



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 November 2010  
EMA/110196/2006

## European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use)

### POLICY/0043

Effective date: 1 December 2010  
Supersedes: Not applicable

## 1. Introduction and purpose

Openness and transparency are paramount values enshrined in the TEU and in the TFEU as they contribute to strengthen the principles of democracy and good administration.

According to Article 15 of the TFEU, a right of access to documents of the EU Institutions, Bodies, Offices and Agencies is granted according to the principles and further conditions as defined by Regulations, namely Regulation (EC) No 1049/2001<sup>1</sup>.

In principle, all documents of the EU Institutions and of the European decentralised Bodies, such as the European Agencies, are accessible to the public.

However, certain public and private interests, such as the privacy and integrity of the individual, in particular in accordance with EU legislation regarding the protection of personal data, or the commercial interests of a natural or legal person, shall be protected by way of exceptions in line with the provisions of Regulation (EC) No 1049/2001.

In addition, EU Institutions and Agencies are entitled to protect their internal consultations and deliberations where necessary to carry out their tasks.

As of its establishment the European Medicines Agency (EMA) 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 EMA Management Board.

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<sup>1</sup> 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.



- The establishment of a dedicated framework for replying to requests for information, as detailed in the EMA Code of Conduct<sup>2</sup>.
- The adoption on 3 December 1997 of a decision on rules on access to EMA documents.

Although since the entry into force of EU legislation the EMA has undertaken a number of initiatives such as the adoption of Implementing Rules by its Management Board<sup>3</sup>, there is a need to establish an EMA policy on Access to EMA 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 EMA documents, hence facilitating the day-to-day operation of public access to EMA documents.

This policy addresses the scope, the principles to be applied, the operational prerequisites and the implementation approach. It takes into account the outcome of a public consultation, as well as recommendations provided by the European Ombudsman on requests for access to EMA documents.

The policy shall be reviewed within 3 years or at an earlier stage if considered necessary.

## 2. Scope

The EMA policy on Access to EMA Documents, which applies in the context of the Agency's activities in the fields of medicinal products for human and veterinary use, has a two-fold approach. One relates to the way the Agency deals with all written requests (including requests made electronically) for access to any document originated, received or held by the Agency (i.e. reactive disclosure). The second one concerns proactive disclosure of EMA documents, either through the Agency's website or other sources of publication.

In the framework of the new visual identity project and the launch of the new Agency's website, a document library search tool, also known as the Agency's register, has been introduced in order to facilitate electronic retrieval of documents in line with the requirements set by Regulation (EC) No 1049/2001.

It should be noted that requests for information fall outside the scope of this policy as they are addressed and will be handled in accordance with the Agency's Code of Conduct.

## 3. Definitions

ADAG:	Access to Documents Advisory Group
CMD(h):	Co-ordination Group for Mutual Recognition and Decentralised procedures - human
CMD(v):	Co-ordination Group for Mutual Recognition and Decentralised procedures - veterinary
EMA:	European Medicines Agency
EU:	European Union
NCA:	National Competent Authority
PhVWP:	Pharmacovigilance Working Party
TEU:	Treaty of European Union

<sup>2</sup> EMA Code of Conduct (Doc. Ref.: EMEA/6470/03/2368).

<sup>3</sup> Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents (Doc. Ref. EMEA/MB/203359/2006 Rev 1).

TFEU: Treaty of the Functioning of the European Union

## 4. Policy statement

The following aspects will be addressed in this policy:

- Principles of the EMA policy
- Output of the EMA policy
- Prerequisites for the operation of the EMA policy
- Implementation of the EMA policy

### 4.1. Principles of the EMA policy

#### General principles

In compliance with principles set in the Treaty, as further defined by provisions of Regulation (EC) No 1049/2001, applicable to the EMA pursuant to Article 73 of Regulation (EC) No 726/2004 and its implementing rules, the Agency will ensure the widest possible access to EMA documents concerning any matter related to the policies, activities and decisions falling within the Agency's remit and responsibilities.

The following general principles shall apply:

- Whilst providing adequate protection of commercial confidential information, personal data and other conflicting interests as identified (see below Chapter on Specific Interests for further information), access to a requested document will be denied only if one of the exceptions listed in Article 4 of Regulation (EC) No 1049/2001 will be considered applicable.
- When only parts of a document contain information that cannot be disclosed, access to the remaining parts of the document shall be granted.
- Likewise, documents or parts thereof may be redacted before disclosure in order to protect information contained therein that cannot be disclosed (i.e. the need to protect commercial confidential information or personal data).
- Irrespective of any applicable exception, access to documents or parts thereof may be granted whenever an overriding public interest in disclosure can be identified by the Agency, either further to a request for access to documents, or on its own initiative.
- In dealing with requests for access to documents, the Agency will also apply the principle of proportionality in order to avoid that performance of core tasks assigned to the Agency is jeopardised (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 Regulation (EC) No 726/2004).
- Accordingly, the Agency will liaise with the applicant<sup>4</sup> in order to seek an agreement on a fair and reasonable solution whenever the request addresses a long list of documents or the document(s) the applicant is interested in require extensive redaction before being disclosed.

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<sup>4</sup> In the context of this Policy the notion of applicant shall mean any natural or legal person filing an application for access to documents pursuant to the principles set in Regulation (EC) No 1049/2001.

## **Specific principles**

### ***Specific interests***

In applying the exceptions listed in Article 4 of Regulation (EC) No 1049/2001 the following interests may be taken into consideration:

- The need to respect Confidentiality Arrangements entered with non-EU Regulatory Authorities.
- The need to protect international relationship with third countries and international organisations.
- The need to protect privacy and integrity of any natural or legal person.

