



Stakeholders' Information

55th Heads of Medicines Agencies Meeting

Hilton Arc De Triomphe Paris Hotel

6-7 November 2008

HMA – HUMAN Meeting

The Heads of Medicines Agencies for human medicinal products met on 6 November 2008. The main discussion points were as follows:

- The CTFG made an update of the activities done in 2008. The Clinical Trials Voluntary Harmonisation Procedure (VHP) that involves a pre-submission of certain types of clinical trials in order to share the assessment and to harmonise its outcome among concerned Member States was endorsed. A pilot phase to test the procedure will start in February 2009. The VHP will be published on the HMA/CTFG Website.
- HMAH discussed an Incident Management Plan to deal with incident and crisis management situations within the European Medicines Regulatory System and agreed to start a pilot phase in 2009 to test the procedure.

HMA – JOINT Meeting

The Heads of Medicines Agencies for human and veterinary medicinal products met on 6 November 2008. The main discussion points were as follows:

- HMA discussed national requirements for the validation of the MA dossier in MRP and DCP procedures. They agreed to make the best efforts to reduce those requirements, established by national legislation, in 2009.
- HMA discussed and analysed some of the conclusions of the 2008 discussions on the use of resources in the European Medicines Regulatory System. HMA will publish information for stakeholders on the outcome of the discussion once they have adopted a consolidated report by the end of 2008.
- HMA agreed to adopt a coordinated position next year on the implementation of eCTD and other types of e-submissions after 2009.
- HMA adopted recommendations for implementing transparency of agendas and minutes in the field of MA assessment at EU level.



HMA – VETERINARY Meeting

The Heads of Agencies for veterinary medicines met in Paris on 7 November 2008.

The main discussion points were as follows:

- HMA V had a constructive dialogue with IFAH-Europe and EGGVP. The main subjects tackled were related to improvement of legislation in the short, medium and long term. Concrete progress has been acknowledged on various topics.
- The HMA Management Group presented the follow up of the implementation of CVMP recommendations regarding **Quinolones and Fluoroquinolones**.
- HMA V launched a reflection paper on a strategic plan aiming at minimising and preventing antimicrobial resistance resulting from use of antimicrobials in animals. It considered the need to adopt a broader approach including human usage of antimicrobials, particularly antibiotics.
- The European Surveillance Strategy Group chair presented an update of the pilot project on **PSUR work-sharing**.
- The French presidency presented the outcomes of the conference titled "Veterinary medicinal products legislation: opportunities for improvement" that was held on September 30th 2008.
- HMA V endorsed the work plan of the Task Force on veterinary legislation (including consultation and organisation of a focus group with stakeholders in 2009).