

## Press Release

### Heads of Medicines Agencies meeting in Helsinki 29-30 November 2006

The Heads of Medicines Agencies (HMA) held their second meeting under Finland's EU Presidency in Helsinki on 29 and 30 November 2006. In addition, the HMA-v held a meeting with the industry associations, IFAH-Europe (International Federation for Animal Health-Europe), and EGGVP (European Group for Generic Veterinary Products).

#### HMA-h (Human medicines)

The Heads of Agencies for human medicines met on 29 November 2006.

The main discussion points:

- The European Commission representatives presented the outcome of the European Commission public consultation entitled "Assessment of the Community System of Human Pharmacovigilance". The Heads of Medicines Agencies welcomed the very thorough consultation and analysis and gave its support to strengthening and streamlining the EU pharmacovigilance system and emphasised the key role of the Member State agencies.
- The HMA-h made a note of the Third Status Report on the Implementation of the Action Plan to further progress the European Risk Management Strategy.
- The chairman of the Clinical Trial Facilitation Group (CTFG) reported on the recent activities of the group. It was agreed that the EMEA will convene a meeting with concerned expert groups on the development of a guidance on First in Man (FIM) trials in high risk products. The challenges will be taken on in close co-operation between EMEA, the European Commission and the HMA-h.

#### HMA-j (Joint meeting)

The Heads of Medicines Agencies for human and veterinary medicines held their joint meeting on 29 November 2006.

The main discussion points and decisions:

- The final report on the outcome of the 1<sup>st</sup> cycle of the Benchmarking of European Medicines Agencies (BEMA) as well as a reflection paper with recommendations by the BEMA Steering Group were presented. The HMA-j acknowledged the work done and supported the recommendations. The HMA will publish the main body of the report, which describes the aims and

background to BEMA in detail with methodology, limitations, key findings and conclusions. The 2<sup>nd</sup> cycle of benchmarking will be organised in the near future.

- The HMA-j adopted the general criteria for observer status in the HMA organisation.
- Chairman of the HMA Strategy Implementation Group presented a final outcome of the consultation with partners and stakeholders, and an analysis of the HMA Strategy Paper Work Plan. The HMA-j acknowledged the work done so far and is looking forward to the upcoming HMA meeting where the group will present their recommendations concerning the process for drafting the next version of the HMA Strategy Paper.
- The HMA-j decided to start a task force for building up a HMA strategy for testing medicinal products, particularly the MRP/DCP-products, in the European Economic Area.
- The European Commission presented a consultation paper on the review of the variation regulation (Better Regulation).

#### **HMA-v (Veterinary medicines)**

The Heads of Medicines Agencies for veterinary medicines met on 30 November 2006.

The main discussion points and decisions:

- The task force for availability for medicines gave its preliminary findings and recommendations. The HMA-v endorsed the general orientation and decided to publish the report during the German EU Presidency on the HMA website.
- The HMA-v gave its support to the CVMP reflection paper on fluoroquinolones. The aim of the Member States is to successfully implement precautionary phrases into SPCs of fluoroquinolone containing products.

The next meeting of Heads of Medicines Agencies will be held under the German Presidency in Dresden from 7 to 9 February 2007.

#### **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.*