

Section 1: Explanatory Note: Developing the Heads of Medicines Agencies Strategy for the European Medicines Regulatory Network – A Discussion Document

The attached document is a contribution to the debate about the future of the European Medicines Regulatory Network. It proposes ways of enhancing the protection of public health and animal welfare in the EEA.

It is a response to the evolving regulatory environment: the recent enlargement, the legislative changes brought about by the implementation of the new legislation, changing public health needs and a reaction to changes and recent developments in the pharmaceutical industry.

It represents a summary of the views of six Drafting Groups, each chaired by a Head of Agency, which dealt with the following themes

- Communication and Information
- Scientific Resources
- Scientific Assessment Process: New products and referrals
- Pharmacovigilance
- Inspection, Laboratory Control and Enforcement
- IT information Systems

The paper consists of the following main parts

- an examination of the current regulatory system (its context rather than an in depth analysis of the legal framework),
- an analysis of the stakeholders in the network,
- proposals to enhance the current system,
- an action plan.

It has been adopted by the Heads of Medicines Agencies (HMA) as the basis for discussion with stakeholders. On its final adoption, it will form the way forward for the Heads of Medicines Agencies for the next 3-5 years.

It complements the existing EMEA Road Map in a number of ways. It is building on the same need to ensure the quality and robustness of assessment, inspection and regulatory action in the system but emphasis is placed on the Mutual Recognition and Decentralised Procedure. It also raises similar issues such as the availability of high quality staff, and the need to interact with a number of internal and external stakeholders. It highlights the need for HMA and the EMEA to work closely together to deal with them. The HMA Strategy paper also fully recognises the role of the EMEA in the coordination of the Centralised Procedure but underlines the fact that the Centralised Procedure can only work effectively with the contribution of national resources.

Finally, although the EMEA Road Map and the HMA Strategy Paper are at different stages of development, they share a common goal which is the enhancement of the current system in the interests of animal welfare and public health.

It does not explicitly state the needs of the different stakeholders in the European Medicines Regulatory Network but they are implicit throughout the document. For example, the needs of the public for access to high quality, safe and effective medicines, and particularly the most innovative ones, is recognised. This is balanced with the requirements for robust assessments, predictability of results and an efficient service. The paper serves to demonstrate that closer

coordination at the level of the Heads of Medicines Agencies is in the interests of both patients and the industry.

HMA is committed to consulting widely on this document. A consultation meeting will be held under the Austrian Presidency. Invitations will be sent out shortly to a range of national and European industry bodies and patient groups. In the meantime, written comments would also be welcome on this document. The initial point of contact will be Nuala Harman from the Heads of Medicines Agencies Permanent Secretariat at hma-ps@imb.ie.

On its adoption, the Strategy will be taken forward by a small Working Group chaired by Jean Marimbert, the head of the French National Competent Authority, AFSSAPS. He will be joined by five senior officials from other national Competent Authorities: Hortensia Segrelles (Spain), Gabriella Conti (Italy), Suzanne Keitel (Germany), Shaun Gallagher (UK) and Mariette Backes-Lies (Luxembourg). Jytte Lyngvig, Chair of the HMA Management Group and Head of the Danish Medicines Agency, will also join the Implementation Group as the HMA Management Group representative.

HMA Management Group