European Medicines Agency

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THE EMEA TRANSPARENCY POLICY
DRAFT FOR PUBLIC CONSULTATION

I INTRODUCTION

Since the establishment of the EMEA, transparency has been an important feature of the Agency's operation. This resulted in the introduction of novel concepts such as European Public Assessment Reports (EPARs) in line with the requirements of new Community legislation, but also led to various initiatives going beyond legislative requirements, adopted by the EMEA Management Board in the form of Transparency Measures[1,2].

Furthermore, the EMEA in its longer term vision[3] indicated that its stakeholders would see over the next few years a gradual and stepwise increase in the Agency's level of transparency, both in the field of non-product as well as product related activities. In order to achieve this objective the EMEA stated that it would involve its partners and stakeholders in discussions on how to meet the increasing demands of civil society (in particular patients/users of medicines as well as healthcare professionals) for earlier information whilst respecting commercial confidentiality of proprietary information.

This document elaborates on the rationale for and the scope of an EMEA Transparency Policy, the objectives to be achieved and the pre-requisites to be fulfilled, as well as the proposed way forward. Furthermore, concrete examples of how the EMEA intends to implement its Transparency Policy over the next years in a stepwise manner are described in Annex I.

II RATIONALE FOR AND SCOPE OF THE EMEA TRANSPARENCY POLICY

Rationale

The rationale for the development of an EMEA Transparency Policy is

- to be able to better address the increasing need for information from civil society,
- to provide for more openness on the various activities undertaken by the EMEA (in particular its opinion/decision-making process),

whilst applying a more robust and consistent approach towards transparency in all areas of its operation.

Transparency is a pivotal element in building trust and confidence in the Agency's operation and in addition it fulfils the right of EMEA stakeholders for impartial and comprehensible information about the medicines regulated by the Agency and their use for the benefit of public and animal health. The main aim of the EMEA

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* Rev: Please note that the numbering on pages 11 and 12 has been revised.

1 Report to the Management Board on the Workshop "A clear step forward: Transparency at the EMEA" (Doc. Ref.: EMEA/MB/053/00).

2 New EMEA Transparency Policy Measures (Doc. Ref.: EMEA/MB/52/03/Rev1/Final).

3 The European Medicines Agency Road Map to 2010: Preparing the Ground for the Future (Doc. Ref.: EMEA/H/34163/03/Final).

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 27
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Transparency Policy, therefore, is to provide more clarity on the Agency's understanding of its responsibility as a public body in the field of medicines regulation.

Although the EMEA has taken various transparency initiatives over the past years, it is acknowledged that until now such initiatives have not been reconciled into a single policy that would facilitate a more robust and consistent approach towards transparency in the various EMEA areas of involvement. It should be reminded in this respect that the EMEA operates in an increasingly complex regulatory environment, currently coordinating the activities of six Scientific Committees in the fields of human and veterinary medicines regulation as well as some 35 Working Parties and other (scientific) fora with challenging and complex interactions and interdependencies at various levels. In addition, requests for access to information and access to documents considerably increased over the past years, illustrating the need to making more information publicly available in a proactive way.

In developing and maintaining an EMEA Transparency Policy all current transparency initiatives will be considered as well as changes stemming from future Community legislation. Developments within the framework of the European Union (EU) Regulatory System Network through initiatives undertaken at Heads of Medicines Agencies (HMA) level will also be taken into account in order to provide for a harmonised approach.

Scope

Transparency implies openness, communication and accountability, whilst respecting the protection of both personal data as well as commercially confidential information. The EMEA embraces these concepts in the development of its Transparency Policy. Transparency shapes and drives what is being provided in terms of information and the way it is communicated. Therefore the EMEA considers that these concepts are important in order to achieve the provision of targeted, understandable and accessible information on medicines, hence contributing to the promotion and protection of public and animal health.

The scope of the EMEA Transparency Policy covers medicines for both human and veterinary use, addressing the particularities of each field. Furthermore, the Policy is not restricted to measures arising from currently applicable Community legislation, but it will provide the Agency's stand on its level of openness toward stakeholders. It is not limited to the level of transparency applied to documents produced by the EMEA, but it will also address other aspects such as the level of interaction with its stakeholders, including involvement in opinion/decision-making. Not only will more openness relate to the Agency's scientific activities, but greater emphasis will also be put on corporate and administrative transparency, in particular as regards the work undertaken at the level of the EMEA Management Board.

