EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency policy on access to documents

POLICY/0043

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1. Introduction and purpose

Openness and transparency are paramount values enshrined in the TEU[1] and in the TFEU[2] 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[3].

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 (MB).

[1] TEU = Treaty of European Union.
[2] TFEU = Treaty on the functioning of the European Union.
[3] 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.

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- The establishment of a dedicated framework for replying to requests for information, as detailed in the EMA Code of Conduct[4].
- The development of rules for the implementation of Regulation (EC) No 1049/2001 on access to EMA documents.

Although since the entry into force of EU legislation EMA has undertaken a number of initiatives such as the adoption of the above mentioned Rules by its MB, there was 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. Such policy was adopted by the MB on 1 December 2010 and it addresses aspects such as the scope, the principles to be applied, the operational prerequisites and the implementation approach.

This revision takes into account the experience gained since the introduction of the policy. It also extends the scope of the policy from pertaining to documents related to medicinal products for human or veterinary use to also pertaining to corporate documents. This revision incorporates the rules for the implementation of Regulation (EC) No 1049/2001 on access to EMA documents as an Annex to this policy. These rules are now presented as arrangements for the implementation of said Regulation.

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

2. Scope

EMA aims to ensure the widest possible access to the documents that it produces or receives and has in its possession.

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

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 EMA Code of Conduct.

It should also be noted that EMA reserves to classify documents for internal purposes such as for internal security reasons or to manage access to its databases according to separate procedures and criteria.

3. Definitions

- "Document" shall mean any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) concerning a matter relating to the policies, activities and decisions falling within the EMA sphere of responsibility.
- "Third party" shall mean any natural or legal person, or any entity outside EMA, including the Member States, other EU or non-EU institutions and bodies and third countries.

[4] EMA Code of Conduct (Doc. Ref.: EMEA/6470/03/2368).

4. Policy statement

The following aspects are addressed in this policy:

- Principles of the policy.
- Output of the policy.
- Prerequisites for operating the policy.
- Implementing the policy.

4.1. Principles of the policy

4.1.1. General principles

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

The following general principles apply:

- Whilst providing adequate protection of commercial confidential information, personal data and other conflicting interests as identified (see below section 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 EMA, either further to a request for access to documents, or on its own initiative.
- In dealing with requests for access to documents, EMA will also apply the principle of proportionality in order to avoid that performance of core tasks assigned to EMA 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, EMA will liaise with the applicant[5] 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.

[5] 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.

4.1.2. 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

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 EMA 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.

EMA 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 specific principle not to undermine the decision-making process, EMA 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[6] or related to preliminary consultations within EMA, without prejudice to the Heads of Medicines Agencies/EMA recommendations on transparency[7].

In practice this means for documents related to medicinal products that these will be considered as non-releasable prior to the availability of the Commission Decision granting, refusing or varying the marketing authorisation for the particular medicinal product, or prior to the receipt of the withdrawal letter submitted by the pharmaceutical company. In case there is no subsequent Commission Decision, the documents will be considered non-releasable until the time of the scientific committee Opinion (irrespective if there is no subsequent Commission Decision or if the procedure is subject to the annual decision of the European Commission). In case of an assessment made by those EMA scientific committees[8], where the assessment is part of an ongoing marketing authorisation application or

[6] "Internal" also refers to documents prepared at the level of the EMA scientific committees and other EMA (scientific) fora.
[7] HMA/EMA recommendations on transparency (Doc. Ref. EMA/484118/2010).
[8] This refers to the CAT (Committee on Advanced Therapies), the PDCO (Paediatric Committee) and the PRAC (Pharmacovigilance Risk Assessment Committee).

variation, this assessment is considered non-releasable until the availability of the Commission Decision on the granting or refusal on, or the variation to the marketing authorisation, or the receipt of the withdrawal letter submitted by the pharmaceutical company.

EMA 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, EMA will always inform the originator prior to disclosure that a request for access has been received. Only in case of doubt on the confidential nature of the document or parts thereof, EMA may consult the originator prior to taking any decision on disclosure.

If the requested document(s) originated from an EU Institution or a National Competent Authority (NCA), EMA 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)[9] / CMD(v)[10], 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 EMA, prior to disclosure.

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

Transparency on the requests and beneficiaries of the requests for access to documents

Transparency on the implementation of the policy will be ensured through provision of information on EMA's handling of requests for access to documents in the EMA Annual Report and Annual Activity Report. The number of requests received as well as the number of requests where access to the document(s) requested was granted or refused will be provided. As per Article 17 of Regulation (EC) No 1049/2001 information on the reason(s) for refusal will be provided in an aggregated way in accordance with the provisions of Article 4 of the same Regulation.

The beneficiaries of the requested documents will at the time of making the request for access to documents be asked to state their affiliation and this information will be made public as part of the transparency on the procedure by publishing the number of requests by type of requester.

4.2. Output of the policy

Applying the aforementioned general and specific principles has resulted in two documents, i.e. the "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, Rev. 1) and the "Output of the European Medicines Agency policy on access to documents related to corporate documents" (Doc. Ref.: EMA/183710/2016) (hereafter referred to as "output tables").

