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Output of the European Medicines Agency policy on access to documents non-related to medicinal products for human and veterinary use

Introductory remarks

Aim of the document

This document needs to be read in conjunction with the following 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.
- European Medicines Agency policy on access to documents (EMA/729522/2016).

This document, which contains guidance for the application of Regulation (EC) No 1049/2001 to documents non-related to medicinal products for human and veterinary use held by the EMA, is not legally binding. For any document not listed, access will be granted or refused in accordance with the principles outlined in the European Medicines Agency policy on access to documents. It should also be noted that EMA has not listed all documents non-

related to medicinal products for human and veterinary use that it holds, but rather those for which it has received more requests, as well as the main documents non-related to medicinal products for human and veterinary use which are available on its webpage. Therefore, this document should be considered as a “living” document which will be updated on a continuous basis taking into account further experience, as well as the legal interpretation of Regulation (EC) No 1049/2001 given by the European Court of Justice.

For documents related to human and veterinary products, please refer to the “Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use” (EMA/127362/2006, Rev. 1).

This document lists a number of document types which may be subject to requests for access to documents.

1. Procurement related documents

These document types have been classified according to the phase of the procurement procedure, as follows:

- 1.1. Documents in relation to the launch of the procurement procedure
- 1.2. Documents in relation to the submission and opening of requests to participate
- 1.3. Documents in relation to the submission and opening of tenders
- 1.4. Documents in relation to the evaluation of tenders
- 1.5. Documents in relation to the award and signature of contract or cancellation of procedure

2. Conflicts of interest declarations

3. SOPs and WINs

4. Corporate documents available on the EMA's website

Some of those documents may be third party documents, such as contracts signed between the Agency and a contractor. Upon receipt of a request for access to such documents, EMA would consult with the relevant third party, as it is currently done with the consultation with the Marketing Authorisation Holder for documents related to medicinal products, in line with Article 4(4) of Regulation (EC) No 1049/2001.

It should be noted that access to documents and/or information concerning procurement procedures made by specific parties (candidates and/or tenderers) in the procedure at different stages is regulated by the Financial Regulation. This document refers to the general right of access to documents made under Regulation (EC) No1049/2001.

Abbreviations

CCI – Commercial confidential information

PPD – Protection of personal data

R – Releasable

Non-R – Non-Releasable

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
1. Procurement						
1.1 Launch of the procurement procedure						
Pre-information notice (PIN)	No	Published on EMA website	Yes	Not applicable	Not applicable	No
Justification for using a negotiated procedure	No	Non-R before the procedure is launched	No	Art. 4.3. 1 st §		Not applicable
		R after the procedure is launched	Yes	Not applicable	Not applicable	Yes (PPD)
Contract notice	No	Published on EMA website	Yes	Not applicable	Not applicable	No
1.2. Submission and opening of requests to participate						
List of candidates who submitted a request to participate in a restricted procedure or competitive procedure with negotiation or negotiated procedure	No	Non-R until the deadline for receipt for tenders has elapsed or until cancellation of the procedure	No	Art. 4.3. 1 st §	Art. 4.1. (a)	Not applicable

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
		R after the deadline for receipt for tenders has elapsed or until cancellation of the procedure, except for the names of natural persons or names of firms identifying one or more natural persons	Yes	Not applicable	Not applicable	Yes (PPD)
Requests to participate	Yes	Non-R until contract signature or cancellation of procedure	No	Art. 4.3. 1 st §		Not applicable
		R after contract signature or cancellation of procedure	Yes	Not applicable	Not applicable	Yes (PPD and CCI)
Written record of the opening of requests to participate	No	Non-R before deadline for receipt of tenders has elapsed or cancellation of the procedure	No	Art. 4.3. 1 st §	Art. 4.1 (a)	Not applicable

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
		R after deadline for receipt of tenders has elapsed or cancellation of the procedure	Yes	Not applicable	Not applicable	Yes (PPD)
Written record of the evaluation of requests to participate	No	Non-R prior to contract signature or cancellation of the procedure	No	Art. 4.3. 1 st §		Not applicable
		R after contract signature or cancellation of procedure	Yes	Not applicable	Not applicable	Yes (PPD and CCI)
Procurement documents (notice, invitation to tender, tender specifications, terms of reference and draft contract)	No	Non-R prior to launch of procedure	No	Art. 4.3. 1 st §		Not applicable

