



Draft Stakeholders' Information

Heads of Medicines Agencies

Château Villiers le Mahieu

10-11 July 2008

HMA_H (Human medicinal products meeting)

The Heads of Medicines Agencies for human medicinal products met on 10 July 2008.

The main discussion points were as follows:

- The CTFG reported on its proposals aiming at harmonising the implementation of Clinical Trials directive. Assessment sharing, harmonisation of procedures and decisions and work sharing are among the objectives of its work plan for 2008-2009 that was endorsed by the HMA. It already agreed on a single core set of requirements for substantial amendments and it proposes improvements in systems for the exchange of safety data. A concept paper is being drafted on work sharing in order to minimise the use of resources by NCA and sponsors. A voluntary harmonised procedure for sharing the assessment of data from multi-national clinical trials applications has been proposed. The HMA endorsed the the work plan and the starting of a pilot phase by the end of 2008.
- The HMA endorsed the key principles for signal management in the EU presented by the Pharmacovigilance Working Party in the context of the European Risk Management Strategy (ERMS). The PhVWP got the agreement of the HMA to finalise a vision document by next autumn and to start a pilot during Q4 of 2008. The aim is to develop a guideline by the end of 2009 and implement it in 2010.

HMA_J (Human and veterinary medicinal products joint meeting)

The Heads of Medicines Agencies for human and veterinary medicinal products met on 10 July

The main discussion points were as follows:

- The HMA allocated a significant part of the meeting for a strategic discussion on resources of the Network. An innovative approach was implemented with participants breaking out in groups to discuss the issue from different perspectives. Particular attention was given to better use and optimisation of resources. The outcome will feed into a follow up discussion during a Strategic Day that will be organised in September 2008.
- The Product Testing Task Force presented a strategy paper for an efficient and cost-effective scheme for laboratory testing of medicinal products, in particular MRP/DCP-products. Special attention was given to synergy between assessment, inspection and laboratory control in order to put in place a risk-based approach to medicinal product testing.



- The Telematics Master Plan was presented by EMEA with the view to adopting it at the next EMEA Management Board meeting in October. EMEA also presented the Memorandum of Understanding for the transfer of data on nationally approved medicinal products into Eudrapharm. HMA acknowledged the resources needed for this activity and discussed the roadmap for implementation.
- HMA were made aware about the development of ICH data exchange standards through ISO and the likelihood that the next major version of eCTD could also follow this path. HMA were encouraged to participate in National 'Mirror Panels' for ISO TC 215 of their National Member Bodies.
- The HMA/EMEA Training Project Team presented a training strategy with several options for endorsement by the HMA. This topic is closely linked to the discussion on resources and its development and will be discussed further at the next Strategic Day.
- A proposal for a specific Rapid Alert System for illegal and counterfeit medicinal products was presented. It will be assessed by the HMA Working Group of Enforcement Officers.

HMA_V (veterinary medicinal products meeting)

The Heads of Medicines Agencies for veterinary medicinal products met on 11 July 2008.

The main discussion points were as follows:

- France on behalf of the HMA Management Group presented the follow up of the implementation of CVMP recommendations regarding Quinolones and Fluoroquinolones. A questionnaire was sent to Member States concerning the precautions for use to include in SPCs. The HMA reviewed the progress of the process and discussed a possible work plan. It was agreed that this is a major concern of public health and the first step of strategic points. The HMA asked the National Competent Authorities to provide the CMDv with the necessary information regarding the products authorized through mutual recognition procedure. The HMA Management Group will prepare a strategic plan on this issue, to be presented in the next HMA meeting in November.
- The European Surveillance Strategy chair presented the outcome of the Copenhagen meeting on May 29th. An update of the pilot project on PSUR work-sharing was given. This project was coordinated by the PSUR synchronisation group, created under the auspices of ESS. The HMA decided to exchange by written procedure on the mandate and role of PHvWP according to the needs of the NCAs. The discussion will continue in November.
- The French presidency announced the conference entitled "Veterinary medicinal products legislation: opportunities for improvement" that will be held in Maisons-Alfort, close to Paris on September 30th. All interested stakeholders are invited to attend this conference: health professionals, consumers, animal health industry, and competent authorities.

This conference will be fed by the first proposals of the HMA Task Force on Veterinary Legislation. This public conference will welcome 200 people. Information (agenda, registration form) are available on www.anmv.afssa.fr. The recommendations issued will contribute to the reflection of the Task Force and to the discussion during the HMA stakeholders meeting in November.