



Portuguese EU Presidency

Stakeholder's Information

Heads of Medicines Agencies Meeting 10th – 11th July 2007, INFARMED, Lisbon

The Heads of Medicines Agencies (HMA) held their first meeting under the Portuguese EU Presidency at INFARMED premises in Lisbon on 10 and 11 July 2007. This was their 50th meeting.

HMA-h (Human Medicines)

The Heads of Medicines Agencies for human medicines (HMA-h) met on 10 July 2007.

The main items were:

- **Guideline on Strategies to identify and mitigate risks for first-in human clinical trials with investigational medicinal products**

The EMEA gave an update report on the development of a guideline on strategies to identify and mitigate risks for first-in human clinical trials with investigational medicinal products. The consultation period of the guideline had ended on April 30th and a workshop was held on June 12th at the EMEA in London, allowing further discussion on the comments received during the consultation period. The final adoption of the guideline by the Committee of Human Medicinal Products (CHMP) of the EMEA is foreseen at the July CHMP meeting. HMA has welcomed the progress made in this regard.

- **Availability of medicines**

A draft report analysing the problem of unavailability of human medicines in the small and medium-size EEA countries was presented. HMA considered this to be a very important European public health concern affecting EEA countries and welcomed the draft report. The report makes a thorough analysis of the legal Community instruments currently available to regulatory agencies, stakeholders and patients to ensure the supply of medicines. The main ideas presented were the importance of a more intense exchange of information between HMA members on the various national experiences and practices and the need for Member States to explain how the existing legal provisions are applied. The report is expected to be adopted at the next HMA meeting in November.

- **GCP Inspection Working Group draft mandate**

A change of status and a new designation for the EMEA Ad Hoc Meeting of GCP Inspection Services to a standing group was discussed and supported by HMA. A mandate and rules of procedure were endorsed by HMA. This was to better reflect the importance and the work of the group. Among the changes introduced by the new mandate, a number of different reporting lines were identified and HMA is one of them.

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

The ERMS is an initiative undertaken within the EU Regulatory System to strengthen the safety monitoring in the EU of medicinal products for human use. In the report presented and discussed at the Lisbon HMA meeting very good progress has been made in relation to the implementation of the ERMS. The Public Status Report was approved by HMA and will be published on both the EMEA and HMA websites. A short press release will jointly be developed by the EMEA and HMA to highlight the main achievements during the reporting period and will include a reference on the ERMS Work Programme for 2007 – 2009 to further implement the ERMS.



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HMA-joint (human and veterinary medicines)

The Heads of Medicines Agencies joint meeting was held on 10th July 2007.

The main items were:

- **HMA Highlights and Achievements**

A presentation and a document on the 50 HMA meetings with the main highlights and achievements of the group were presented by the Portuguese EU Presidency. The document prepared by the EU Presidency on the main achievements of HMA will be published at www.hma.eu at a later moment.

- **Paediatric Regulation**

The HMA discussed the implementation of the Paediatric Regulation, particularly the coordination of the work by the CMD(h) between agencies and the EMEA with regard to the assessment of paediatric data for products authorised under the mutual recognition procedure. HMA endorsed a mandate to CMD(h) to coordinate this exchange of information with the EMEA, among other relevant tasks.

- **Telematics Master Plan**

The EU Telematics Master Plan sets out the plans for the design, implementation and operation of the EU Telematics systems in the context of the known needs and constraints, and an agreed set of prioritisation criteria. This document, which had been discussed in the previous HMA meeting in Bonn, was endorsed by HMA. The EU Telematics Master Plan is to be proposed for adoption at the next meeting of the EMEA Management Board on 4 October.

- **Continuous development of HMA**

HMA were presented with a report on the continuous development of HMA cooperation following a HMA-wide consultation made in February 2007 and the Management Group's Strategic Day on 17 April. The report included a set of important conclusions and recommendations for the future direction of HMA. The recommendations proposed were supported by HMA and an action plan will follow.

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

An update report on the 2nd BEMA cycle was presented by the BEMA Steering Group. The progress achieved so far in the preparation of the 2nd cycle was welcomed by HMA and the proposed methodology was discussed and endorsed.

Best Practice Session

HMA meetings usually include a Best Practice Session in which regulatory agencies share among each other experiences and good practices on their activities. On 11 July the Italian agency programme for independent research as well as the Portuguese experience on Clinical Trials evaluation were presented and discussed.



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HMA-v (veterinary medicines)

The Heads of Medicines Agencies for veterinary medicines was held on 11th July 2007.

The main items were:

- **IFAH Benchmarking report**

Following IFAH's annual Conference on the topic: "Veterinary Medicines Regulation – Is Europe still at the cutting edge of innovation" a short outcome and a general overview of the IFAH benchmarking study was presented and discussed. Regarding the critical points identified by the Industry including innovation restrictions in the area of veterinary medicines, some reflections will be made in order to discuss these issues again at the next HMA meeting in November.

- **Challenges with Generic Medicines Authorisation**

HMA discussed art. 13 of Directive 2001/82/EC as amended by Directive 2004/28/EC in regard to generics and the acceptance of more or fewer indications in comparison to the national reference product. The general approach to this subject was supported by HMA. Following further consideration by CMD(v), the HMA is aiming at a final decision at their next meeting in November.

- **e-submissions in the veterinary sector**

Welcoming the Industry position regarding the objective of e-submissions, it was agreed that national agencies should be ready for e-submission by the end of 2009. Contact points from veterinarian agencies still need to be identified.

The next HMA meeting will take place on 6 and 7 November 2007 in Funchal, Madeira.

For additional information please contact:

Vasco Maria
Head of INFARMED
Av. do Brasil 53
1749-004 Lisboa
Portugal
Telephone: + 351 21 798 71 09

Carlos Agrela Pinheiro
Head of the General Directorate of Veterinary
Largo da Academia Nacional de Belas Artes n.º 2
1249-105 Lisboa
Portugal
Telephone: + 351 21 323 95 00

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.