Particular attention has been given to ensure that the EMEA initiatives on transparency are consistent with and complementary to the transparency recommendations outlined by HMA in their Strategy Paper[4]. Whilst recognising the limitations provided by national legislation on freedom of information, efforts will be undertaken to strive for harmonisation of key elements on transparency across the EU. Finally, it should be emphasised that preliminary feedback from the EMEA partners and stakeholders on their needs for information and their expectations (conclusions from a Workshop on the Development of an EMEA Transparency Policy held at the EMEA on 22 January 2009)[5] has been taken into consideration when drafting the EMEA Transparency Policy.

[4] The Heads of Medicines Agencies Strategy Paper: Developing the Heads of Medicines Agencies Strategy for the European Medicines Regulatory Network – A Discussion Document.

[5] Report on Workshop on the Development of an EMEA Transparency Policy (Doc. Ref. EMEA/91746/2009).

III OBJECTIVES OF THE EMEA TRANSPARENCY POLICY

Three important objectives have been identified:

1. To apply a more proactive approach towards transparency in the daily operation of the EMEA

Although the EMEA as of its start of operation has continuously engaged in reinforcing its transparency (often going beyond the legislative provisions in force) it is the Agency's view that in order to meet increasing demands for more openness it should intensify its efforts in this field. This can be undertaken by applying a more proactive approach.

Three important pre-requisites need to be fulfilled in order to achieve this objective:

- Finding the right balance between transparency and protection of commercial confidentiality.

  In order to achieve this objective there is a need to redefine the balance between transparency and protection of commercial confidentiality of proprietary information. This will require a revision of the existing principles of commercially confidential information[6] through a dialogue with the Agency's stakeholders. In addition, the EMEA believes that the aspect of commercially confidential information can be best reviewed through a concerted action with the National Competent Authorities (NCAs) of the Member States in order to achieve a harmonised EU approach in this field.

- Increasing the understanding of activities undertaken by the EMEA, including the Agency's opinion/decision-making.

  It needs to be recognised that the EU Regulatory System is characterised by a quite complex architecture, with the EMEA often being in a coordinating role for the networking model. Not only is the Agency's role in the EU Regulatory System often poorly understood by the general public and the media, in addition there exists also confusion on the exact activities undertaken by the EMEA. Another aspect is the need to provide clarity on the Agency's opinion/decision-making process, not only from a procedural perspective, but even more importantly with respect to the (scientific) rationale for the EMEA opinion/decision-making. This is of particular importance for strengthening trust and confidence in the Agency's deliverables.

  This objective will require efforts to raise the level of the public's awareness of the EMEA and to create a better understanding of the Agency's remit. In addition, better explaining the EMEA processes for opinion/decision-making and further substantiating the (scientific) rationale for such opinion/decision-making, and subsequently translating this in communication material better adapted and targeted to the various stakeholders should be a primary focus.

- Promoting good administrative and regulatory practices.

  The availability of a Transparency Policy also requires that a culture of transparency is embedded in the day-to-day operation of the EMEA. Engraining such culture in the functioning of the Agency will necessitate a consistent approach in the application of transparency throughout the EMEA, and the best way to achieve this is in the context of the Agency's Integrated Quality Management (IQM) system. Furthermore, the necessary (technical) tools to allow for an efficient implementation of the EMEA Transparency Policy will need to be put in place.

[6] Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents (Doc. Ref.: EMEA/45422/2006).

2. To further strengthen interaction with EMEA stakeholders

Over the past years the Agency has developed various initiatives to engage and interact with its stakeholders. Whilst the focus has been first on pharmaceutical industry, efforts, particularly in the field of medicines for human use, more recently have targeted patients, healthcare professionals, and other healthcare decision makers. Although several stakeholders have expressed satisfaction with initiatives developed by the EMEA to involve them in the Agency's activities (reference is in this respect made to the outcome of yearly surveys performed by the Agency), there are also requests to reinforce such interaction, building on current achievements,

Meeting this objective will require a continuation of the ongoing dialogue with stakeholders to further define the level of interaction with the EMEA, including its Scientific Committees, and, where relevant, other scientific fora which fall under the Agency's responsibility.

