

Stakeholder's Information

Heads of Medicines Agencies Meeting 26th – 27th April 2007 Bonn/Königswinter

Heads of Medicines Agencies meeting in Bonn/Königswinter 26th -27th April 2007

The Heads of Medicines Agencies (HMA) held their second meeting under the German Presidency at Bonn/Königswinter from 26th to 27th April 2007.

HMA-H (Human Medicines)

The Heads of Agencies for human medicines (HMA-H) met on 26th April 2007.

The main items were:

Clinical Trials Directive

EMA gave a progress report on the development of a guideline on requirements for first-in-man clinical trials for potential high-risk medicinal products. The draft guideline was adopted for 2 months public consultation in March 2007. As the next step, a workshop is scheduled for 12th June 2007 to discuss major comments received from stakeholders. The final adoption of the guideline by CHMP is foreseen for July 2007. HMA welcomed the progress made.

In addition, HMA discussed measures for further harmonising the clinical trials procedure between Member States.

European Risk Management Strategy

The EudraVigilance Steering Committee in collaboration with its working group, the EudraVigilance Expert Working Group, conducted a survey addressed to all National Competent Authorities as regards a number of aspects in relation to the implementation of EudraVigilance in 2006. As a result, a EudraVigilance Action Plan has been drafted to solve issues identified as needing improvement, e.g. in relation to the implementation of Directive 2001/20/EC in the Member States as regards expedited legal reporting requirements and reporting principles. HMA endorsed the Action Plan as such. An implementation plan will be prepared by the EudraVigilance Expert Working Group and will be put forward to the EudraVigilance Steering Committee for approval. Both HMA and the EMA's Management Board will receive regular reports.

Implementation of the Paediatric Regulation

The Paediatric Regulation ((EC) No 1901/2006, amended by Regulation (EC) No 1902/2006) was published on 27th December 2006 and entered into force on 26th January 2007. Since the Paediatric Regulation has created a number of responsibilities and activities for both the EMA and the Member States, a document was presented that summarises the tasks, the potential impact on Member States (National Competent Authorities) and provides an analysis of the resources involved. The responsibilities and activities will again be discussed during the Portuguese Presidency.

HMA-J (Joint meeting)

The Heads of Agencies joint meeting was held on 26th April 2007.

The main items were:

Telematics Masterplan

The EU Telematics Master Plan has been prepared at the request of the Telematics Steering Committee in order to better co-ordinate and implement the IT projects in the European Medicines Regulatory Network and to set out the short and medium term planning of the EU Telematics programme.

The Telematics Masterplan was presented by EMEA, followed by an exchange of views by HMA. Points for discussion were the limited resources and the prioritisation of projects. The Masterplan was supported by HMA as such, but will be redrafted in the light of this discussion. The revised Masterplan will then be discussed during the first meeting of the Portuguese Presidency.

The EU Telematics Master Plan is to be proposed to the EMEA Management Board for adoption during their September 2007 meeting.

Resources

A report was given on the planning of resources in the European network. A revised report will be ready for discussion at the HMA meeting in Lisbon in July 2007.

In addition, the role of scientific working parties in the human and veterinary sector of the European Regulatory Network and the need for their strengthening was discussed. The HMA agreed that the issue should be tabled on the agenda of a HMA meeting in a year's time.

Report from the HMA Strategy Paper Implementation Group (HMA SIG)

The consultation of HMA's Strategy Paper with partners and stakeholders received a number of comments. HMA SIG presented a plan for an update of the Strategy Paper to reflect these contributions. HMA endorsed their proposal together with the milestones and a timeline for the amendment of the HMA Strategy Paper.

Report from the BEMA SG

An update on the work of the BEMA Steering group was given. It was reported that the new BEMA Steering Group held its first meeting on 23th April 2007. Short presentations based on the first BEMA assessment comprised the drivers of the first cycle, methodology, the main findings and the current mandate from the HMA. A revised paper will be prepared that will focus on a revised methodology and will include evidence based peer reviews.

The work of the BEMA SG was supported by HMA.

Mandate for the GMP Inspectors Working Group

A change of status for the EMEA Ad Hoc GMP Inspection Services to a standing working group to better reflect the importance of their work was presented and endorsed by HMA.

Mandate for HMA Working Group of Communication Professionals (HMA WGCP)

The draft mandate for the HMA WGCP was presented and adopted by HMA. This new group will foster the communication between the European Medicines Regulatory Network, its stakeholders and the general public, including the media.

Mandate for the HMA Training Project Team (HMA TPT)

The draft mandate for the HMA TPT was presented and adopted by HMA. It is the objective of this ad hoc group to formalise a common system of training and continuous education of scientific and regulatory staff of the EU/EEA national competent authorities and EMEA.

HMA-V (Veterinary meeting)

The Heads of Agencies for veterinary medicines (HMA-V) met on 27th April 2007.

The main discussion points were:

Availability of Veterinary Medicines

As a follow-up to a report on the availability of veterinary medicines presented during the Dresden HMA-v meeting in February 2007, a plan was now presented on the actions to be taken by HMA-V. The Task Force on Availability on Medicines representing the EU Commission, European Medicines Agency, industry, veterinarians and HMA-V had identified the main obstacles to availability as the economic climate facing the animal health industry and the legislative environment. The report made a number of recommendations to address the problem in the short, medium and longer terms, including additional incentives to develop medicines (data protection, co-ordination of research etc), amendments to variations regulations, improvement and harmonization of the 'cascade' provisions, as well as recommendations for the improvement of regulations aiming at better protecting animal health and public health as well. The Action plan was adopted by HMA-V and it was agreed that the full report should be published.

European Surveillance Strategy in the Veterinary Field (ESS)

The revised action plan of the ESS meeting in Paris on 29th January 2007 was presented. The structure of the revised Action Plan presents itself now as a table, giving detailed information on prioritisation, responsibilities, resources, milestones. Out of these overall important tasks, some first rate priorities were chosen by ESS. In general the Action Plan was adopted by HMA-V, taking into account a resetting of timescales and some rewording. During the discussion emphasis was put on worksharing between national competent authorities. The choice of the first rate priorities was also supported by HMA. An updated Action Plan will be presented during the Portuguese Presidency.

Generic Medicines Authorisation in the Veterinary Field

During the HMA meeting in February 2007 in Dresden it was discussed to provide a brief summary on the current discussion in CMD(v) on applications for marketing authorisation for generic medicinal products in the case of divergences between the national SPCs of the reference product as regards indications and use in species. These discussions have been initiated by CMD(h) proposing to the European Commission the concept of the highest common denominator instead of the lowest common denominator which was applied hitherto. A harmonised approach of the national agencies is needed in order that generic applications can continue to be processed efficiently. Legal advice from the European Commission is awaited.

e-Submission in the Veterinary Sector

The Telematic Implementation Group Electronic Submissions (TIGes) veterinary subgroup presented the finalised document on project initiation and the finalised Terms of Reference. These documents were supported by HMA-V. The readiness for e-submission by the end of 2009 will be discussed during the Portuguese Presidency.

For additional information please contact:

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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 EU.