

Stakeholders' Information

The use of resources within the European Medicines Regulatory System

The Heads of Medicines Agencies (HMA) is concerned about optimising the use of resources within the European Medicines Regulatory Network (EMRN) and is fully engaged in implementing measures to improve its overall efficiency and coordination within the fields of responsibilities of the National Competent Authorities (NCAs).

Considering the increasing workload in all areas of activity by HMA and with a view to achieving its common mission in promoting public and animal health in Europe, HMA has endorsed the adoption of a public health priority setting agenda based on risk based approaches.

At the meeting held on 5th September 2008 in Paris by the French EU Presidency, the HMA made some important conclusions as a follow-up of previous discussions on the use of resources within the EMRN.

A range of solutions was proposed to improve efficiency which would fit to the different National and European activities. On 31st December 2008 the HMA endorsed the outcome of these discussions resulting in a list of proposals requiring future action by HMA:

Conclusions/Actions

- **NCAs workload:** It was commonly accepted that given the expiration of patents and data protection for various medicinal products over the next number of years, NCAs will face an even heavier workload. Furthermore, an increase of DCPs is to be expected. The pharmaceutical industry should provide an estimate on the number of future applications to allow NCAs to plan their work in advance.
- **Improving efficiency of the EMRN:** NCAs agreed on important measures for the improvement of efficiency namely the adoption of a booking system with time slots, the avoidance of duplication of assessments, the promotion of work sharing and exchange of expertise within the Network to improve its overall efficiency. It was also agreed that industry should acknowledge its responsibility for producing a complete and high quality dossier.
- **Proposals for increasing efficiency in Mutual Recognition and Decentralised Procedures:** It was agreed to reconsider and improve work sharing within the Network and encourage NCAs to develop a common understanding of risk based approaches. It was also agreed to develop a harmonised booking system, encourage training and sharing of expertise between experienced Reference Member States (RMS) and those less experienced. In this context, it should also be clearly pointed out that actions need to be also taken by industry to improve the evaluation process, such as to look for other RMS, keep product lines together and avoid parallel booking. Support was given for a common application format.

- **More efficient use of IT systems:** The coordination of IT systems among the EMRN needs special attention by HMA. The implementation of a harmonised portal for submitting applications was supported by HMA.
- **HMA/EMA Training Strategy:** Adopted a proposal for a “road map” for training with clear orientations on the development of training for staff, in close coordination with EU and national training schemes.

The HMA, in particular its Management Group, will draft an action plan which will focus on the implementation of these conclusions on a short and medium term basis.

HMA Management Group

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