EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Deputy Executive Director

Guide on access to unpublished documents

Documents Access and Publication (DAP) service

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First revision *Scope of Rev.1: reflect the EMA decision as of mid-June 2018 to only process access to documents requests submitted by citizens of the European Union and natural or legal persons residing or having their registered office in an EU Member State (revised Q2), explain what content might be redacted in a requested document (new Q11), clarify the queuing system (new Q14) and the release of documents in batches (new Q15).*	24 September 2018

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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Introduction (background)

This document complements Policy 43: European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use). Policy 43, 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. The present guide describes how the Agency deals with all written requests, especially 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.

This guide, developed by the ATD team within the Documents and Publication (DAP) Service, should be read in conjunction with the information already provided by the Agency on the dedicated webpage on Access to Documents.

Questions & Answers

Q1. How can I request a document?

Requests for access to documents should be made directly via the web form. As the requester, you should clearly identify the document(s) that you are requesting. If you are unsure which document is needed, we advise you to provide as much information as possible in the free text part of the web form, under "Your question(s)". Once received, the designated Access to Documents (ATD) coordinator at the European Medicines Agency (the Agency) will contact you to clarify your request and assist you, if necessary.

In the web form, you will be asked to provide your name, the name of your employer or organisation (if applicable), contact details, the subject of your request and your location. You should write the full details of your request in the appropriate space.

Providing the reason for your request is optional. However, if you choose to provide the reasons for the request, it may help the Agency in certain cases to identify the correct document(s) and facilitate the decision concerning their release.

Should you wish to request documents for several medicinal products, it is recommended that you submit a separate request for each medicinal product, to help with the administrative referencing. Depending on the extent of your request (number and size of documents requested), the request may be split in one or more batches (see Q15).

Please provide as much detail as possible when completing your request (see Q4), ensuring you include your correct and complete contact details. If the contact details you provide are incomplete or inaccurate, this may prevent the Agency from communicating with you and delay, or even render impossible the processing of your request.

Moreover, in case of incomplete or incorrect data in the web form, the Agency's decision on your request may not reach you.

Q2. Who can request a document?

Citizens of the European Union (EU) and natural or legal persons residing or having their registered office in an EU Member State have the right of access to EMA documents, under Article 2(1) of Regulation (EC) No 1049/2001. This right to access concerns documents held by EMA (that is to say, documents drawn up or received by EMA and in its possession) (see Q3).

Q3. What type of documents can I request?

You may request any type of documents held by the Agency. Your request should clearly identify the documents requested that are not already published (see also Q4 and Q10). Guidance can be found here on what the Agency publishes on medicines and when.

Q4. What if I am not sure which document I want?

Guidance on how to search documents published by the Agency is available here.

Searches can also made be across the European public assessment reports (EPAR) published for all medicines authorised at a European Union level. Search is possible by key words (such as by name of medicinal product or name of active substance), by therapeutic area and by sub-types of medicines (such as generics or orphan medicines).

If you are not sure which document you need, we advise you to give as much information as possible in the free text part of the web form. Once received, an ATD coordinator will contact you to clarify your request and assist you.

Q5. In what language may I submit a request for a document?

English is the official working language of the Agency. If a request is sent to the Agency in another official language of the EU, the correspondence between the requester and the Agency will be in the language of the request.

However, the Agency decision letter will always be in English and the relevant documents will be provided in the language in which the Agency holds them, mainly in English. The Agency is not responsible for the translation of the documents it holds and will not accept requests for translation of documents.

The Agency's translation practice for documents published on the website is:

- EPAR: An EPAR is not a single document but an information resource containing several components, including a core set of regulatory documents. Most components are in English, however the EPAR summary for the public, the summary of product characteristics, the package leaflet, the labelling and the list of all authorised presentations are published in all official EU languages.
- Referral documents: background information and Annex I, II and III are published in all EU official languages.
- Annual reports and work programmes as well as other statutory documents are published in English.

All other published documents are therefore currently available in English only, including scientific guidelines for human medicines and for veterinary medicines.

Q6. How will my request be processed?

A flow-chart of the ATD process is given in the annex.

- After submitting your request via the web form, you will receive an automated acknowledgement of receipt with a unique reference number (for example ASK-12345). This ASK reference number must be used every single time you contact the DAP Service regarding that particular request.
- When your request starts being processed, you will receive another acknowledgement e-mail from the ATD coordinator in charge of your request, possibly seeking some clarifications as the DAP Service can only process clear requests.
- If you have already submitted one or more ATD requests, your new request will be placed in a queue. You will be informed systematically when this is the case (see Q14).
- Each request for access to documents is carefully evaluated on a case-by-case basis by a dedicated team.
- Should your request be for a large number of documents or for large documents, they may be released in one or more batches. You will be informed systematically when this is the case (see Q15). You should use this opportunity to identify the priority in which you wish the Agency to process the documents under your request.

