



Press release

EU Heads of Medicines Agencies (Human and Veterinary) meeting

The EU Heads of Medicines Agencies (Human and Veterinary) held their second meeting under the Austrian Presidency in Vienna, at 11th and 12th May 2006.

HMA – Human Meeting

A project status report on the assessment of the community system of pharmacovigilance (Fraunhofer Study) was presented by the European Commission. The public consultation period ended on 12th of May. The consultation responses are now being analysed by the Commission, which will have a significant impact future initiatives. These will be outlined in close cooperation with HMA

An update on how the Clinical Trial Directive is being implemented across Europe 2 years after mandatory implementation of this directive was presented. HMA also discussed how to learn from recent clinical trial with TGN1412. It was agreed by the HMA that a coherent and harmonised approach in analysing the problems and setting up the network will take place.

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

- Information about the operation of the revised mandate of the Pharmacovigilance Working Party
- ERMS action plan
- Progress on the PSUR work sharing project and on the
- Progress on implementation of Eudravigilance in the member states

HMA – Joint Meeting

A progress report about the ongoing work implementing the new pharmaceutical legislation was presented. The topic of transparency was discussed and member states shared practical experience on these issues. HMA agreed that there should wherever possible be consistency in the approach taken.

Reports from the chairpersons of CMD-h (Truus Janse-de Hoog) and CMD-v (Esther Werner) on the ongoing activities of the groups were presented by the HMA. Discussion focused on data about the numbers and reasons of CMD-referrals. HMA committed to encourage CMD members to find common solutions within the CMD referral phase in order to enhance the efficiency of the system. The further development of the CMD referrals will be followed closely by the HMA.

HMA agreed to an unified HMA website (human and veterinary), and the website will be redesigned with links to the CMD websites.

Progress report from the HMA management group was presented, focusing on the following issues:



- General information on ‘Benchmarking of European Medicines Agencies’ was adopted for publication on the website.
- The current composition of the HMA - MG was endorsed by the HMA deferring the planned replacement or re-election of the members HMA – MG until the 3rd HMA Meeting of 2007.

HMA – Veterinary Meeting

The Veterinary members of the Heads of Medicine Agencies met in Vienna on 12th May 2006. The major discussion points and decisions were:

- A new mandate for the Pharmacovigilance Working Party was endorsed allowing the Working Party to provide advice on pharmacovigilance issues to National Competent Authorities. This effectively extends the scope of the work of the Pharmacovigilance Working Party to include advice on veterinary medicines authorised through the national, mutual recognition and decentralised procedures.
- Support was given to form an e-Vet subgroup of the Telematics Implementation Group on e-submissions (TIGes) to consider the matter of e-submissions in the veterinary sector. The group would consist of members from the regulatory network and the European industry bodies.
- An additional item was discussed concerning the authorisation of veterinary vaccine diluents. An interim strategy was agreed to assist the CMD-v in finding a solution to the regulatory challenges that exist.

On the 12th of May a Meeting with Interested Parties, discussing the strategy paper was organised. This was to complement the consultation on the strategy paper, which runs until 31 May (more details are available on the website).