The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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Press release
EMEA launches action plan for improvements for human medicines

The European Medicines Evaluation Agency (EMEA) today published a range of initiatives aimed at improving the way the Agency handles its work in relation to medicines for human use.

The initiatives contained in the action plan are part of the Agency's ongoing integrated quality management initiative and also take into account an audit of the scientific committee responsible for human medicines (the CPMP) held in 2003. The impact of EU enlargement in May 2004 and the need to prepare for future revisions to pharmaceutical legislation are also considered.

The EMEA intends to implement the action plan over a period of 18 months, with the first results of the initiatives expected to become visible in the second half of 2004. Regular progress reports will be published to inform the Agency's stakeholders on the achievements made.

The key objectives of the action plan are to:

- Reinforce the Agency's scientific evaluation processes
- Further improve the transparency of the procedures
- Provide for a better functioning of its scientific committee, the CPMP
- Strengthen the capacity of the Agency's professional workforce to equip them for a more scientific role in the future

The action plan will be a significant initiative in helping the EMEA meet its mission of contributing to the protection and promotion of public health in the European Union.

EMEA Executive Director, Thomas Lönngren, said, "the Agency is confident that the implementation of the actions contained in the action plan will enable the EMEA to meet the important challenges which will affect the EU regulatory system over the next few years and, as a result, to position itself successfully in an ever developing international regulatory environment".

--ENDS--

NOTES:

1. Key elements from the action plan are included in annex.
2. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int

Enquiries please contact:

Noël Wathion, Head of Unit, Post-authorisation evaluation of medicines for human use
Tel. (44-20) 74 18 85 92

Martin Harvey Allchurch, EMEA press officer
Tel. (44-20) 74 18 84 27, E-mail: martin.harvey-allchurch@emea.eu.int

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.eu.int http://www.emea.eu.int

Key elements of the EMEA action plan to further improve its processes in relation to medicines for human use

Strengthening of the scientific evaluation processes

Objectives

- To further improve the quality and the scientific and regulatory consistency of the work undertaken by the EMEA and the CPMP.

Actions

- A strengthening of the quality assurance:

  Such further improvement of the quality assurance should be achieved at the different steps of the scientific evaluation processes.

- An enhanced consultation of the EMEA/CPMP by pharmaceutical companies during the development of a medicinal product:

  Building on recent initiatives such as the creation of a permanent group, the Scientific Advice Working Group, and an increased interaction with sponsors mainly through the conduct of oral explanations, further gains in efficiency of the scientific advice/protocol assistance procedure will be explored.

- An increased involvement of high-level specialised expertise during the scientific evaluation processes:

  The concept of the newly established Therapeutic Advisory Groups will be further developed in order to allow consultation in relation to centralised applications and issues relating to the development of CPMP guidelines.

  In addition, a system capable to conduct pharmacovigilance for centrally processed applications in a more pro-active way, characterised by the involvement of specialised expertise, will be implemented. The introduction of such system, which is part of the elaboration of the EMEA Risk Management Strategy, should allow for efficient and timely handling of safety concerns, both pre- and post-authorisation.[1]

Increased transparency

Objectives

- To further improve the openness and transparency of the activities undertaken at the level of the CPMP.

Actions

- The transparency of CPMP activities, as well as the communication of such activities to the Agency's stakeholders will be revised. This will include a systematic and pro-active consultation of the EMEA's stakeholders in the development of CPMP guidance documents[2].

[1] Detailed guidance on such system will be published at the beginning of 2004.

[2] These actions will complement the recently announced new EMEA transparency initiatives. Please refer to 'New EMEA Transparency Policy Procedures' (EMEA/MB/52/03/Rev1/Final), dated 31 October 2003.

Better functioning of the CPMP

Objectives

- To further clarify the interaction between the CPMP and the EMEA secretariat as well as their relationship with pharmaceutical industry.
- To further improve organisational aspects in relation to the functioning of the CPMP and its Working Parties.

Actions

- The respective role and responsibilities of the CPMP and the EMEA secretariat in the different processes managed by the Agency will be more clearly described.
- Likewise, the relationship between the CPMP/EMEA secretariat and pharmaceutical companies in such processes will be further addressed.
- Improvements in the organisational field will look at further delegating certain CPMP tasks to existing or new CPMP Working Parties or Ad-Hoc Groups and better defining the role and tasks of such forums, including their participation in the EMEA planning process.

Strengthening the Agency's professional workforce

Objectives

- To provide for a high quality and efficiency of operation in relation to the Agency's core activities.
- To prepare for a pronounced change in the Agency's role and responsibilities as envisaged in the review of pharmaceutical legislation.

Actions

- The integrated quality management system available at the EMEA will be strengthened in order to achieve an adequate level of scientific and regulatory consistency in the outcome of the scientific evaluation processes. New management tools will be developed and existing tools will be revised.
- The recruitment and professional training strategies will be re-focused to ensure that the Agency's staff is of the highest quality in order to face the challenges ahead.