



## STAKEHOLDERS' INFORMATION

63<sup>rd</sup> meeting of Heads of Medicines Agencies (HMA)

25-26 October, 2010, Antwerp, Belgium

### Heads of Medicines Agencies adopt Strategy to 2015 in Antwerp

On 25 October, 2010 the European Heads of Medicines Agencies (HMA) endorsed a five-year strategy for the European Medicines Regulatory Network (known as the 'Network') at its meeting in Antwerp. The Strategy, which will run from 2011-2015, builds upon the work of the previous HMA Strategy, which was published in 2007. The aim of the new strategy is to identify key challenges which the Network faces over the next five years and how the Network can best respond to these challenges. While the Strategy covers the diverse activities of the Network, a number of key themes have emerged where the HMA believe they can make a real difference over the next five years. They are:

- (i) safeguarding public and animal health, particularly through strengthening surveillance of the benefits and risks of medicines in the European population;
- (ii) supporting innovation, particularly through efficient and proportionate regulation of innovative medicines and clinical trials, e.g. by using the Voluntary Harmonization Procedure;
- (iii) further improving the operational efficiency of medicines authorization by the Decentralized and Mutual Recognition Procedures.

The adopted document is published at the HMA website – [www.hma.eu](http://www.hma.eu) .

At its next meeting in Hungary in February 2011, the HMA will consider the mechanism for implementing the Strategy over the next five years.

### Common EU Submission Platform

HMA discussed the feasibility study on the Common EU Submission Platform. It was agreed to further elaborate on governance and technical aspects of the new portal, which will be followed by a pilot involving National Competent Authorities and stakeholders.

### Observer status given to the Croatian Agency

HMA endorsed the participation of the Croatian Agency for Medicinal Products and Medical Devices as an observer at HMA meetings in 2011. Observers may attend the HMA meetings at the invitation from the acting Presidency, but may not vote or participate in the adoption of a decision.



## **Recommendations adopted on the release of information with regard to new applications before and after decision on granting MA**

HMA endorsed the HMA/EMA recommendations on release of information with regard to new applications before and after opinion or decision on granting a marketing authorization (human) and agreed to the publication of the document on the EMA and HMA website. HMA requested the HMA/EMA Transparency Group to examine whether the recommendations should be complemented in order to be applicable in the veterinary field. These recommendations are to be published in the HMA and EMA websites.

## **Strengthening resources allocated for Clinical Trials harmonization**

HMA endorsed the proposals made by the HMA Management Group for improving the Voluntary Harmonization Procedure (VHP) for multinational clinical trials. These include the setting up of a central repository for Clinical Trial Applications (CTA) to be hosted in the existing Eudra Clinical Trial database at EMA.

## **HMA meet with stakeholders on 25 and 26 October**

At its meeting in Antwerp HMA also held meetings with stakeholders. On 25 October a meeting with HMA veterinary stakeholders IFAH, EGGVP and FVE was held where the issues of electronic submission and the review of veterinary legislation were under discussion. The following day EGA discussed its vision document to 2015 with HMA.

## **Functioning of Mutual Recognition and Decentralised Procedures**

A status report was given by the Task Force on Availability of Resources at National competent Authorities (NCA's) for MRP/DCP. HMA endorsed the prolongation of the pilot for the assessment report feedback form for 1 more year. Furthermore, HMA endorsed the start of the Active Substance Master File (ASMF) project and supported the establishment of a central database.

## **HMA discussed the future of CMDh (Coordination Group)**

HMA endorsed the recommendations made by CMDh working party on the 'Future of CMDh' on specific topics such as the future workload of CMDh, taking into account the new pharmacovigilance legislation, the optimization of the predictability and the transparency of



the DCP. This discussion on the future of CMD(h) will continue at the next HMA meeting in Budapest.

### **Future of veterinary pharmacovigilance under discussion**

HMA discussed the future of veterinary pharmacovigilance following discussions held by the Committee of Veterinary Medicinal Products (CVMP) in the frame of the European Commission consultation on “Better Regulation for Veterinary Pharmaceuticals”. According to the discussion some areas may require changes in a near future, such as the clarity of responsibility between Marketing Authorisation Holders and Competent Authorities, enforcement requirements, a veterinary pharmacovigilance master file, electronic reporting, PSURs frequency, renewals and signal detection.