



Stakeholders information

58th meeting of the Heads of Medicines Agencies 7-8 July 2009 Stockholm, Sweden

Heads of Medicines Agencies – Human session on 7 July 2009

- EMEA presented a review over regulatory actions taken in connection with suspension of medicinal products. It was acknowledged that although the EU regulatory system performed very well in relation to the regulatory measures taken, there are areas for further improvement. HMA supported the creation of a closer link between CHMP and Clinical Trials Facilitation Group in the context of clinical trials. EMEA will start drafting an implementation plan to be presented at the HMA January 2010 meeting.
- EMEA gave an update regarding publication of PhVWP Monthly Report. It was proposed to annex to the PhVWP Monthly Reports the rationale and the content of the recommendation for changes to the product information at high level (ie. no SmPC or PL texts). Readers will be referred to the CMD(h) section of the HMA website for advice on the implementation of the PhVWP recommendations. Publication is proposed for the week after CHMP/PhVWP meeting together with the CHMP Monthly Report. The proposed concept of PhVWP Monthly Reports was approved by the HMA, with implementation as of September 2009. Due to the dual mandate the reports will be published on both EMEA and HMA websites.

Heads of Medicines Agencies – Joint session on 7 July 2009

- HMA Management Group presented the draft mandate and timetable for a new group dedicated to strategic issues; HMA Task Force on the HMA Strategy Paper II. In order to ensure coherence with the EMEA road map, cooperation with EMEA is recommended. It was agreed that the area of medical devices would also be included in the strategy planning.
- Optimisation of use of resources being a key issue for the HMA strategy, the HMA MG proposed that the Task Force on Availability of Resources at NCAs for MRP and DCP continues, until its remit and objectives are concluded. The HMA MG also proposed that the Resource Planning Group would report to the October 2009 HMA meeting and the future work on resources should be integrated in the Task Force on the HMA Strategy Paper II.

- A draft training strategy was presented by the HMA/EMA Training Project Team, and was adopted by the HMA for release for public consultation for three months until October 2009. The creation of an EU office for training, virtual and/or physical was also discussed. Revision and adoption of the Strategy and Action Plan is foreseen for the January 2010 HMA meeting.
- EMA informed the HMA that the EMA Transparency Policy is released for public consultation until 25 September 2009. A 2nd workshop with EMA partners and stakeholders will be held on 19 October 2009. The revised policy will be put to the December 2009 EMA MB meeting for adoption and publication.
- EMA presented the proposed mandate for the Pharmacovigilance Inspectors Working Group. The ad hoc group would now be transformed into a more permanent group.

Heads of Medicines Agencies – Veterinary session on 8 July 2009

- The European Surveillance Strategy Group chair presented new elements, e.g. a risk-based approach, to be included in the pilot project on **PSUR work-sharing**. Wide support was given for continuing the project, though some elements are to be further elaborated. Industry will be approached for their commitment to participate actively. The topic will be discussed at the October 2009 HMA meeting.
- The EMA and former CZ presidency presented recommendations from a joint HMA/EMA coordination meeting on antimicrobial resistance in May 2009 together with stakeholders. HMA V presented and discussed a revised HMA action plan on antimicrobial resistance in relation to veterinary medicines which had been revised in the light of the coordination meeting.
- HMA-V discussed a planned survey on the legal status of antimicrobials. questionnaire from the EMA regarding information from Member States on macrolide and lincosamide containing products authorised as veterinary medicinal products was endorsed.