These output tables list the various documents prepared or submitted in the context of the EMA's activities in the areas of medicinal products for human and veterinary use, as well as various corporate documents. They provide information on aspects such as:

[9] CMD(h) = Co-ordination group for Mutual recognition and Decentralised procedures – human.
[10] CMD (v) = Co-ordination group for Mutual recognition and Decentralised procedures – veterinary.

- The classification of the documents ("releasable" or "non-releasable").
- 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.

Both output tables have to be considered "living" documents and will be updated on a continuous basis taking into account further experience gained, e.g. by including additional documents, by taking into account the legal interpretation of Regulation (EC) No. 1049/2001 given by the European Court of Justice.

4.3. Prerequisites for operating the policy

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

- The establishment of a formal procedure to classify EMA documents for the purposes of Regulation (EC) No. 1049/2001.
- The establishment of a formal procedure for ensuring adherence to the protection of commercial confidential information and personal data.

Establishment of a formal procedure to classify EMA documents for the purposes of Regulation (EC) No 1049/2001 regarding public access to documents

For the purpose of implementing Regulation (EC) No 1049/2001 the aforementioned general and specific principles are applied in order to classify documents into either "releasable" or "non-releasable".

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 non-releasable by default and specific principles as outlined above will apply further to requests for access.

A dedicated internal entity, the Document Access and Publication Service, has been set up to operate the process for 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, 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 achieving a harmonised approach across EMA. A quality assurance system is built into this redaction process.

4.4. Implementing the policy

EMA's implementation of the concept of public access to EMA documents is a two-fold approach:

- One relates to the adequate follow-up to written requests for access to any document in full respect of EU legislation, as outlined in this policy. The key features (i.e. classification of EMA documents, handling of initial and confirmatory applications) will be adhered to.
- The other is the proactive disclosure of EMA documents on the EMA website as part of the EMA's continuous commitment to transparency. This includes information on the medicinal products and regulatory procedures for which EMA is responsible as well as agendas and minutes of the scientific committees' meetings. Information on EMA such as its reports, funding and financial management and other corporate documents are also proactively published on the EMA website.

  The information proactively published will be increased with the introduction of proactive publication of clinical data for medicinal products for human use (EMA Policy/0070) and with the coming into force of other relevant legislative provisions.

  EMA may establish other rules regarding the publication of documents in order to ensure an appropriate level of transparency, in accordance with Article 80 of Regulation (EC) No 726/2004.

EMA is not a legislative body and holds only documents relating to administrative procedures. The requirement imposed by Recital 6 and Article 12 of Regulation (EC) No 1049/2001 to give wider access to documents relating to a legislative procedure and to make such documents directly accessible to the greatest possible extent would, therefore, not apply to the documents held by EMA.

For the above reasons, EMA considers that the various electronic document databases and systems currently made publicly available by EMA effectively enable the citizens to exercise the rights given to them by Regulation (EC) 1049/2001, as required by Article 73 of Regulation (EC) No 726/2004 and Articles 2(4) and 11 of Regulation (EC) No 1049/2001.

It should be emphasised that the aforementioned approach does not undermine EU citizens' rights to the widest possible access to documents held by 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. The ultimate objective of this two-fold approach is to increase the transparency of the decision making process.

The implementation of the policy will be monitored to ensure efficiency and effectiveness, that lessons learnt will be taken into account and remedial action can be taken when necessary in future revisions 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

6. Changes since last revision

The following changes have been made:

- The scope of the policy has been extended to include corporate documents. A second output table has been created dealing with access to corporate documents.

- The classification of the documents has been changed into “releasable” or “non-releasable”.
- The section on protection of internal deliberations has been amended to clarify when procedures are considered to be concluded and a section on transparency has been added to clarify the level of transparency on the requests, and on the beneficiaries of the requests.
- The rules for the implementation of Regulation (EC) No 1049/2001 have been changed into arrangements for the implementation of said Regulation and these arrangements have been added as an annex to this policy, although relevant information (i.e. on the scope, on the definitions) has been included in the body of the policy.
- The implementation of the policy has been reworded to emphasise the documents that are proactively published. An explanation as to how the Agency meets its legal obligations as required by Article 73 of Regulation (EC) 726/2004 and Articles 2(4) and 11 of Regulation (EC) 1049/2001 has been added.

London, TBC

Guido Rasi
Executive Director

ANNEX

Arrangements for implementing Regulation (EC) No 1049/2001 on access to EMA documents

Article 73 of Regulation (EC) No 726/2004 foresees that 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 will apply to the Agency and that it is necessary to establish rules implementing Regulation (EC) No 1049/2001.

These arrangements elaborate on a number of aspects, such as the possible exceptions for providing access to EMA documents, the process for handling requests for access to EMA documents, the arrangements for consulting with third parties.

1. Exceptions

Access to certain documents shall be refused by virtue of application of one of the following exceptions:

1. EMA shall refuse access to a document where disclosure would undermine the protection of:

   a) the public interest as regards public security, defence and military matters, international relations, the financial, monetary or economic policy of the Community or a Member State;

   b) privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data.

