COMMENTS FROM:

FORMINDEP

Contact person: Anne Chailleu, a.chailleu@formindep.org

1. GENERAL COMMENTS

Stakeholder No. <to be completed by EMEA>	*General Comment (if any)*	*Outcome (if applicable) <to be completed by EMEA>*
	A.1. Ensuring transparency is a legal obligation as well as the principal mandate of EMEA The European Union Treaty Declaration Nr 17 on the right of access to information states '*transparency of the decision making process strengthens the democratic nature of the institutions and the public's confidence in the administration.*' As a European Commission Agency, EMEA has a *duty* of transparency and communication to the public. Its obligations have been specified clearly and repeatedly in a number of regulations: • 1049/2001 EC, • 726/2004 EC confirmed explicitly in 2004 that 1049/2001 EC did apply to the EMEA. • 1367/2006 EC • 2001/83 EC A full 8 years after Regulation 1049/2001 EC came into	

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	force, the EMEA is still not complying fully with the above mentioned legal directives. An example of this non-compliance is point 23 of the tentative policy on transparency which contemplates the *stepwise* implementation of an EMEA public register of documents, *without an explicit target date.* This is a continued violation of regulation 1049/2001 which demands the existence of such a register and Regulation; 726/2004 of 2004 which reaffirmed the applicability of regulation 1049/2001 to the EMEA and demanded: '*The Agency shall set up a register pursuant to Article 2(4) of Regulation (EC) No 1049/2001 to make available all documents that are publicly accessible pursuant to this Regulation.The Management Board shall adopt the arrangements for implementing Regulation (EC) No 1049/2001 within six months of entry into force of this Regulation.'* Five years later, the EMEA is still equivocating about the creation of a public register. Such a delay can only be construed as an act of **maladministration**, which may lead to the lodging of a complaint with the Ombudsman or possible litigation before the European Court of Justice. • **FORMINDEP demands that any misleading**	

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	statement such as « *initiatives going beyond legislative requirements* » (lines 13-14) be withdrawn. EMEA's exemplarity in the field of transparency may have been a reality in 1995 but this is not the case anymore. • **Furthermore, the legal grounds for transparency should be recalled. Transparency is not an act of good will on the Agency's part** *'to be able to better address the increasing need for information from civil society'* (line 32). It is a legal obligation of the Agency and its principal mandate, and should be presented as such. The basic building block of transparency is the compliance of the EMEA with existing rules and regulations, which should be clearly and unambiguously stated in chapter II, section 'Rationale'. Several points of the current proposal diverge, sometimes significantly, from the European regulation in force: • Section 'Scope' of the present policy only addresses access to '*documents* ***produced*** *by the EMEA*' (line 72) as opposed to documents *held* by the EMEA. This restricted access violates article 73 of 726/2004 which states that '*Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30*	

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	May 2001 regarding public access to European Parliament, Council and Commission documents shall apply to documents ***held*** *by the Agency'*. **FORMINDEP opposes this restricted access to documents which can have nefarious consequences for transparency and demands that the proposed policy address 'documents *held* by the Agency', which is the only legally valid expression to be used.** • FORMINDEP welcomes the Agency's objective to provide '*targeted, understandable and accessible information on medicines*' (line 65). However, we would like to remind the Agency that communicating documents produced explicitly to this end cannot be a substitute for the communication of *original* working documents (with the exceptions laid in article 4 of regulation 1049/2001). Though adapting the documents with a view to easing the general public's comprehension is welcome, this should be *presented as a complement* to the publication of the original documents, which is required by regulation and does not require additional investment. • FORMINDEP takes note of the proposal to review the principles of commercially confidential information (line 103-104). However, this review being an explicit *prerequisite* (line 98) prior to the implementation by	

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	the EMEA of a proactive transparency policy, the definition of commercially confidential information should not be decoupled from the present policy and should instead be embedded in the proposal. FORMINDEP reminds the Agency of its policy (EMEA/45422/2006 *Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents*). Since its adoption, in 2006, did not result in any major changes to the European legal framework , the proposed revision of these principles seems unjustified. FORMINDEP manifests its unease that a revision decoupled from the present policy would not offer any guarantee of transparency or non-regression vis-à-vis the policy currently in force. **FORMINDEP strongly recommends that the existing definition of commercially confidential information be embedded in the proposed policy.** The principle that transparency is the rule and confidentiality, always duly motivated and subordinated to the overriding public interest, is the exception, should be explicitly reaffirmed, in line with the regulation in force: *'In principle, all documents of the institutions should be accessible to the public. However, certain public and private interests should be protected* ***by way of***	

