

Summary Report of HMA meeting

Luxembourg 23rd May - The Heads of Medicines Agencies (HMA) of the European Economic Area met in Mondorf-les-Bains, Luxembourg 2nd - 3rd May 2005.

Specific Items from the meeting of the Heads of Medicines Agencies Meeting (Joint Medicines):

Benchmarking European Medicines Agencies (BEMA)

The progress report from BEMA Steering Group was presented. 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. 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 on the future European Medicines Regulatory Network:

The chairmen of drafting groups covering the issues of the strategy paper

- 1) communication and information
- 2) scientific resources
- 3) scientific assessment process
- 4) pharmacovigilance
- 5) inspection and laboratory control and enforcement,
- 6) IT information systems

reported on progress made.

Quality issues:

The European Directorate for the Quality of Medicines (EDQM), Council of Europe, reported on achievements within the network of Official Medicines Control Laboratories (OMCL) and drew the attention to what could be improved for the benefit of Public Health, making the best use of existing human, scientific, technical resources and the best ratio cost/benefit both at national and at European level.

Also there was focus on a number of key topics of OMCLs activities and certification of suitability for active substances

Good Manufacturing Practice (GMP) Requirements for Active Substances: An update paper was presented to the HMA by the EMEA on developments since its meetings in Scheveningen, September 2004, related to inspections of active substance manufactures.

A clearer picture has now emerged as to how GMP compliance of active substance manufacturers will be verified and how inspections will be conducted in a resource-efficient, risk-based manner.

The European Commission distributed a note to the Heads of Agencies, reflecting on EU position on an ICH concept for “quality systems for Continuous Improvement” (quality guideline Q10).

Mutual recognition and Decentralised Procedure:

The HMA ad hoc Working Group on the Decentralised Procedure met in Lisbon on 11th April and reported on a proposal for a revised Flow Chart of the Decentralised Procedure simplifying the procedure.

Implementation of new legislation:

Results of the meeting hosted by the EMEA on creating an overview of implementation on new legislation were reported. Furthermore the HMA agreed to establish a Working Group consisting of national Agencies and EMEA staff and members from MRFG and VMRFG to further elaborate on Article 126b of Directive 2001/83/EC

Specific Items from the meeting of the Heads of Medicines Agencies Meeting (Human Medicines):

ERMS:

European Risk Management Strategy – The HMA and the EMEA decided to publish a progress report and an action plan on further progress.

Specific Items from the meeting of the Heads of Medicines Agencies Meeting (Veterinary Medicines):

Availability of medicines:

The meeting received an update and had a discussion on the issues relating to Minor Use/Minor Species (MUMS) products. A revised document of the unavailability of medicines for the animal health market, especially MUMS was addressed.

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. They meet four times a year usually under the chairmanship of the Member State that holds the Presidency of the EU.

The next meetings of Heads of Medicines Agencies will take place in Edinburgh on 14th and 15th July 2005.