European Medicines Agency

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Draft
EMEA POLICY ON THE PRACTICAL OPERATION OF ACCESS TO EMEA DOCUMENTS

I INTRODUCTION

The concept of openness and transparency with respect to the work of the European Union (EU) Institutions, as referred to in the Treaty on the EU, guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the EU citizen. This is of particular importance in the context of improving the transparency of the decision-making process. An important factor in contributing to this objective is the right of public access to documents.

As of its establishment, the EMEA has embraced openness of operation as an important feature. This approach has been underpinned by a number of initiatives, such as:

- An ever increasing transparency as a result of various transparency measures adopted by the EMEA Management Board.
- The establishment of a dedicated framework for replying to requests for information, as detailed in the EMEA Code of Conduct.
- The adoption on 3 December 1997 of a decision on rules on access to EMEA documents.

Community legislation[1] states that, in order to ensure the full application of the legislative provisions to all activities of the EU, all Agencies established by the EU Institutions should apply the principles laid down in Community legislation regarding public access to documents. Hence, the need for the EMEA to comply with the new legal framework on public access to documents. Although since the entry into force of Community legislation the EMEA has undertaken a number of initiatives such as the adoption of Implementing Rules by its Management Board[2], there is a need to establish an EMEA Policy on Access to EMEA Documents in order to build-up a more robust system, capable of handling in a more efficient and consistent way increasing demands for access to a wide variety of EMEA documents, hence facilitating the day-to-day operation of public access to EMEA documents.

This document elaborates on the scope of the draft Policy, the principles to be applied, the prerequisites for operating the draft Policy, as well as the implementation whereby a two-phase approach is envisaged.

1 Regulation (EC) Nº 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents; recital (8).
2 Rules for the implementation of Regulation (EC) Nº1049/2001 on access to EMEA documents (Doc. Ref. EMEA/MB/203359/2006 Rev1).

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LEGISLATIVE FRAMEWORK

Community legislation[3] refers to the fact that existing legislation on public access to European Parliament, Council and Commission documents also applies to documents held by the EMEA. Furthermore, the legislative texts elaborate on the fact that the EMEA should set-up a public register, that its Management Board should adopt Implementing Rules and that complaints with the European Ombudsman or legal action at the level of the Court of Justice are possible further to decisions taken by the EMEA on requests for access to EMEA documents.

Recital (11) of Regulation (EC) Nº 1049/2001 states that, in principle, all documents of the EU Institutions should be accessible to the public. However, certain public and private interests should be protected by way of exceptions. It is also said that the EU Institutions should be entitled to protect their internal consultations and deliberations where necessary to safeguard their ability to carry out their tasks. When assessing these exceptions the EU Institutions should take account of the principles in Community legislation concerning the protection of personal data, in all areas of EU activities.

II OUTLINE OF THE DRAFT EMEA POLICY ON THE PRACTICAL OPERATION OF ACCESS TO EMEA DOCUMENTS

It should be emphasised that the focus of the draft EMEA Policy currently is on access to documents in the context of the authorisation and supervision of medicinal products for human and veterinary use.

II.1 Scope of the draft EMEA Policy

The draft EMEA Policy on Access to EMEA Documents consists of two pillars. One pillar relates to all written requests (including requests made electronically) for access to any document held by the Agency. This means any document the EMEA produces or receives and has in its possession. The second pillar refers to public access to an electronic register of documents available through the Agency's website.

Outside the scope, and therefore not included in the draft EMEA Policy, are requests for information, as well as requests for access to databases held by the Agency. Requests for information, which involve either an explanation of the content of a document or an answer to a specific query, will be handled in accordance with the EMEA Code of Conduct. Access to databases held by the EMEA will be addressed in (a) dedicated Policy Paper(s).

II.2 Principles of the draft EMEA Policy

General principles

In accordance with the legislative provisions (both Regulation (EC) Nº 1049/2001 and Regulation (EC) Nº 726/2004), the Agency will ensure the widest possible access to EMEA documents concerning a matter relating to the policies, activities and decisions falling within the Agency's sphere of responsibility, whilst guaranteeing compliance in particular with the protection of commercial confidentiality, personal data and commercial interests of a natural or legal person.