2. EMA shall refuse access to a document where it determines that disclosure would be likely to undermine the protection of:

   a) commercial interests of a natural or legal person, including intellectual property,

   b) court proceedings and legal advice,

   c) the purpose of inspections, investigations and audits,

   unless there is an overriding public interest in disclosure.

3. Access to a document, produced or received and in possession of EMA, which relates to a matter where the decision has not been taken, shall be refused if EMA determines that disclosure of the document would seriously undermine the decision-making process, unless there is an overriding public interest in disclosure.

   Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within EMA shall be refused even after the decision has been taken if EMA determines that disclosure of the document would seriously undermine the Agency's decision-making process, unless there is an overriding public interest in disclosure.

4. As regards third-party documents, EMA shall consult the third party with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it has already been determined that the document shall or shall not be disclosed.

5. A Member State may request EMA not to disclose a document originating from that Member State without its prior agreement.

6. If only parts of the requested document are covered by any exceptions, the remaining parts of the document shall be released.

2. Requests for access

1. Applications for access to EMA documents, which are not publicly available, shall be made in writing including electronic form, and in a sufficiently precise manner to enable EMA to identify the document(s).

2. If an application is not sufficiently precise, EMA shall ask the applicant to clarify his request and shall assist the applicant in doing so. The deadline for reply shall start once EMA has sufficient information to process the request.

3. In the event of an application relating to a very long document or to a very large number of documents, EMA may confer with the applicant informally, with a view to finding a fair solution.

3. Handling of initial applications

1. An application for access to a document shall be handled promptly. An acknowledgement of receipt shall be sent to the applicant. Within 15 working days from receipt of the application, EMA shall either grant access to the document requested and provide access in accordance with Article 9 within that period or, in a written reply, state the reasons for the total or partial refusal and inform the applicant of his or her right to ask EMA to reconsider its position in accordance with paragraph 2 of this Article.

2. In the event of a total or partial refusal, the applicant may, within 15 working days of receiving EMA's reply, ask EMA to reconsider its position by submitting a confirmatory application.

3. In exceptional cases, for example in the event of an application relating to a very long document or to a very large number of documents, the time-limit provided for in paragraph 1 may be extended by 15 working days, provided that the applicant is notified in advance and that detailed reasons are given.

4. Failure by EMA to reply within the prescribed time limit shall entitle the applicant to a confirmatory application.

4. Handling of confirmatory applications

1. The EMA Executive Director shall take the decisions relating to requests to EMA to reconsider its position. Such requests shall be handled promptly. Within 15 working days from receipt of such a request, EMA shall either grant access to the document concerned and provide access in accordance with Article 9 within that period or, in a written reply, state the reasons for the total or partial refusal. In the event of a total or partial refusal, EMA shall inform the applicant of the remedies open to him or her, namely to lodge a complaint to the European Ombudsman or institute Court proceedings against EMA, under Article 195 or 230 of the EC Treaty, respectively.

2. In exceptional cases, for example in the event of an application relating to a very long document or to a very large number of documents, the time limit provided for in paragraph 1 may be extended by 15 working days, provided that the applicant is notified in advance and that detailed reasons are given.

3. Failure by EMA to reply within the prescribed time limit shall be considered as a negative reply and entitles the applicant to lodge a complaint to the European Ombudsman or institute Court proceedings against the Agency, under Article 195 or 230 of the EC Treaty, respectively.

5. Consultations

1. Where EMA receives an application for access to a document, which it holds, but which originates from a third party, EMA shall check whether one of the exceptions provided for by Article 3 applies.

2. If, after that examination, EMA considers that access to it must be refused under one of the exceptions provided for by Article 3, the negative answer shall be sent to the applicant without consultation of the third-party author.

3. EMA may grant the application without consulting the third-party author where the document requested has already been disclosed either by its author or under Regulation (EC) No 1049/2001 or similar provisions.

4. Unless the document originates from a Member State, EMA may grant the application without consulting the third-party author where it is obvious that the disclosure, or partial disclosure, of its contents would not affect one of the interests referred to in Article 3.

5. In all other cases, and in particular if an application for access concerns a document originating from a Member State, the third-party author shall be consulted.

6. The third-party author consulted shall have a deadline for reply, which shall be no shorter than five working days but must enable EMA to abide by its own deadlines for the reply. In the absence of an answer within the prescribed period, or if the third party is untraceable or not identifiable, EMA shall decide in accordance with the rules on exceptions in Article 3, taking into account the legitimate interests of the third party on the basis of the information at its disposal.

7. If EMA intends to give access to a document against the explicit opinion of the author, it shall inform the author of its intention to disclose the document after a ten-working day period and shall draw his attention to the remedies available to him to oppose disclosure.

6. Exercise of the right of access

1. Applicants shall have access to documents either by receiving a copy, in paper or electronic format, or by consulting specific documents on EMA's premises. Copies of less than 20 pages or direct access in electronic form shall be free of charge. As regards documents of more than 20 pages, the charge shall not exceed the real cost of producing and sending the copies.

2. All documents are subject to EMA's copyright policy available on EMA's website (www.ema.europa.eu).