In the above mentioned cases partial access to the concerned documents may be granted if this does not undermine the interests at stake.

Protection of privacy and the integrity of the individual will be ensured in accordance with EU legislation concerning protection of personal data, namely Regulation (EC) No 45/2001.

### ***Balance between public and private interests***

In other circumstances the decision whether to release a document or parts thereof may depend on the outcome of the balance between public and private interests.

For instance, in case of a document containing information of commercial interest the Agency has to strike the balance between the right of the applicant to gain access to documents and the interest of industry to have commercial confidential information duly protected.

The Agency will ensure protection of commercial interest in accordance with the notion of commercial confidential information. In view of the lack of a legal definition and for the purpose of this policy 'commercial confidential information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information.

### ***Protection of internal deliberations***

With regard to the interest not to undermine the decision-making process, the Agency shall only release final documents once the concerned procedure has been finalised.

This will exclude from disclosure preparatory documents, i.e. working documents, internal notes, and documents containing opinions for internal use<sup>5</sup> or related to preliminary consultations within the Agency, without prejudice to the Heads of Medicines Agencies/EMA recommendations on transparency, which will be subject to a specific implementation plan.

The Agency shall consider, on a case-by-case basis, the need to grant public access prior to the finalisation of the concerned procedure in case of an overriding public interest in disclosure, either further to a request for access to documents, or on its own initiative.

### ***Third-party consultation***

When the applicant requests access to a third-party document, the Agency will always inform the originator prior to disclosure that a request for access has been received. Only in case of doubt on the

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<sup>5</sup> "Internal" also refers to documents prepared at the level of the EMA Scientific Committees and other EMA (scientific) fora.

confidential nature of the document or parts thereof, the Agency may consult the originator prior to taking any decision on disclosure.

If the requested document(s) originated from an EU Institution or a NCA, the Agency shall consult the concerned authority prior to taking any decision on disclosure.

EMA Scientific Committees, Working Parties and other EMA (scientific) fora are not to be considered as third parties. This principle shall not apply to documents originated, held or received by fora such as the CMD(h) / CMD(v), PhVWP, inspectors groups, which relate to non-Centrally Authorised Products. They are considered to be originated, received or held by the NCAs and therefore the Chairman and the concerned NCAs shall be consulted by the EMA, prior to disclosure.

In all cases final decision on disclosure will be the sole responsibility of the Agency.

#### **4.2. Output of the EMA policy**

Applying the aforementioned general and specific principles has resulted in the document "Output of the European Medicines Agency policy on Access to Documents Related to Medicinal Products for Human and Veterinary Use" (Doc. Ref.: EMA/127362/2006) (hereafter referred to as "output table").

This output table lists the various documents prepared or submitted in the context of the Agency's activities in the areas of medicinal products for human and veterinary use. It provides information on aspects such as:

- The classification of the documents ("public" or "confidential").
- If access is granted or not.
- The reference to the applicable legislative provision in Regulation (EC) No 1049/2001.
- The need to redact EMA documents prior to disclosure, etc.

The output on any other activities falling within the Agency's sphere of responsibilities will be incorporated in the output table when more experience on requests for access to documents has been obtained.

#### **4.3. Prerequisites for the operation of the EMA policy**

The prerequisites to operate the EMA policy on access to documents are:

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

##### ***Establishment of a formal procedure for the assignment of the classification of EMA documents***

An Agency wide list of all EMA documents which fall within the scope of access to documents will be established. Subsequently, the aforementioned general and specific principles are applied in order to classify documents into one of the categories, "public" or "confidential".

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

- The classification of all currently available EMA documents.

- The subsequent classification of any new type of EMA document.

Third-party documents will be classified as confidential by default and specific principles as outlined above will apply further to requests for access.

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

An internal “virtual” group, the ADAG, has been set up to facilitate the operation of access to EMA documents. The mandate of the ADAG focuses on:

- Advising, when necessary, if the submitted request is either a request for access to documents or a request for information.
- Providing clarification, when necessary, for progressing the request for access to documents.
- Ensuring consistency, when requested, in the handling of requests for access to EMA documents.

***Establishment of a formal procedure for ensuring adherence to the protection of commercially confidential information and personal data***

As already stated before, the EMA will, prior to public access to EMA documents, ensure compliance in particular with the protection of commercially confidential information, personal data and other conflicting interests as identified. Criteria that will be applied to achieve this objective are either enshrined in EU legislation (i.e. on the protection of personal data) or detailed in this policy (i.e. the definition of commercial confidential information to be applied for the deletion of such information).

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

***4.4. Implementation of the EMA policy***

The EMA will implement the concept of public access to EMA 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 EU legislation, as outlined before. The key features of the Implementing Rules (i.e. classification of EMA documents, handling of initial and confirmatory applications) will be adhered to. Proactive disclosure of public EMA documents through the Agency’s register of documents will, however, during this first phase be restricted to the types of EMA documents currently already publicly available on the Agency’s website and to any EMA 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 EMA 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 EMA. 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 EMA documents. In addition, during the first phase, the Agency will review the current content, layout and structure of all document types for which public access may be granted. Where relevant, fora such as the EMA Management Board, the EMA 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 in order to increase the transparency of the decision making

process. This will be complemented with the provision of adequate training to EMA staff in order to ensure an efficient implementation of the policy.

## **5. Related documents**

- 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  
[http://www.europarl.europa.eu/RegData/PDF/r1049\\_en.pdf](http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf)
- Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMA documents  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2010/02/WC500070829.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/02/WC500070829.pdf)

## **6. Changes since last revision**

New policy.

London, 24 November 2010

Signature on file

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