[3] Regulation (EC) Nº 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; article 73.

When operating the process on provision of access to EMEA documents the Agency will take due account of the concept of proportionality in order to avoid that the core task of the EMEA (i.e. to "provide the Member States and the Institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it", as laid down in Community legislation) is jeopardised. The Agency will, therefore, when needed, in accordance with the legislative provisions, confer with the applicant requesting access to EMEA documents with a view to finding a fair solution. The EMEA will refuse access to a document only by virtue of application of one of the exceptions mentioned in article 4 of Regulation (EC) Nº 1049/2001, article 3 of the Implementing Rules, respectively.

In addition, the EMEA will manage the process on provision of access to EMEA documents by applying the Implementing Rules, as adopted by its Management Board. Such Implementing Rules fully comply with Community legislation (i.e. Regulation (EC) Nº 1049/2001 and Regulation (EC) Nº 726/2004).

Specific principles

The following specific principles with respect to the application of the exceptions mentioned in article 4 of Regulation (EC) Nº 1049/2001, article 3 of the Implementing Rules, respectively, will be adhered to:

- Taking into account that the disclosure of documents prior to the decision-making would seriously undermine the decision-making process, the EMEA will only publicly release documents (whereby the outcome of the process is either a final or a preparatory[4] document) once the decision-making process has been concluded[5]. The Agency will not publicly release working documents.
- The EMEA will consider, on a case-by-case basis, the need to grant public access prior to the decision, in case of an overriding public interest in disclosure, either after receipt of a request for access to EMEA documents, or on its own initiative.
- The EMEA will, where relevant, redact documents prior to public disclosure in order to guarantee compliance in particular with the protection of commercial confidentiality, personal data and commercial interests of a natural or legal person. The protection of privacy and the integrity of the individual will be ensured in accordance with Community legislation regarding the protection of personal data. The protection of commercial interests of a natural or legal person, including intellectual property, will be ensured in accordance with the EMEA document "Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents" (Doc. Ref: EMEA/45422/2006).
- The EMEA will, with respect to third-party[6] documents, strive as much as possible to determine as of the outset if a particular document shall or shall not be disclosed. Consequently, the third party consultation in order to assess if any of the exceptions for refusing access to a document apply should be

[4] Preparatory documents are documents containing opinions for internal use which are part of deliberations and preliminary consultations within the Agency.

[5] This is without prejudice to the Heads of Medicines Agencies / EMEA recommendations on transparency related to agendas / minutes on product related issues, which will be subject to a specific implementation plan.

[6] "Third party" shall mean any natural or legal person, or any entity outside the Agency, including the Member States, other Community or non-Community Institutions and Bodies, and third countries. This definition also relates to the EMEA stakeholders such as pharmaceutical industry, patients and consumers organisations, healthcare professionals organisations, academia and learned societies.

restricted to a minimum. However, as regards Member States, other Community or non-Community Institutions and Bodies, and third countries, their prior agreement is always needed before access can be granted. Any documents which are produced by the Member State (scientific) resources within the context of the EMEA responsibilities (at the level of the EMEA Management Board, the EMEA Scientific Committees and their Working Parties, and other groups) will not be regarded as third-party documents, and are considered to be EMEA documents.

II.3 Output of the draft EMEA Policy

Applying the aforementioned general and specific principles has resulted in the attached "Output of the Draft EMEA Policy on the Practical Operation of Access to EMEA Documents in the Context of the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use" (Doc. Ref. EMEA/659316/2008/Final). This output table lists the various documents prepared in the context of the authorisation and supervision of medicinal products[7]. It provides information on aspects such as the classification of the documents (public, restricted or confidential), if access is granted or not, the legal reference to the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents if access is refused, the need to redact EMEA documents prior to disclosure, etc.

