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Consultation (9-30 July 2010) on HMA's Strategy, 2011-2015

Comments from the Finnish medicines Agency

Dear Prof. Kent,

Thank you for the opportunity to review and comment on the draft HMA strategy 2011-2015. We find the draft document very useful in describing the current status of the EU regulatory network. Enclosed you will find some general remarks that may be useful in completing the HMA strategy 2011-2015.

EU regulatory network

The document gives a good rationale for the network-based regulation of medicinal products in the EU where culture, economy, structure of the health care, and medical praxis vary between Member States. Nevertheless, HMA should take the lead in diminishing the impact of these factors on the efficient conduct of Mutual Recognition Procedures (DCP/MRP). We agree in that the main topics are *risk-based regulation*, *harmonisation of assessment*, *work-sharing*, *training and compatible IT infrastructure*.

The roles of the EMA and the NCAs

The document highlights the complementary roles of EMA and NCAs. The document does not go on to predict the future in this area. In our opinion, the roles of the EMA and the NCAs, on one hand, and the scope of the centralised and DCP/MRP procedures, on the other hand, should be truly complementary. The overlap between the scopes of the centralised and de-centralised procedures will hinder the simplification of the regulatory procedures, i.e. the conduct of risk-based regulation.

Proportionate regulation and availability of pharmaceuticals

The document gives a good recipe for the improvement and harmonisation of the scientific assessment. In our opinion, the administration of the DCP and MRP as well as the work-sharing procedures could be simplified. Currently, the advantage gained through reduced overlap in scientific assessment is lost through the complex administrative procedures.

HMA should, indeed, be active in promoting an improved legislation that would foster a more rational and proportionate regulation. This could reduce the regulatory burden for the

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industry and give relief for the NCAs in terms of available resources. Adding some room for national interpretation would facilitate the availability of medicines as well as speed up the national phases of the MA procedures.

Risk-based management of resources, reducing administrative burden and improving regulatory efficiency

The document gives a good description of the future challenges of the EU regulatory network. In order to meet these challenges, the NCAs must have courage to trust each others and accept deviations from old national policies. Harmonisation is inevitable and the NCAs should rather speed up than retard the harmonisation. By this way, resources can be allocated to meet new challenges provided by new science, technology and legislation.

Yours sincerely

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