

*CONSULTATION
WITH HMA's PARTNERS AND STAKEHOLDERS ON
THE HEADS OF AGENCIES STRATEGY PAPER ON
THE EUROPEAN MEDICINES REGULATORY NETWORK*

22 March 2006

Introductory Note

The Heads of Medicines Agencies (HMA), which is the working forum of heads of human and veterinary regulatory agencies for medicinal products in the EU Member States and the EEA-EFTA States, Iceland, Liechtenstein and Norway (referred to hereafter as the EEA) has a legitimate and key role as a partner in the European Medicines Regulatory Network.

At a time of significant changes in the field of medicinal products, the Heads of Medicines Agencies have decided to open a consultation process on the Strategy Paper they have recently adopted (<http://heads.medagencies.org>).

The HMA Strategy Paper

The HMA Strategy Paper is a contribution to the debate about the future of the 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.

The HMA Strategy Paper 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 places emphasis on the Mutual Recognition, Decentralised and national procedures, which are under HMA responsibility. 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 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 working closely together with national authorities.

The document 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.

At this initial phase, the Action Plan deals mostly with aspects that are related to the interaction between regulatory bodies and working groups with regulatory responsibility in the system, with the aim of strengthening the Network.

The HMA have identified a number of actions that are key for enhancement of the current system. They decided to start now with the implementation of this first version of the Action Plan and develop the strategy and actions over time. Therefore it is anticipated that this document will be revised regularly and

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stakeholders will be involved in the debate on the future actions deriving from the Strategy.

The HMA Strategy Paper is intended to be a tool for continuous improvement of the Network through a regular communication process between HMA and stakeholders.

It serves to demonstrate that closer coordination at the level of the Heads of Medicines Agencies in their interaction with other regulatory partners and stakeholders will benefit the system and serve the interest of protection of animal welfare and public health in the EEA.

Description of the consultation process

- A consultation exercise is envisaged starting in March 2006.
- Collation of contributions and analysis of feedback will be done during the summer (June-July).
- A document on the outcome of the consultation will be drafted and presented to Heads of Medicines Agencies in September 2006.
- The scope of the consultation is European, but each national competent authority can organise a national consultation with partners and stakeholders. The inclusion of national feedback may enrich the exercise providing additional views relevant for the European scope.
- In order to have a harmonised approach similar communication tools for the national consultation should be used.
- National contribution to the consultation will be incorporated after the September 2006 meeting.
- A final draft of the document on the outcome of the consultation will be prepared for the November 2006 meeting and finalised by the end of the year.
- The final document on the outcome of the consultation will be published on the HMA website, ensuring transparency of content and source of the feedback received.
- The next version of the Strategy Paper should take into account the outcome of the consultation exercise.
- A process for drafting the next versions of the HMA Strategy Paper will also be presented as part of this initiative for continuous improvement of the system.

A questionnaire is proposed in order to focus the feedback of stakeholders during the consultation of the HMA Strategy Paper and facilitate its treatment.

The point of contact for feedback will be Nuala Harman from the Heads of Medicines Agencies Permanent Secretariat at hma-ps@imb.ie. Comments should be sent by 31 May 2006.

Questionnaire

In order to focus the feedback of stakeholders and facilitate its treatment a questionnaire is proposed. A limited number of questions will guide stakeholders in this exercise.

Chapters 1 to 5 of the HMA Strategy Paper contain several proposals to enhance the current system both in terms of the interaction of HMA among themselves and with regulatory partners and stakeholders.

In line with these proposals of the HMA Strategy Paper the following questions should be addressed:

1. In what areas should HMA provide clarification regarding its role in the Network?
2. What additional remarks would you propose to complete HMA's analysis of the current regulatory system?
3. What additional actions would you suggest with a view to implement the main orientations under the headings in chapter 5 of the Strategy Paper?
4. What kind of information could HMA provide in addition to what is proposed in the EMEA Road Map?
5. What are the preferred ways of communication between HMA and stakeholders (Web Portal, newsletters, meetings, other)?
6. What kind of process would you suggest for regular information exchange between HMA and stakeholders to ensure continuous input for improvement of the strategy and action plans?