



Portuguese EU Presidency

Stakeholder's Information

Heads of Medicines Agencies Meeting 6 – 7 November 2007, Funchal, Madeira

The Heads of Medicines Agencies (HMA) held their second meeting under the Portuguese EU Presidency at Hotel Pestana Carlton in Funchal, Madeira on 6 and 7 November 2007. This was the 51st HMA Meeting.

HMA-h (Human Medicines)

The Heads of Medicines Agencies for human medicines (HMA-h) met on 6 November 2007.

The main items were:

- **Clinical trials**

The HMA, the European Commission and the EMEA discussed some of the conclusions of the 3rd October European Commission - EMEA Conference on the Operation of the Clinical Trials Directive and Perspectives for the Future. HMA considered that the Conference was a positive action to evaluate the current state of play on the implementation of this legislation and discussed various issues related to it. Furthermore, HMA recognised the need to foster a common approach to the regulation of clinical trials conducted in the EU.

In this context, HMA further adopted a revised mandate and rules of procedure of the HMA Clinical Trials Facilitation Group (CTFG) with the main objective of improving harmonisation of the assessment decisions and administrative procedures for clinical trials in the EU.

- **Availability of medicines**

A report on the availability of human medicinal products in EU was adopted by HMA. The aim of the document is to review the current situation in Member States on the unavailability of medicinal products and to promote an exchange of information on existing measures and possible solutions. The report makes a thorough analysis of the legal Community instruments currently available and points out a set of recommendations. The report will be followed by an action plan.

- **European Risk Management Strategy (ERMS)**

HMA adopted the European Risk Management Strategy (ERMS) work programme for 2008 and 2009 describing how to further implement the ERMS initiatives envisaged for the next two years and agreed on its publication at the HMA and EMEA websites. An update report on the various issues currently being dealt by the ERMS Facilitation Group was also given to HMA. Among other items, the Group is currently discussing its Action Plan for 2008 and 2009, the European Commission legislative proposals, the publication of Pharmacovigilance Working Party Assessment Reports and the preparation of a guideline on the use of article 107 of Directive 2001/83/EC. The ERMS is an initiative undertaken within the EU Regulatory System to strengthen the safety monitoring of medicinal products for human use in the EU.



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HMA-joint (human and veterinary medicines)

The Heads of Medicines Agencies joint meeting was held on 6 November 2007.

The main items were:

- **Variations Regulations**

The European Commission presented the objectives and substance of the Public Consultation on the 'comitology' part of the revision of the Variations Regulations launched on 25.10.2007. HMA supported the European Commission's initiative and were asked to send comments until 4 January 2008, end of the consultation period.

- **E-submission/ e-CTD**

E-submission and e-CTD have previously been considered a strategic issue requiring further discussion by EU regulatory agencies, particularly bearing in mind the deadline of 2009 to have the infrastructure and processes in place to handle electronic submissions. HMA had a general discussion on e-Submission and e-CTD, the electronic standards, the results of a survey to national activities and future challenges requiring HMA response. The aim of this discussion was to promote a common understanding of the programme to achieve electronic submission and the benefits it is expected to deliver. HMA recognised the importance of the coordination and interoperability among the various systems and that these issues require further discussion by HMA.

- **Continuous Development of HMA Cooperation**

Further to the adoption of the Continuous Development of HMA Cooperation Report at the HMA in July 2007, the group discussed and agreed on the HMA mission/vision statement.

- **Homeopathic documents**

HMA adopted two documents on homeopathic medicinal products. The module 1.2. for the application form of homeopathic medicinal products for human use and the guidance on module 3 of the homeopathic medicinal product dossier will be published at the HMA website.

- **BEMA (Benchmarking of European Medicines Agencies)**

HMA discussed and adopted several documents under the preparation of the 2nd BEMA cycle.



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HMA-v (veterinary medicines)

The Heads of Medicines Agencies meeting for veterinary medicines was held on 7 November 2007.

The main items were:

- **Meeting with stakeholders**

HMA(v) held a meeting with stakeholders, namely the International Federation for Animal Health Europe (IFAH-Europe) and the European Group for Generic Veterinary Products (EGGVP). The main issues discussed were related with the availability of veterinary medicines and linked to this data protection; generic applications; and referrals in the Mutual Recognition and Decentralised procedures. The meeting was considered by all parties as a positive step towards the improvement of the EU regulatory environment in Europe.

- **Update on European Surveillance Strategy Action Plan and progress report on PSUR work sharing**

HMA adopted an amended version of the European Surveillance Strategy Action Plan as agreed by the European Surveillance Strategy Working Group. The main changes relate to the implementation timeframes. A progress report on the Periodic Safety Update Report work sharing initiative was given, highlighting the establishment of the PSUR synchronisation group according to a HMA decision taken at the last meeting in Lisbon, on July 2007.

- **Veterinary Generic Medicines Issues**

HMA discussed a series of principles taken from a draft CMD(v) guidance document for member states concerning the processing of generic applications through MRP/DCP. The aim of the document is to achieve a harmonised approach. The CMD(v) will continue to develop the document and HMA will consider it again.

The next HMA meeting will take place on 14 and 15 January 2008 in Brdo, Slovenia.

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The Heads of Medicines Agencies (HMA) is the 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 Council of the European Union.