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	exceptions.' (Regulation 1049/2001, recital, 11). Furthermore, FORMINDEP wishes to convey its concern regarding the divergence between this internal policy EMEA/45422/2006 and its practical implementation. This policy justifies the withholding of commercial information only in cases where this information could '*prejudice to an unreasonable degree the commercial interests'*. EMEA's current practice indicates an abusively broad interpretation of 'commercial confidentiality', which includes up to the very *date* of a report. Withdrawing so many crucial data from documents indicates that EMEA places the protection of information that is not even commercially confidential above the *overriding interest* of public health. **FORMINDEP reiterates its concern about practices deviating substantially from the European regulation as well as from EMEA's own internal policies. These deviations indicate a systematic erosion of the public's right to access administrative documents, which is detrimental to the overriding interest of public health.**	

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	FORMINDEP wishes that the definition of 'commercially confidential' information be explicitly stated, in line with regulation 1049/2001, without any delay. Future clarifications should not cut back on the vested right of the public to access administrative documents. Considering the delay in the Agency's compliance with European regulation or its own internal policies ('*New EMEA transparency policy measures*' of 2003, '*The European Medicines Agency Road Map to 2010 : Preparing the Ground for the Future*'), **FORMINDEP strongly requests the inclusion in the transparency policy of a detailed calendar outlining the implementation procedure. A yearly status report should be made public.** **A.2 Harmonizing national practices** In several instances the proposed policy states the need for EMEA to coordinate its transparency policy with the 27 Member States National Competent Authorities' (NCA). FORMINDEP welcomes the idea of a harmonisation guaranteeing all citizens of the Union equal treatment,	

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	however we would like to highlight two risks that this approach is likely to raise: - This harmonisation cannot be used to **justify further delay**s in the implementation of key European regulations. **Harmonisation is not a mandatory requirement of the** EMEA charter, and **should not be considered a *prerequisite*** to an EMEA policy. The **eight year dela**y in the implementation of regulation 1049/2001 should be a clarion call for immediate implementation of the transparency directive. - Line 80 '*Whilst recognising the limitations provided by national legislation on freedom of information, efforts will be undertaken to strive for harmonisation of key elements of transparency across the EU*.' In accordance with well settled case law of the European Union Court of Justice, Treaties and the laws adopted by the Union on the basis of the Treaties **have primacy over the laws of the Member States**. EMEA has therefore, no legal ground whatsoever to invoke '*the limitations provided by national legislation on*	

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	freedom of information' to settle its own policy. Interestingly, the policy does not refer to the problem posed by several EU Member States (United Kingdom, Sweden, Denmark, Finland, the Netherlands…) whose legislation regarding freedom of information is more advanced than current European regulation and EMEA practices. Furthermore, article 126b of regulation 2001/83 imposes on NCAs transparency rules more extensive than EMEA rules. **Consequently, FORMINDEP would appreciate a clear adherence of EMEA transparency policy to European regulations in force and the best practices prevalent within the EU or internationally. Provisions of regulation 2001/83 should be considered as a best practice to be applied to the EMEA as well.** **A.3 Equal treatment of EMEA stakeholders** Article 13 of regulation 726/2004 states: *'In the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned,* ***to the exclusion of***	

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	economic and other considerations.' FORMINDEP regrets that EMEA's tentative transparency policy establishes a *de facto* hierarchy between stakeholders, by placing the protection of commercially confidential information (line 99) before transparency in the decision making process (line 109) and good administrative practices. • **FORMINDEP suggests a re-ordering of priorities in chapter III.1. Consistent with the EMEA's charter,** the promotion of good administrative practices *should precede* the understanding of these practices. **Protection of commercially confidential information, which is only an *exception* to the rule of public access laid down in article 4 of regulation 1049/2001, should be relegated to the last.** • **FORMINDEP also recommends an explicit reaffirmation of the principle of equal treatment of the Agency's stakeholders.** Some practices of the Agency depart from this principle, e.g. **:** -The names of the examiners of the marketing authorization are communicated to the industry holder during examination while other stakeholders are denied this information, even after decisions are	

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	taken. The public is systematically subjected to the legitimate principle of non- interference in the decision making process but industry is not subjected to the same. Such practices seriously compromise the independence and integrity of the decision making process and violate the Agency's principle of equal treatment of stakeholders. **A4. Principle of non discrimination on the basis of nationality or residence** **A4.1 Electronic access** FORMINDEP wishes to strongly remind the Agency of its **European** status : as a European Commission Agency, **the EMEA is bound to treat all EU citizens equally.** However **several practices contradict this basic principle** as well as the Code of good administrative conduct that applies to EMEA agents, e.g.: Some documents are made accessible to the public '*for consultation at EMEA's premises*'. **This practice discriminates against the overwhelming majority of EU citizens who do not live in London** and does not comply	