The output on any other activities falling within the Agency's sphere of responsibilities will be incorporated in the attached document when more experience in the field of the authorisation and supervision of medicinal products for human and veterinary use has been obtained.

II.4 Prerequisites for the Operation of the draft EMEA Policy

The prerequisites to operate the draft EMEA Policy on Access to EMEA Documents are:

- The establishment of a formal procedure for the assignment of the classification of EMEA documents.
- The establishment of a formal procedure for ensuring adherence to the protection of commercial confidentiality and personal data.

Establishment of a formal procedure for the assignment of the classification of EMEA documents

As a starting point, an Agency wide list of all EMEA documents which fall within the scope of access to documents will be established. Priority is given to documents in the context of the authorisation and supervision of medicinal products for human and veterinary use. This list is provided as Annex 1. Subsequently, the general and specific principles, as outlined in Section III.2, are applied in order to classify documents into one of the three categories, i.e. "public", "restricted" or "confidential".

This requires a formal procedure for the assignment of the classification of EMEA documents, capable to address two situations:

- The classification of all currently available EMEA documents.
- The subsequent classification of any new type of EMEA document.

[7] The same principles will be applied, *mutatis mutandis*, to access to documents related to medicinal products for paediatric use, including documents related to the Paediatric Committee's activities. Information on these documents will be included in the output table at a later stage.

Internal guidance describes the procedure to be followed, including the roles and responsibilities of all involved persons, as well as the involvement of (senior) management for final decision-making.

An internal "virtual" group, the Access to Documents Advisory Group (ADAG), is set-up to facilitate the operation of access to EMEA documents. The mandate of the ADAG focuses on (1) advising, when necessary, if the submitted request is either a request for access to documents or a request for access to information, (2) providing clarification, when necessary, for progressing the request for access to documents, (3) ensuring consistency, when requested, in the handling of requests for access to EMEA documents.

Establishment of a formal procedure for ensuring adherence to the protection of commercial confidentiality and personal data

As already stated in Section III.2, the EMEA will, prior to public access to EMEA documents, guarantee compliance in particular with the protection of commercial confidentiality, personal data and commercial interests of a natural or legal person. Criteria that will be applied to achieve this objective or either enshrined in Community legislation (i.e. on the protection of personal data) or detailed in existing EMEA documents (i.e. for the deletion of commercially confidential information).

A formal procedure for ensuring adherence to these principles is in place. This procedure foresees in a redaction of the documents prior to their disclosure. This should allow to achieving a harmonised approach across the Agency. A Quality Assurance system is built into this redaction process.

III IMPLEMENTATION OF THE DRAFT EMEA POLICY

In practice, the EMEA will implement the concept of public access to EMEA documents in two phases:

- The first phase will concentrate on the adequate follow-up to written requests for access to any document in full respect of Community legislation, as outlined in Section III. The key features of the Implementing Rules (i.e. classification of EMEA documents, handling of initial and confirmatory applications) will be adhered to. Proactive disclosure of public EMEA documents through the Agency's register of documents (once established) will, however, during this first phase be restricted to the types of EMEA documents currently already publicly available on the Agency's website and to any EMEA document for which access has been granted as a follow-up to a written request.
- The second phase will see the gradual population of the electronic register of EMEA documents as part of the Agency's website. To ensure adequate implementation of this second phase an Action Plan will be drafted.

It should be emphasised that this two-phase approach will not undermine EU citizens' rights to the widest possible access to documents held by the EMEA. It should rather be seen as the most cost-effective way (in particular from a workload and human resources perspective) to implement the concept of public access to EMEA documents. In addition, during the first phase, the Agency will review the current content, layout and structure of all document types for which public assess may be granted. Where relevant, fora such as the EMEA Management Board, the EMEA Scientific Committees and their Working Parties will be involved in this exercise. The ultimate objective of this initiative is to further improve these document types with a view to increasing the transparency of the decision-making process. This will be complemented with the provision of adequate training to EMEA Staff in order to ensure an efficient implementation of the draft EMEA Policy.