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
		R after launch of procedure	Yes	Not applicable	Not applicable	Yes (CCI, including those cases where the exception on confidentiality of Art. 153(1) of the rules of implementation of the Financial Regulation applies)
Additional information, questions & answers	No	Non-R prior to publication of information or information made available to candidates or tenderers	No	Art. 4.3. 1 st §	Unfair treatment of tenderers	Not applicable

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
		R from publication or information made available to candidates or tenderers	Yes	Not applicable	Not applicable	Yes (CCI, including those cases where the exception on confidentiality of Art. 153(1) of the rules of implementation of the Financial Regulation applies)

1.3. Submission and opening of tenders

Received tenders	Yes	Non-R prior to contract signature	No	Art. 4.3. 1 st §	Art. 4.2. 1 st indent	Not applicable
		Non-R after contract signature	No	Art. 4.2. 1 st indent	Art. 4.1 (a)	Not applicable
Decision appointing the committees for the opening and evaluation of tenders	No	Non-R prior to contract signature or cancellation of procedure	No	Art. 4.3. 1 st §	Art. 4.2. 1 st indent	Not applicable

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
		R after contract signature or cancellation of procedure	Yes	Not applicable	Not applicable	Yes (PPD, including the names of the members of the committee)
Written record of the opening of tenders	No	R	Yes	Not applicable	Not applicable	Yes (PPD)
1.4. Evaluation of tenders						
Declarations on the absence of conflicts of interest and confidentiality signed by the evaluators	No	R	Yes	Not applicable	Not applicable	Yes (PPD, including names of the members of the committee)

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
Clarification requested from tenderers during evaluation and their replies	Yes	Non-R prior to contract signature or cancellation of the procedure	No	Art. 4.3. 1 st §	Art. 4.2. 1 st indent	Not applicable
		R after contract signature or cancellation of the procedure	Yes	Not applicable	Not applicable	Yes (PPD and CCI)
Evaluation report ^a	No	Non-R prior to contract signature or cancellation of the procedure	No	Art. 4.3. 1 st §		Not applicable
		R after contract signature or cancellation of the procedure	Yes	Not applicable	Not applicable	Yes (PPD and CCI)
1.5. Award and signature of contract or cancellation of procedure						
Award decision	No	Non-R prior to adoption of the decision	No	Art. 4.3. 1 st §		Not applicable
		R after adoption of the decision	Yes	Not applicable	Not applicable	Yes

^a For tenderers, a degree of privileged access right is provided for in Article 113(2) of the Financial Rules applicable to the general budget of the Union (Regulation (EU, EURATOM) No 966/2012 of the European Parliament and of the Council), which are applicable to the EMA as per Article 85.1 of the EMA's Financial Regulation applicable to the budget of EMA adopted by the Management Board on 15 January 2014. Those requests are therefore not dealt with under the provisions of the Regulation (EC) No 1049/2001 on Access to Documents, but under the relevant provisions of the Financial Regulation.

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
Notification of contract award to the successful tenderer	No	Non-R prior to contract signature or cancellation of the procedure	No	Art. 4.3. 1 st §		Not applicable
		R after contract signature or cancellation of the procedure	Yes	Not applicable	Not applicable	Yes (PPD and CCI)
Contract and its annexes	Yes	Non-R prior to contract signature or cancellation of the procedure	No	Art. 4.3. 1 st §	4.2. 1 st indent	Not applicable
		R after contract signature or cancellation of the procedure	Yes	Not applicable	Not applicable	Yes (PPD and CCI)
Notifications of contract award to unsuccessful tenderer	No	Non-R prior to contract signature or cancellation of the procedure	No	Art. 4.3. 1 st §		Not applicable
		R after contract signature or cancellation of the procedure	Yes	Not applicable	Not applicable	Yes (PPD and CCI)

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
Decision to cancel the procedure	No	R from signature of the decision and information to the tenderers ^b	Yes	Not applicable	Not applicable	No
Notification to tenderers of cancellation of procedure	No	R from the notification to tenderers having been made	Yes	Not applicable	Not applicable	Yes (PPD)
Award of cancellation notice	No	Published on EMA website	Yes	Not applicable	Not applicable	No
2. Conflict of interest declarations						
Conflict of interest declaration for staff - current	No	For EMA management: published on EMA website For all other EMA staff: R	Yes	Not applicable	Not applicable	No
Conflict of interest declaration for staff - previous	No	R	Yes	Not applicable	Not applicable	Yes (PPD)
Conflict of interest declaration for experts - current	No	Published on EMA website	Yes	Not applicable	Not applicable	No

^b As soon as the decision is taken it must be communicated to tenderers.