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	with the spirit of regulation 1049/2001. • **We propose that the transparency policy state *explicitly* that documents will be made public in *electronic* format (in particular in the register), and *at request* by electronic/surface mail at the requestor's preference, in line with articles 10.1 and 11.1 of regulation 1049/2001.** **A4.2 Translation of documents** Translating *ex ante* each and every document is a burden that may endanger the Agency's ability to perform its tasks. **However, a selection of key documents should be available *ex ante* in all EU official languages.** **FORMINDEP regrets that EMEA goes backwards in this domain.** The Agency's annual report, which is key to the EU citizens' information, was **available in all EU official languages in 2004,** but only a summary version was translated in 2005 and 2006. **From then on it has been exclusively published in English.** In this context, **FORMINDEP deplores the organisation of the present public consultation : consulting the European public during the summer break, on the basis**	

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	of a document available only in English, is contrary to the principles of transparency that this document is supposed to promote, and deprives most European citizens of their right to contribute. Translating this key policy which is a mere 12 pages, into every official EU language is the least the Agency could have done to encourage public debate. • In this context, we submit our contribution in both French and English, and we request that both versions be posted on EMEA's web page dedicated to this public consultation. • **We demand the publication without delay of the translations of the document presented to public consultation (EMEA/232037/2009- rev*) into all EU official languages. The consultation should be extended by 2 months after the publication of the last version, in order to avoid any discrimination of EU citizens based upon their nationality and residence.** • **We provide in the annex a list (non exhaustive) of documents that should be made available in the electronic register still to be created. We specify which documents should be made available *ex ante* in all the EU official languages.** **A.5. Transparency of the decision making process**	

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	Any working document should permit the identification of its author(s) and drafting process. Meeting minutes should mention the attendees, their roles, the detail of votes and abstentions. **With a view to harmonising NCAs practices with the EMEA's on the basis of best practices, EMEA documents should comply with article 126b of regulation 2001/83, as amended by 2004/27, applicable to all NCAs:** *"the Member States shall ensure that the competent authority makes publicly accessible its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions'* **All experts should be identified, be they permanent European experts or additional *ad hoc* experts. Public declarations of interests relative to every meeting should be published at the same time.** **A.6. Implementation of EMEA transparency policy** **A6.1 Performance indicators**	

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	Article 17.1 of regulation 1049/2001 EC reads : 1. *Each institution shall publish annually a report for the preceding year including the number of cases in which the institution refused to grant access to documents, the reasons for such refusals and the number of sensitive documents not recorded in the register.* **Formindep regrets again a decline of the EMEA in this respect.** The annual report for year 2006 did include the complete report on the number of requests for document/information and appeals, their outcome (making a clear distinction between the communication of *complete* and *partial* documents), time taken for the provision of documents and the motivations for partial or total refusal of access. **These key data are missing from subsequent annual reports (2007 and 2008).** **Formindep demands that the performance indicators defined in the annual report for 2006 be published in *every* annual report, in line with article 17.1 of regulation 1049/2001.** **Appendix 1 - Register of documents**	

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	The following documents should a minima be part of the public register: **(Note : * =translated *ex ante* in all EU official languages)** • All EMEA internal policies, procedures, rules and regulations* • All European rules and regulations imposed on EMEA* • EPARs* • Variations reports* • PSURs* • Yearly statistics of access to documents* • List of experts and ad hoc experts with their updated DoI. • Implementing calendar for this transparency policy and corresponding yearly status report.*	

2. SPECIFIC COMMENTS ON TEXT

Line No of the first line(s) affected.<e.g. Line 20-23>	Stakeholder No. <to be completed by EMEA>	Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">	Outcome <to be completed by EMEA>
Lines 10-15		Comments: Proposed change (if any): Since the establishment of the EMEA, transparency has been an important feature of the Agency's mandate. This resulted in the introduction of novel concepts such as European Public Assessment Reports (EPARs) in line with the requirements of new Community legislation, (suppressed.) and Transparency Measures[1,2].	
Lines 16-22		Comments: Proposed change (if any): 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 Agency's stakeholders demands in line with legal	

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		obligations.	
Lines 23-27		***Comments:*** ***Proposed change (if any):*** ***This document elaborates on the rationale for and the scope of an EMEA Transparency Policy the objectives to be achieved (suppressed..)as well as the proposed way forward. Furthermore, a detailed calendar of how the EMEA intends to implement its Transparency Policy over the next years are described in Annex I.***	
Lines 31-36		***Comments:*** ***Proposed change (if any):*** ***The rationale for the development of an EMEA Transparency Policy is*** ***to meet the Agency's legal obligations in the field of transparency***	

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		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.*	
Lines 37-42		*Comments:* *Proposed change (if any):* *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 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.*	

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Lines 43-53		Comments: **Proposed change (if any):** 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.	
Lines 54-58		Comments: **Proposed change (if any):** In developing and maintaining an EMEA Transparency Policy all current transparency initiatives will be considered as well as changes stemming from future Community legislation.	