3. To enhance and promote closer interaction with the NCAs within the frame of the EU Regulatory System Network on transparency related aspects

The past decade has seen a gradual increase in efforts to build a network of excellence between EU Regulatory Authorities. Both the EMEA Road Map and the HMA Strategy Paper have highlighted the need for close collaboration in a wide area of activities. Also the field of transparency will require close cooperation between all EU Regulatory Authorities. As much as possible one should strive for harmonisation of key elements on transparency across the EU, whilst recognising that existing national legislation on freedom of information will set the limitations of such harmonised approach.

This will require that efforts are undertaken to ensure that the EMEA initiatives in the field of transparency are in compliance with and complementary to the recommendations outlined in the HMA Strategy Paper. As a consequence, the ongoing dialogue with NCAs on transparency related aspects will have to be strengthened over the next years.

IV MEETING THE OBJECTIVES: PROGRESS TO DATE AND PROPOSED WAY FORWARD

In order to achieve the aforementioned objectives, further work needs to be undertaken over the next years, building on current achievements. The Agency's proposed way forward is described below as well as the current state-of-play, and has been classified as per the objectives outlined in Section III.

Objective 1: Apply a more proactive approach towards transparency in the daily operation of the EMEA

Since the establishment of the EMEA the focus primarily has been on a proactive publication of EMEA documents, both for product related and more general EMEA information, and efforts have been intensified over time. For instance, as of March 2009 the Agency has further strengthened its level of transparency by making available in a dedicated area on the EMEA website all non-confidential Management Board documents (including agendas and minutes).

Work undertaken on improving the understanding of the Agency's opinion/decision-making relates to discussions at the level of the Committee for Human Medicinal Products (CHMP) on benefit/risk assessment methods in the context of the evaluation of marketing authorisation applications for medicines for human use, whereby the focus is on providing recommendations on ways to improve the methodology, but also the consistency, transparency and communication of the benefit/risk assessment by the CHMP.

In order to raise awareness of the EMEA, a first EMEA Media Workshop was held in June 2008. In addition, discussions with patients and consumers on how to best communicate benefits and risks of medicines were initiated in June 2008.

Transparency also requires engraining a culture of openness in the daily operation of the EMEA. The importance of good administrative and regulatory practices is fully recognised by the Agency. Its IQM system has been further developed over time and management assurance about the Agency's processes and output is now fully integrated in the day-to-day operation of the EMEA. In order to successfully implement the EMEA Transparency Policy in all its facets a consistent internal approach vis-à-vis the application of transparency aspects will be required.

To make further progress in this field the EMEA envisages to

- Review the balance between transparency and the protection of commercial confidentiality of proprietary information by redefining the notion of commercially confidential information and subsequently arriving at a harmonised EU view on this topic. This should preferably lead to the disclosure of selected pieces of information prior to decision-making, without undermining the decision-making process (e.g. the release of a minimum set of information on the submitted applications for marketing authorisation).
- Gradually improve, once the decision-making process has been concluded, the proactive disclosure of EMEA documents/information throughout the lifecycle of medicines for human and veterinary use. The identification of key milestones for the disclosure of such documents/information should facilitate this process.
- Improve the visibility of the Agency and undertake efforts to better explain how conclusions are being reached at the EMEA as well as the (scientific) rationale for these conclusions. This should lead to a further strengthening of the EMEA stakeholders' trust in the Agency's deliverables.
- Embed a culture of transparency in the Agency's operations in order to achieve a consistent approach in the application of the various principles of the EMEA Transparency Policy.

Objective 2: Further strengthen interaction with EMEA stakeholders

Starting with a structured dialogue with pharmaceutical industry (both in the human and veterinary medicines sector), the EMEA has gradually broadened such dialogue to other stakeholders. Alongside the participation of civil society representatives in a number of EMEA Scientific Committees and the EMEA Management Board, an important milestone has been the first meeting of the EMEA Patients' Organisations Working Group on 8th May 2003. Not only was such Working Group later on transformed in a formal Working Party, a similar initiative was introduced by establishing a Healthcare Professionals' Organisations Working Group on 11th November 2006.

