis management on mutually recognised and nationally authorized products will be drafted by the chairs of CMD and pharmacovigilance working parties
- The HMA Strategy paper has been published on HMA web sites (<http://heads.medagencies.org/> and www.hevra.org/)
- An agreement of giving EMEA access to a set of CTS test data was agreed

Reports from the chairpersons of CMD-h (Truus Janse-de Hoog) and CMD-v (Esther Werner) were recognised by the HMA. The Decentralised procedures is now going to be used and the number of CMD referrals are increasing. In the majority of cases (human and veterinary) the member states involved in the procedures were able to reach an agreement on the authorisation of the medical products. HMA will follow the development closely.

HMA – Veterinary Meeting

HMA-V received a detailed report on the progress of the European Technology Platform for Global Animal Health. The recommendations in the Strategic Research Agenda (SRA) were discussed and the general direction of the SRA was endorsed along with a number of suggested modifications to the text. The ambitious aims of the platform for veterinary research were fully recognised by the HMA-V.

A report from the European Surveillance Strategy Working Group made the proposal for the CVMP to consider a dual mandate in cooperation with the NCAs for the Pharmacovigilance Working Party to let the Working Party consider pharmacovigilance issues on all medicinal products in Europe irrespective of the licensing route. This was supported by the HMA-V

The Terms of Reference for the Task Force on Availability of Medicines were endorsed.

The next meeting of Heads of Medicines Agencies will take place in Vienna, from 11th – 12th May 2006.