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		(suppressed.)	
Lines 60-67		**Comments:** **Proposed change (if any):** Transparency implies openness, communication and accountability *(suppressed..)*. 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.	
Lines 68-77		**Comments:** **Proposed change (if any):** 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	

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		its level of openness toward stakeholders. It is not limited to the level of transparency applied to documents held 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.	
Lines 78-87		*Comments:* *Proposed change (if any):* *(.suppressed.)*	
Lines 89-97		*Comments:* *Proposed change (if any):* *III OBJECTIVES OF THE EMEA TRANSPARENCY POLICY 89*	

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		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 (suppressed..) 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.	
Lines 98-108		Comments: Proposed change (if any): (.suppressed.)	
Lines 109-126		Comments: Proposed change (if any): 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	

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		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.*	
Lines 127-135		*Comments:*	

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		Proposed change (if any): ***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. (suppressed..)***	
Lines 137-150		***Comments:*** ***Proposed change (if any):*** ***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***	

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		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.*	
Lines 151-165		*Comments:* *Proposed change (if any):* *3. (suppressed)*	
Lines 167-171		*Comments:* *Proposed change (if any):* *IV MEETING THE OBJECTIVES: PROGRESS TO DATE AND PROPOSED WAY FORWARD 167* *In order to achieve the aforementioned objectives, and have the Agency comply with its legal obligations (1049/2001 EC) (suppressed..) The Agency's proposed way forward and*	

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		***implementing calendar** is described below as well as the current state-of-play, and has been classified as per the objectives outlined in Section III.*	
Lines 172-186		***Comments:*** ***Proposed change (if any):*** ***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***	

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		by the CHMP.	
Lines 187-196		*Comments:* ***Proposed change (if any):*** ***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.***	
Lines 197-215		*Comments:*	

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		Proposed change (if any): ***To make further progress in this field the EMEA envisages to*** □ □ ***.(suppressed..) improve, once the decision-making process has been concluded, the proactive disclosure of EMEA documents/information within the electronic register established under 1049/2001 EC, 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.***	
Lines 216-231		***Proposed change (if any):*** ***Objective 2: Further strengthen interaction with EMEA stakeholders Starting with a structured dialogue with pharmaceutical industry (both in the human and veterinary***	

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		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.*	
Lines 232-245		*Proposed change (if any):* *Objective 3: Enhance and promote closer interaction with the NCAs within the frame of the EU Regulatory System Network on transparency*	

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		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 as per directive 726/2004 article 126b.*** ***(suppressed.)***	
Lines 247-266		***Proposed change (if any):*** ***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***	

Line No of the first line(s) affected.<e.g. Line 20-23>	*Stakeholder No. <to be completed by EMEA>*	*Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">*	*Outcome <to be completed by EMEA>*
		ultimate aim is to further strengthen trust and confidence in the Agency's operation. (suppressed) *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. (suppressed)* *An implementing calendar and yearly status report shall be published.*	

Line No of the first line(s) affected.<e.g. Line 20-23>	*Stakeholder No. <to be completed by EMEA>*	*Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">*	*Outcome <to be completed by EMEA>*

Please feel free to add more rows if needed.

2. SPECIFIC COMMENTS ON ANNEX 1

Ojective No and key transparency initiative No. <e.g. 2.7 >	Stakeholder No. <to be completed by EMEA>	Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">	Outcome <to be completed by EMEA>
		Comments: **Proposed change (if any):** ***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.(suppressed) The various key transparency initiatives will be progressed in accordance with the yearly EMEA Work Programmes adopted by the Management Board.***	
1.1		**Comments:** **Proposed change (if any):** **(Suppressed)**	
1.2		**Comments:**	