Over the next years the EMEA will further progress existing interactions with civil society representatives (in particular patients, but also healthcare professionals), especially at the level of the EMEA Scientific Committees. Aspects to be covered in the frame of these interactions should include both product related issues as well as the development of guidelines and policy documents. This should ultimately result in (revised) frameworks of interaction with these civil society representatives.

Objective 3: Enhance and promote closer interaction with the NCAs within the frame of the EU Regulatory System Network on transparency related aspects

Cooperation in the field of transparency between the EMEA and the NCAs within the context of the EU Regulatory System Network so far mainly concentrated on activities whereby the EMEA operates as a coordinator for such Network. Recently it was agreed at HMA level to enhance this cooperation also in other areas where it would be

of benefit to strive for a coordinated approach at EU level, e.g. as regards the publication of agendas and minutes of EMEA Scientific Committees' meetings.

Therefore, further work in this field will focus on identifying where it would be of benefit for the efficiency of the EU Regulatory System Network to arrive at a harmonised approach on transparency related aspects for medicines regulation throughout a product lifecycle. In addition, efforts should also be directed on achieving as much as possible a consistent implementation across the EU.

V CONCLUSIONS AND NEXT STEPS

The EMEA believes that the vision outlined in this Transparency Policy is a further step in the direction of more openness on the way the Agency operates. This should not only lead to a better understanding of the Agency's deliverables, including the rationale for such deliverables, but also to more engagement of EMEA stakeholders in the work performed by the Agency. The ultimate aim is to further strengthen trust and confidence in the Agency's operation. Continuing the current dialogue with all stakeholders, in close collaboration with the NCAs in order to achieve, where feasible, a common approach, will be of outmost importance for a successful outcome.

The draft EMEA Transparency Policy is subject to public consultation until 25 September 2009. In addition, a 2nd Workshop with EMEA partners and stakeholders on the development of the EMEA Transparency Policy is scheduled to take place at the EMEA on 19 October 2009. Following an analysis of the comments received and subsequent adoption by the Agency's Management Board, the EMEA will publish the final Transparency Policy. In parallel a Consequence Analysis will be developed in order to assess the workload consequences and the (human) resources' needs to allow for an effective implementation of the final EMEA Transparency Policy. It is important to emphasise that a stepwise implementation will be foreseen. The various key initiatives will be included in the yearly planning cycle of the EMEA as per the Agency's Work Programmes adopted by the Management Board.

Annex 1

IMPLEMENTATION OF THE EMEA TRANSPARENCY POLICY
EXAMPLES OF KEY TRANSPARENCY INITIATIVES

Reference is made to Chapter IV of the EMEA Transparency Policy. Examples of how the EMEA envisages to implement its Transparency Policy in the different areas of operation are provided below. They have been classified as per the objectives of the EMEA Transparency Policy described in Chapter III. It should be emphasised that a stepwise implementation is foreseen. The various key transparency initiatives will be progressed in accordance with the yearly EMEA Work Programmes adopted by the Management Board.

1. To apply a more proactive approach towards transparency in the daily operation of the EMEA

Balance between transparency and commercially confidential information	
Key Transparency Initiatives	1. Redefine the notion of commercially confidential information, in close collaboration with the NCAs, leading to a harmonised EU view in this field, hereby taking due account of the outcome of the public consultation on the EMEA Access to Documents Policy[7]. 2. Progress the implementation of the EMEA Access to Documents Policy, taking into account the outcome of the public consultation, including the establishment of the EMEA public register of documents.
Proactive disclosure of EMEA documents/information throughout the product lifecycle	
Key Transparency Initiatives	3. Proactively publish additional product related documents: - Agendas and Minutes of EMEA Scientific Committees' meetings (follow-up to the 20 November 2008 joint EMEA/HMA recommendations[8]). - PhVWP Monthly Reports (for medicines for human use). 4. Progress the implementation of the EudraVigilance Access Policy (for medicines for human and veterinary use)[9], taking into account the outcome of the public consultation.

