

## Stakeholder's Information

### Heads of Medicines Agencies Meeting 8 - 9 February 2007 Dresden

#### Heads of Medicines Agencies meeting in Dresden 8-9 February 2007

The Heads of Medicines Agencies (HMA) held their first meeting under the German Presidency at Dresden from 8 to 9 February 2007.

#### New HMA Website

Following a decision to merge the websites of the Heads of human and veterinary medicines agencies, a new joint website of HMA was presented during the Dresden meeting (<http://www.hma.eu>). The website offers information on activities of HMA and the two Coordination Groups for Mutual Recognition and Decentralised Procedures (CMDs) such as press-releases, information on the permanent HMA working groups, topics discussed by HMA and regulatory guidance. The new site is presented with a new design and site structure supporting direct access to information. New features have been built-in such as frequently asked questions, meeting calendars, contact form and newsletter subscription. The website is based on a content management system to facilitate future updating and maintenance.

#### HMA-V (Veterinary meeting)

The Heads of Agencies for veterinary medicines (HMA-V) met on 8 February 2007.

The main discussion points were:

#### Availability of veterinary medicines

The Task Force on Availability on Medicines representing the EU Commission, European Medicines Agency, industry, veterinarians and HMA-V presented its report on the availability of veterinary medicines. The report identifies the main obstacles to availability as the economic climate facing the animal health industry and the legislative environment. The report concludes that whilst there have been considerable efforts to address the problem there remain unmet therapeutic needs for veterinary medicines in the EU. The report also concludes that it is still quite early to gauge the impact of legislative measures to address the situation which were introduced in 2005 and that a further survey should be conducted in 2-3 years. The report makes 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 variation regulations, improvement and harmonization of the 'cascade' provisions, as well as recommendations for the improvement of the regulatory environment (Annex 1 of the Veterinary Directive, Revision of the MRL regulation)."

#### Generics in veterinary medicines

The outcome of a questionnaire on how to process generic applications in cases where the originator product in the reference member state (RMS) has more or fewer indications than the corresponding product in the concerned member state (CMS), was presented. With regard to the approach in the human field, to accept the highest number of indications, a proposal by the EU Commission to introduce a similar approach in the veterinary field was discussed. It became obvious that to date no common approach exists among national competent authorities. However, the answers to the questionnaire indicate that the majority of Member States was in favour of progressing with the implementation of the highest number of indications both to facilitate the approval process of generic veterinary medicines. Many Member States expressed their opinion that access to a complete set of documentation is a prerequisite for such an approach together with accompanying measures to ensure fair treatment of the reference products.

### HMA-J (Joint meeting)

The Heads of Agencies joint meeting was held on 8 February 2007.

The main items were:

#### **Working Group of Enforcement Officers (WGEO)**

The HMA management group adopted the draft mandate for the recently established HMA Working Group of Enforcement Officers. The working group shall contribute to the protection of public health and animal health and welfare by ensuring that the manufacturing and distribution chains of medicinal products adhere to the regulations, by disrupting illegal activities and by sharing information.

#### **Best practice sharing**

A major aim of the benchmarking exercise (BEMA) in 2005 and 2006 was to identify best practices. In order to facilitate the sharing of best practises among the national competent authorities, examples from a German and the Dutch agency were presented and discussed.

### HMA-H (Human Medicines)

The Heads of Agencies for human medicines (HMA-H) met on 9 February 2007.

The main items were:

#### **Report of guidelines for first-in-man clinical trials**

MHRA presented the final outcome of the Expert Scientific Group on Phase 1 Clinical Trials (ESG) which was established following the incidents with the clinical trial of the TGN 1412 antibody. (The full report is available at:

[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4141039&chk=Qczxog](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4141039&chk=Qczxog))

The CHMP has established a drafting group to prepare a guideline on the conduct of first-in-man trials on high-risk medicinal products. Upon request of HMA-H and CHMP, the drafting group is established as a multidisciplinary taskforce including members nominated by HMA-H, CHMP, CTFG, Commission and EMEA. The draft guideline document is to be published for consultation in March 2007.

#### **Implementation of the paediatric regulation**

The Paediatric Regulation ((EC) No 1901/2006, amended by Regulation (EC) No 1902/2006) was published on 27 December 2006 and entered into force on 26 January 2007. Pursuant to this regulation, a Paediatric Committee is to be established by 26 July 2007 and shall cover defined expertise. Member States are requested to appoint the members for this committee. A joint EC-EMEA action plan was published on the websites of both institutions. A working group including members of CMD(h) was established for actions concerning Member States and the EMEA.

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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.*