Ojective No and key transparency initiative No. <e.g. 2.7 >	Stakeholder No. <to be completed by EMEA>	Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">	Outcome <to be completed by EMEA>
		Proposed change (if any): ***(suppressed) Immediate implementation of the EMEA public register of documents.***	
1.3		***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]) following best practice set in directive 726/2004EC article 126b.*** ***- PhVWP Monthly Reports (for medicines for human use).*** ***-PSURs***	
1.4		***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.***	
1.5		***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.*** ***-(suppressed) Periodic Safety Update Reports (PSURs) and the subsequent variation reports for centrally authorised products, traceable updating of EPARs (suppressed)*** ***- Direct Healthcare Professional Communications : (SUPPRESSED)***	

Ojective No and key transparency initiative No. <e.g. 2.7 >	*Stakeholder No. <to be completed by EMEA>*	*Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">*	*Outcome <to be completed by EMEA>*
1.6		*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).*	
1.7		*7. Organise Workshops with Media on a yearly basis.*	
1.8		*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).*	
1.9		*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)).*	
1.10		*10. Improve methodologies for assessing the post- marketing benefits and safety of medicinal products.*	

Ojective No and key transparency initiative No. <e.g. 2.7 >	*Stakeholder No. <to be completed by EMEA>*	*Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">*	*Outcome <to be completed by EMEA>*
1.11		*(suppressed)*	
1.12		*12. Assess the impact of scientific advice on the outcome of marketing authorisation applications.*	
1.13		*13. Assess the completeness of information outlined in the EPARs for orphan drugs (in collaboration with KCE, Belgian Healthcare Knowledge Centre, Belgium).*	
1.14		*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.*	
1.15		*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.*	
1.16		*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.*	
1.17		*17. Explore for orphan medicines how to optimally inform the public of the outcome of the review of the criteria for (orphan)*	

Ojective No and key transparency initiative No. <e.g. 2.7 >	*Stakeholder No. <to be completed by EMEA>*	*Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">*	*Outcome <to be completed by EMEA>*
		designation at the time of marketing authorisation.	
1.18		*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.*	
1.19		*19. Improve the information the EMEA provides to the public on herbal medicinal products.*	
1.20		*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.*	
1.21		*21. Re-launch the revised EMEA website.*	
1.22		*22. Complete and implement the EMEA corporate identity project which will optimally increase the Agency's visibility.*	
1.23		*23. immediately establish the EMEA public register of documents and comply with directive 1049/2001EC.*	
1.24		*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.*	

Ojective No and key transparency initiative No. <e.g. 2.7 >	Stakeholder No. <to be completed by EMEA>	Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">	Outcome <to be completed by EMEA>
1.25		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.	
1.26		26. Draft specific Performance Indicators to measure the implementation of the EMEA Transparency Policy, in particular establish a yearly report on the application of 1049/2001EC based upon the Commission report: http://ec.europa.eu/transparency/access_documents/docs/rapport_2007/COMM_PDF_COM_2008_0630_F_EN_RAPPORT.pdf	
1.27		27. Provide training for EMEA staff on the implementation of the EMEA Transparency Policy.	
2.1		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].	
2.2		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.	
2.3		3. Develop an EMEA stakeholders' public 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	

Ojective No and key transparency initiative No. <e.g. 2.7 >	*Stakeholder No. <to be completed by EMEA>*	*Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">*	*Outcome <to be completed by EMEA>*
		relevant stakeholders in a targeted manner.	
2.4		*4. Formalise interaction with Healthcare Professionals' Organisations by developing a dedicated framework on interaction.*	
2.5		*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.*	
2.6		*6. Make public the outcomes of the process for qualification of novel methodologies for drug development.*	
2.7		*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.*	
2.8		*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).*	
2.9		*9. Promote the use of alternative meeting methods (video-conferencing, webstreaming of meetings).*	
3.1		*1. Revise the Early Notification System used to inform the EU Regulatory System Network prior to each CHMP meeting on*	

Ojective No and key transparency initiative No. <e.g. 2.7 >	*Stakeholder No. <to be completed by EMEA>*	*Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">*	*Outcome <to be completed by EMEA>*
		envisaged CHMP recommendations for regulatory actions (based on identified safety concerns) accompanied by communication to the general public.	
3.2		*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.*	
3.3		*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.*	
3.4		*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.*	

Ojective No and key transparency initiative No. <e.g. 2.7 >	*Stakeholder No. <to be completed by EMEA>*	*Comment and Rationale; proposed changes <if changes to the wording are suggested, they should be highlighted using "track changes">*	*Outcome <to be completed by EMEA>*
3.5		*5. Prepare and publish at the EMEA website the inventory of paediatric needs.*	
3.6		*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.*	
3.7		*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).*	
3.8		*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.*	
3.9		*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.*	

Please feel free to add more rows if needed.