7 Draft EMEA Policy on the Practical Operation of Access to EMEA Documents (Doc. Ref.: EMEA/110196/2006/Final).

8 Recommendations on transparency related to agendas/minutes on product related issues (implementation of Article 126b of Directive 2001/83/EC as amended and Article 80 of Regulation (EC) No 726/2004) (Doc. Ref.: EMEA/623107/2008).

9 Draft EudraVigilance Access Policy for Medicines for Human Use (Doc. Ref.: EMEA/187439/2006/Final) and Draft EudraVigilance Access Policy for Medicines for Veterinary Use (Doc. Ref.: EMEA/113700/2008).

	5. Proactively publish additional information elaborating on the benefit/risk of medicinal products for human use: - Pharmacovigilance Newsletters/Safety Bulletins in relation to emerging safety information for centrally authorised products. - Information stemming from the assessment of Periodic Safety Update Reports (PSURs) and the subsequent variation procedures for centrally authorised products through the updating of EPARs (joint HMA/EMEA initiative which should be considered within the wider context of efforts to improve transparency on safety related aspects). - Direct Healthcare Professional Communications proposed by the Marketing Authorisation Holders and discussed by the CHMP. 6. Prepare for the implementation of new Community legislation (in the field of pharmacovigilance for medicines for human use) as regards the introduction of the novel concept of public hearings (in a first step the focus will be on determining the key characteristics of such public hearings).
Visibility of the EMEA and understanding the Agency's opinion/decision making	
Key Transparency Initiatives	7. Organise Workshops with Media on a yearly basis. 8. Organise Workshops and training on regulatory and scientific aspects with external stakeholders, for instance on advanced therapies and nanotechnology, including any emerging topics resulting from new Community pharmaceutical legislation, and organise additional specific Workshops for Small and Medium-sized Enterprises (SMEs). 9. Initiate/continue methodology and outcomes – assessment projects, such as: - Progressing work in the field of the methodology for benefit/risk analysis of medicinal products for human use (follow-up to the CHMP initiative). - Developing and testing tools and processes for balancing multiple benefits and risks as an aid to informed regulatory decisions about medicinal products (in collaboration with the London School of Economics, United Kingdom (UK)). 10. Improve methodologies for assessing the post-

	marketing benefits and safety of medicinal products. 11. Assess the content of benefit-risk communication – expectations from key opinion leaders (in collaboration with the Kings College, UK). 12. Assess the impact of scientific advice on the outcome of marketing authorisation applications. 13. Assess the completeness of information outlined in the EPARs for orphan drugs (in collaboration with KCE, Belgian Healthcare Knowledge Centre, Belgium). 14. Develop collaborative projects with European universities and other research organisations to enable the conduct of scientific projects pertinent to the core activities of the EMEA, and to enhance the visibility of the Agency within the scientific community. 15. Explore, through a dialogue with EU Health Technology Assessment (HTA) Bodies, how the Agency's scientific evaluation and recommendations on the benefit/risk balance of medicinal products for human use (as reflected in EPARs) could further contribute to the cost/effectiveness assessment performed by HTA Bodies. 16. Review the lay-out and content of EPARs to better describe the rationale for opinion-making and to better reflect ethical issues related to clinical trials conducted in non-EU countries that are included in an initial application for marketing authorisation. 17. Explore for orphan medicines how to optimally inform the public of the outcome of the review of the criteria for (orphan) designation at the time of marketing authorisation. 18. Provide up-to-date scientific and regulatory guidance on the establishment of Maximum Residue Limits (MRLs), proposals for modified standard withdrawal periods for the use of veterinary medicines under the cascade and the extended list of essential substances for use in horses. 19. Improve the information the EMEA provides to the public on herbal medicinal products.
Good administrative and regulatory practices: integration of the principles of transparency in the Agency's daily operation	
Key Transparency Initiatives	20. Implement the Public-Facing Online Information (PFOI) project across all public-facing EMEA managed websites in order to ensure that they are easy to use and access by the Agency's

	stakeholders. 21. Re-launch the revised EMEA website. 22. Complete and implement the EMEA corporate identity project which will optimally increase the Agency's visibility. 23. Establish the EMEA public register of documents. 24. Optimise current surveys on the performance of the EMEA for both medicines for human and veterinary use to strengthen the quality assurance systems in place. 25. Review and update, where necessary, external and internal EMEA guidance (including Standard Operating Procedures (SOPs) and Working Instructions (WINs)) to reflect changes stemming from the implementation of the EMEA Transparency Policy. 26. Draft specific Performance Indicators to measure the implementation of the EMEA Transparency Policy. 27. Provide training for EMEA staff on the implementation of the EMEA Transparency Policy.

