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Post-authorisation Evaluation of Medicines for Human Use

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REPORT ON WORKSHOP ON THE DEVELOPMENT OF AN EMEA TRANSPARENCY POLICY

EMEA, 22nd January 2009

Background Information

The EMEA organised a Workshop on the Development of an EMEA Transparency Policy on the 22 January 2009, chaired by Mr Thomas Lönngren (Executive Director, EMEA) and Mr Noël Wathion (Head of Post Authorisation Human Unit, EMEA).

Objective of the Workshop

One of the EMEA priorities for 2009 is to further increase transparency and provide for more openness on the operation of EMEA activities. In order to achieve this, the EMEA is currently working on the development of an EMEA Transparency Policy.

As part of the Agency's consultation with its partners and stakeholders on the development of such Transparency Policy, the EMEA organised a Workshop with representatives from the Member States, Patients, Learned Societies, Healthcare Professionals and European Pharmaceutical Industry Associations (for human and veterinary medicinal products) to discuss the key principles of the Transparency Policy. The concept of (commercial) confidential information was also discussed [joint EMEA/HMA (Heads of Medicines Agencies) initiative]. The objective of the Workshop was to provide an opportunity for a first discussion with invited stakeholders to express their initial thoughts and provide feedback on their understanding and expectations on the level of transparency of EMEA activities.

The agenda of the Workshop can be found here

Attendance

The EMEA invited members from Patients', Consumers', Healthcare Professionals' Organisations, Learned Societies and Farmers' Unions. The topic of commercial confidential information was addressed with input from both the joint EMEA/HMA Group on Transparency and Emacolex (the European Medicines Agencies Cooperation on Legal Issues). Representatives from European Pharmaceutical Industry Associations (for human and veterinary medicinal products) were also invited.

From the invited members, a total of 34 external participants and 26 EMEA staff attended the Workshop.

The detailed list of participants at the Workshop can be found here

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Identified issues for discussion and content of the presentations

The morning session of the Workshop was dedicated to a high level discussion on the draft EMEA Transparency Policy. Six presentations were delivered. The scope of the discussion was to address the following issues:

- *Experience* with the current EMEA's transparency measures along with the *expectations on product* related issues [products before/after authorisation along with specific transparency measures on emerging issues (e.g. safety issues, quality defects etc) irrespective of the status of the authorisation of the medicinal product].
- *Expectations on non-product* related issues (e.g. drafting of Guidelines, EMEA Committees' Monthly Reports etc).
- Improvement of EMEA interaction with its stakeholders.

The afternoon session of the Workshop focused on a discussion on commercial confidential information aspects (joint EMEA-HMA initiative). Six presentations were delivered. The scope of the discussion was to address the (common) understanding on what is considered commercial confidential information and therefore should not be disclosed.

The EMEA paper on "Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents" (EMEA/45422/2006, 15 April 2007) was used as a platform and starting point for the discussion.

The list of 11 presentations can be found here

Feedback from the participants

The participants welcomed the opportunity to discuss with the EMEA the development of its Transparency Policy and therefore highlighted the value of this Workshop as a first step in this process. In general, their feedback was positive with regards to the current transparency measures. An open and fruitful discussion took place and the following main feedback was received:

General comments

- Improve the visibility of the EMEA and promote further the awareness on the EMEA's role and activities in the context of the European Regulatory System Network. The development of a more user-friendly EMEA website and its cross-reference in the NCAs' website would facilitate further awareness.
- Strive for harmonisation and optimally reach a common approach with the NCAs within the framework of the European Regulatory System Network on transparency related issues, recognising the existence of national legislation on freedom of information and also differences at EEA level with regards to capacity, culture, implementation of transparency measures, patient-doctor relationship in terms of communication etc.
- Explore how the EMEA's scientific evaluation and recommendations on the benefit/risk balance of medicinal products could further contribute to the cost/ effectiveness assessment performed by Health Technology Assessment (HTA) bodies within the EU. On this point, Mr Thomas Lönngren informed that the EMEA will continue exploring the optimal collaboration between EMEA and HTA bodies. It was noted that this activity was recommended by the High Level Pharmaceutical Forum.
- Carefully consider the content of information, how and particularly when this information will be shared and made publicly available during the life cycle of a medicinal product (i.e. before /during/after marketing authorisation) in the course of the development of future EMEA transparency measures.
- Further encourage the interaction between the EMEA and its stakeholders.

Expectations on product related issues

The experience with the current transparency measures was considered positive by the participating stakeholders. The following main comments were raised for future consideration:

- Further develop the involvement and interaction of Patients' and Consumers' Organisations in EMEA activities. In particular, further define the extent of the participation of Patients' Organisations in the EMEA Scientific Committees, including their involvement in the benefit/risk considerations by the CHMP.
- Consider transparency with regards to the rationale on the selection and involvement of scientific experts (e.g. in Scientific Advisory Groups).

Expectations on non-product related issues

The stakeholders' feedback focused on the request for early awareness and involvement of the stakeholders on non-product related issues such as the development of EMEA policy documents and Guideline development. In particular the following main comments were raised:

- Consider early involvement of the Stakeholders in the drafting of new Guidelines (Concept Paper stage) in order to provide an understanding on the rationale and the criteria that led to their development.
- Consider more time for comments for draft Guidelines released for external consultation in order to allow the optimum involvement and feedback from the stakeholders' experts. In addition, increase transparency with regards to the rationale on the final (non) acceptance of comments received.
- Strive for more consistency on the transparency measures applied on the variety of the ongoing Working Parties' activities.

Commercial confidential information aspects

In principle, the need for a harmonised European approach with regards to the general principles for active publication and for reactive disclosure of EMEA documents was flagged by the participants. On this aspect the following main comments were raised:

- The need for common (European) definitions on commercial and personal data information should be considered.
- Protection of personal data information provided to the Regulatory Authorities should be ensured.
- The optimum timing of the disclosure of information was considered important and would need careful reflection.
- The need for high quality of the disclosed information along with how this information is reaching the patients (e.g. elderly patients, with no access to computer, not speaking English etc) should be considered.
- The need to rapidly move towards more consistent transparency was flagged; however a stepwise approach is needed. For instance, a next step could be the implementation of transparency on the release of (reports of) PSURs; on this particular issue it was commented that the disclosure of this information by the Authorities has already considerable resource implications.

Conclusions and Future steps/actions

Stakeholders recognised and welcomed that openness and transparency with respect to the activities of the EMEA is very important in order to promote public health in accordance with the principles outlined in the European Pharmaceutical legislative framework.

The following future steps and actions were indicated by the EMEA:

- The EMEA will draft its Transparency Policy along with an Impact assessment, also taking into account feedback received at today's Workshop.

- The draft EMEA Transparency Policy will be presented to the June 2009 Management Board meeting in view of the start of an external consultation (mid June 2009-end September 2009).

- Discussion on the EMEA Transparency Policy will take place at the Heads of Medicines Agencies meeting in July 2009.

- Discussion on the EMEA Transparency Policy will also take place at the scheduled EMEA Patients' and Consumers' Working Party (PCWP) and the EMEA/CHMP Healthcare Professionals' Working Group (HCP WG) meetings.

- A follow-up Workshop on the EMEA Transparency Policy to be organised with stakeholders should optimally take place in autumn 2009.

- The EMEA Transparency Policy, Impact Assessment and Implementation Plan should be presented to the December 2009 Management Board meeting in view of their adoption and subsequent publication.