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
Conflict of interest declaration for experts - previous	No	R	Yes	Not applicable	Not applicable	Yes (PPD)
Conflict of interest declaration for Committee and Management Board Members - current	No	Published on EMA website	Yes	Not applicable	Not applicable	No
Conflict of interest declaration for Committee and Management Board Members - previous	No	R	Yes	Not applicable	Not applicable	Yes (PPD)
3. SOPs and WINs						
SOPs and WINs – current version	No	Published on EMA website	Yes	Not applicable	Not applicable	No
SOPs and WINs – previous versions	No	R	Yes	Not applicable	Not applicable	No
4. Corporate documents available on the EMA's website						
Annual report	No	Published on EMA website	Yes	Not applicable	Not applicable	No
Work programme	No	Published on EMA website	Yes	Not applicable	Not applicable	No
Annual Budget	No	Published on EMA website	Yes	Not applicable	Not applicable	No
Report on budgetary and financial management	No	Published on EMA website	Yes	Not applicable	Not applicable	No

Document type ¹	Third-party document ²	Classification ³	Access ⁴	Reference ⁵	Additional justification ⁶	Need for redaction of document prior to disclosure ⁷
Annual accounts	No	Published on EMA website	Yes	Not applicable	Not applicable	No
European Court of Auditors final report on the annual accounts of the European Medicines Agency	No	Published on EMA website	Yes	Not applicable	Not applicable	No
Agendas and minutes of the Management Board	No	Published on EMA website	Yes	Not applicable	Not applicable	No

¹ Refers to any document the EMA produces, receives or has in its possession.

² Means any natural or legal person, or any entity outside the EMA, including the Member States, other EU or non-EU Institutions and Bodies, and third countries. Either "Yes" or "No" to be filled in. "Yes" may/shall lead to a consultation exercise with the third party (cfr. policy for further details) with a view to assessing whether an exception listed in Article 4 of Regulation (EC) No 1049/2001 is applicable, unless it is clear that the document shall or shall not be disclosed.

³ Refers to classification in one of the following categories: Releasable (R) or Non-Releasable (Non-R). In certain situations the documents are published on the EMA website. If this is the case, this will be indicated.

⁴ Either access to be granted (Yes) or to be refused (No); in case of third-party consultation the granting or not of access will depend on the outcome of such consultation.

⁵ Only to be filled in if access to EMA documents is refused by virtue of application of one of the exceptions mentioned in Article 4 of Regulation (EC) No 1049/2001, i.e. by referring to:

- Article 4.1.(a)

The Agency shall refuse access to a document where disclosure would undermine the protection of the public interest as regards public security, defence and military matters, international relations, the financial, monetary or economic policy of the EU or a Member State.

- Article 4.1.(b)

The Agency shall refuse access to a document where disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with EU legislation regarding the protection of personal data.

- Article 4.2. 1st indent

The Agency shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property.

- Article 4.2. 2nd indent

The Agency shall refuse access to a document where disclosure would undermine the protection of court proceedings and legal advice.

- Article 4.2. 3rd indent

The Agency shall refuse access to a document where disclosure would undermine the protection of the purpose of inspections, investigations and audits.

- Article 4.3. 1st paragraph

Access to a document, produced, received or in possession of the Agency shall be refused if disclosure of the document would seriously undermine the decision-making process.

- Article 4.3. 2nd paragraph

Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the Agency shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the Agency's decision-making process.

⁶ Additional justification to be provided in order to further elaborate on the rationale for not providing access as per the reference to the exceptions mentioned in Article 4.

⁷ Redaction of EMA documents will be carried out to remove any reference to commercial confidential information or to personal data.