2. To further strengthen interaction with EMEA stakeholders

Key Transparency Initiatives	
Key Transparency Initiatives	1. Revise existing formal interaction with Patients'/Consumers' Organisations by reflecting on how to further increase patients' involvement in EMEA activities, resulting in amendments to the current framework on interaction[10]. 2. Involve Patients'/Consumers' representatives more systematically in the activities of the Pharmacovigilance Working Party (PhVWP) (for human medicines), taking into account the outcome of a 3 months pilot phase introduced in April 2009. 3. Develop an EMEA stakeholders' database to allow identification of the relevant stakeholders to be consulted when a topic emerges and to subsequently ensure that EMEA information (including documents under consultation) can reach timely the relevant stakeholders in a targeted manner. 4. Formalise interaction with Healthcare

[10] Framework on the Interaction between the EMEA and Patients' and Consumers' Organisations (Doc. Ref.: EMEA/354515/2005-Final).

	Professionals' Organisations by developing a dedicated framework on interaction. 5. Develop and subsequently implement a European Medical Information Network (EMIN), designed to assist the Community and the Member States (as per existing legislative provisions) in providing information to healthcare professionals and the general public on medicinal products for human use evaluated by the EMEA. 6. Make public the outcomes of the process for qualification of novel methodologies for drug development. 7. Review the level of involvement, including the stage of such involvement, of EMEA stakeholders in the drafting and finalisation of guidelines, policy documents, etc. 8. Hold Workshops / Seminars with stakeholders on emerging technologies (e.g. in the fields of nanotechnology, translational medicines development) and emerging regulatory issues (for instance on statistics in clinical trials). 9. Promote the use of alternative meeting methods (video-conferencing, webstreaming of meetings).

3. To enhance and promote closer interaction with the NCAs within the frame of the EU Regulatory System Network on transparency related aspects

Key Transparency Initiatives	
Key Transparency Initiatives	1. Revise the Early Notification System used to inform the EU Regulatory System Network prior to each CHMP meeting on envisaged CHMP recommendations for regulatory actions (based on identified safety concerns) accompanied by communication to the general public. 2. Proactively publish Agendas and Minutes of EMEA Scientific Committees' meetings as per the agreement with the NCAs for a coordinated approach within the EU. 3. Achieve a coordinated approach within the EU Pharmacovigilance System on safety related aspects as regards: - The provision of information stemming from the assessment of PSURs (joint HMA/EMEA initiative). - Transparency on the outcome of discussions at the level of the PhVWP (e.g. the publication of PhVWP Monthly

	Reports for medicines for human use and the publication of Executive Summaries of Pharmacovigilance Assessment Reports), taking into account the outcome of the PhVWP survey on pharmacovigilance transparency and public communication policies in the Member States (medicines for human use). These transparency initiatives should be considered within the wider context of efforts to improve transparency on safety related aspects. 4. Strengthen transparency as regards access to Eudra databases: - Implementation of the EudraVigilance Access Policy for medicines for human and veterinary use. - Provision of access to data held in EudraGMP. 5. Prepare and publish at the EMEA website the inventory of paediatric needs. 6. Publish information stemming from the implementation of the European Network of Centres for Pharmacovigilance and Pharmacoepidemiology (ENCePP), e.g. the results of commissioned pharmacoepidemio-logical studies. 7. Improve transparency on safety and clinical trials related information, including extended access to information on paediatric clinical trials by fully integrating the paediatrics component in the EudraCT database and by providing public access to specified data (protocols and results). 8. Explore with the NCAs in the context of the joint EMEA/HMA discussions what other areas in medicines regulation (for both the human and veterinary medicines sector) could benefit from a coordinated EU approach. 9. Organise Workshops/Seminars for EU Regulators on transparency related aspects in order to strive for a consistent implementation across the EU, whilst benefiting from the expertise provided by the NCAs.