

Summary Report of HMA meeting

Reykjavik, 28th February 2005 - The Heads of Medicines Agencies (HMA) of the European Economic Area met in Reykjavik, Iceland 23rd – 24th February 2005. Representatives from the European Commission and the European Medicines Agency (EMA) also attended the meeting, as well as an observer from Romania. This was one of two meeting sessions planned during the Luxembourg Presidency of the European Union. Some of the highlights emanating from the joint meeting were:

- Benchmarking Human and Veterinary Agencies – The aim of Benchmarking of European Medicines Agencies (BEMA) is to contribute to the development of a world class regulatory system for medicinal products, based on a network of agencies operating to best practice standards. The results of BEMA will be used by each agency for continuous improvement. BEMA consists of a self-assessment, from March to end of May 2005, and peer-review visits from May 2005 to end of April 2006.
- Strategy of the future European Medicines Regulatory Network – The paper ‘HMA Strategy on the future European Medicines Regulatory Network’ was adopted as the backbone for drafting a full document. It will focus on ‘The future network in the regulatory field of medicinal products between the European Medicines Agency (EMA) and the national competent authorities (NCAs), which should be further developed and clarified with particular reference to the risk/benefit assessment of medicines. The new regulatory legislation in an enlarged Europe must take into account public health needs and aim at giving the highest level of performance, transparency and credibility. It should take up issues such as communication and information, scientific resources, the assessment process, pharmacovigilance, inspection and laboratory control as well as enforcement, IT information systems and availability of medicines, with the aim of strengthening the regulatory network. Drafting groups will be chaired by Heads of agencies
- The Rules of procedure for the Heads of Medicines Management Group – The Rules, which clarify the co-coordinating role of the Management Group and its supervision of the Permanent Secretariat, their respective duties, composition and tasks, were adopted.
- HMA Guideline – The guideline for Heads of Medicines Agencies which deals with administrative issues related to meetings, chairmanship, working methods and decision and voting arrangements was approved.
- CTS issues – The meeting noted the work being done to date by the ad hoc working group on the Communication and Tracking System (CTS) for the procedure on mutual recognition of medicines authorizations.
- Submission of eCTD target date – eCTD is the electronic format for the marketing authorization application developed by ICH. The end of 2009 was adopted as the target date.
- Implementation of new legislation – The implementation is going on in different fora. To help the transposition in the Member states and to clarify what is dealt with and what is still under consideration, it was decided to convene a meeting of HMAs, EMA and the Commission, if necessary followed by a workshop. EMA will send an invitation to all Heads of Agencies.

Specific issues from the meeting of Heads of Medicines Agencies - Veterinary (HMA-V):

- Pharmacovigilance – The ad hoc group of European Surveillance Strategy (ESS) has identified the main items in developing an action plan, taking into account resources, systems, training and workload and the need to prioritize action in light of their findings, having decided on criteria for measuring success. The meeting emphasized getting the importance of veterinary pharmacovigilance across by any appropriate means and the need to bring the small veterinary enterprises into the functioning of the electronic systems.
- Availability of medicines – The unavailability of medicines for the animal health market, especially medicines for minor use or for minor species (MUMS) was addressed, since it may compromise animal welfare as well as consumer safety. The meeting suggested several ways to remedy the situation, some of which would be taken up in the forthcoming MUMS conference in July, inter alia changing legal (EU), regulatory and scientific as well as budgetary provisions, a part of which concerns vaccines for diseases of great budgetary consequence, as set out in a European Technology Platform for Global Animal Health.

Specific issues from the meeting of the Heads of Medicines Agencies-Human (HMA-H):

- European Risk Management Strategy - The ad hoc working group on progress of the European Risk Management Strategy (ERMS) presented a first draft of a progress report, for publication on the website. It was decided to create a document consisting of a progress report and an action plan on safety or risk/benefit of medicines to be published.
- Community System of Pharmacovigilance - The Commission introduced the Assessment of the Community System of Pharmacovigilance, including site visits to all National Competent Authorities (NCAs) within the EU, to be conducted between March and June this year. The meeting agreed that the Commission and contractors could ask the ERMS working group for advice.
- Eudravigilance - EMEA's proposals regarding further progress of the implementation of Eudravigilance were presented. The implementation of electronic reporting is to be achieved by 20th November 2005. Regarding reporting case narratives in English it should be only on request and then within 24 hours or the next working day.
- Paediatric data - Netherlands has prepared a list of products for which there are already assessment reports available. They will send letters to EU headquarters of the medicinal companies to submit data to all national agencies. Then for each of the products a rapporteur and a co-rapporteur will be appointed. A timetable and procedure as for a type II variation, as for a new indication will be followed.
- Mutual recognition and Decentralized Procedure - The HMA considered the issues related to implementation of the new Decentralized Procedure and start of official activities of the new Coordination Group for the Mutual Recognition and Decentralized Procedures (CMD), foreseen in the new Community Legislation, for 1st November 2005. It was agreed to set up a

small joint ad hoc group chaired by Ireland, consisting of Heads of Medicines Agencies, senior staff and members from MRFG and VMRFG, to consider the implementation of the new decentralized procedure under the Framework Document for the Coordination Groups (Human and Veterinary) adopted by HMA in 2004 based on the proposals presented by the MRFG. Agreement is sought for the HMA meeting in May, in Luxembourg, in order to present the outcome to stakeholders. HMA also noted that the CMD will start informally its activities under its new membership in April 2005, as foreseen in the Framework Document.

- Meeting Dates - The UK presented the meeting dates of the HMA under the UK presidency.
- Training - Italy informed about a training course for assessors of the clinical part of the dossier, which will be held in Rome 16th-17th of June 2005. The nomination form has to be returned to Italy before 15th March 2005.

The Heads of Medicines Agencies is a European Regulatory network comprised of human and veterinary medicines agencies within the European Union and the EEA/EFTA States, the European Economic Area. It is a forum for discussing practical issues related to co-ordination and application of Medicines Acts under EU law. At each gathering there are three sessions held, one for Heads of Veterinary Regulatory Agencies, one for Heads of Human Medicines Agencies and a Joint meeting.

The next meeting sessions of the Heads of Medicines Agencies are to be held at Mondorf-les-Bains (The Mondorf Baths) in Luxembourg 2nd – 4th May 2005, where one of the subjects to be discussed will be European plans for regulating paediatric clinical trials.

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