- Within 15 working days following the day of receipt/clarification of your request, you will either receive a decision letter or be informed that the timeline has been extended by a further 15 working days. If the deadline is extended, the Agency will provide you with the reason for this extension (see Q13).
- When your request relates to a document that was provided by, or contains information provided by a third party, the Agency will consult them during the processing of your request for access to documents (see Q10).

The Agency decision and the document (if releasable) will be sent to you electronically via a secure transmission system called EudraLink (see Q7). The document may be released immediately or 10 working days after the Agency decision was sent to you (this happens when the Agency and the third party have diverging views concerning the release of the document itself or concerning the level of redactions applied to the document (see Q10 and Q11).

Q7. If access is granted, how will I receive the documents?

You will receive the document(s) via a secure electronic system called EudraLink. You will have a maximum of 90 days to download/open the link to the document(s). You will be alerted about the EudraLink transmission via a short e-mail.

By clicking on the link provided in the EudraLink message, a new page will open where you will be able to see and access the Agency decision and any attached documents.

You will be asked to confirm that you have received the package by clicking on the "*Confirm*" button.

Please always confirm receipt as this is important for the DAP Service to be able to track timelines, especially if you have requested several documents that will be released in batches (see Q15). The Agency might decide to close a request if the requester does not confirm receipt of the EudraLink messages.

Documents sent to you may contain redacted text, such as commercially confidential information (CCI) and protected personal data (PPD) (see Q11).

Q8. What can I do if I am refused access to documents?

If access to the document(s) you requested is not granted, you will receive a refusal letter within 15 working days from the initiation of your request (or within 30 working days if the deadline was extended).

If you are not satisfied with the decision of the Agency, you may ask the Agency to reconsider its decision by sending a written request called a "confirmatory application" ("appeal") via the web form. You are kindly invited to provide your reasons for appealing against the decision to refuse access, which should be taken into account by the Agency in adopting a final decision.

When sending a confirmatory application, please ensure that the subject field of the request contains the appropriate ASK number and mentions "Confirmatory Application" (i.e. Confirmatory Application ASK-12345).

Once your confirmatory application has been received, you will be informed of the Agency's decision within 15 working days. This period may be extended by a further 15 working days. If the deadline is extended, the Agency will provide you with the reason for this extension.
If the refusal is confirmed, you will also be informed of any further remedies available to you (see Q13).

Q9. When is it most likely that the Agency will refuse access?

The Agency will refuse access to a document where disclosure would undermine the protection of:

- public interest as regards public security, defence and military matters, international relations, the financial, monetary or economic policy of the European Union or a Member State;
- the privacy and integrity of one or more individuals, in particular in accordance with EU legislation regarding the protection of personal data;
- the commercial interests of a natural or legal person, including intellectual property, unless there is an overriding public interest in disclosure;
- the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure;
- Court proceedings and legal advice, unless there is an overriding public interest in disclosure.

Access to a document held by the Agency, which relates to a matter where the decision has not been taken, shall be refused if 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 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, unless there is an overriding public interest in disclosure (see Article 4(3) of the Regulation (EC) No 1049/2001).

If only parts of the requested document are covered by any of the exceptions, the remaining parts of the document shall be released. In such cases, the Agency will release "redacted documents"; these are documents in which the sensitive information has been blacked out. For information about redactions relating to privacy or commercial interests, see Q11.

Q10. Will the Agency grant access to documents produced by others?

Yes, documents submitted to the Agency can be released by the Agency. The entity, which produced and submitted these documents in the first place, is called a "third party". Policy 43 defines a third party as any natural or legal person, or any entity outside EMA, including the EU Member States, other EU or non-EU institutions and bodies and third countries.

Upon receipt of a request for access to such documents, the Agency will liaise with the third party to discuss which content/information in these documents may need to be protected before the documents can be released (see Q9 and Q11).

In particular, third parties are invited to justify why some content/information is identified as commercially confidential and to indicate the personal data that need to be protected. Thus, some parts of the requested documents might be redacted (blacked out to protect the interests defined in Q9).

Q11. What kind of content/information might be redacted to protect privacy or commercial interests?

Content covered by the exception related to privacy

'Protected Personal Data' (PPD) refers to protected data related to a living individual, who can be identified from that data. Personal data are redacted to prevent that disclosure could lead to infringement of personal integrity or cause personal harm. The guiding principle is that it should never

be possible to identify a natural person from the information disclosed, apart from a limited number of cases (such as individuals, who have legally defined responsibilities and roles with respect to aspects of the marketing authorisation dossier for a medicinal product or individuals involved in an EMA activity like scientific committee members).

Content covered by the exception related to commercial interests

'Commercially Confidential Information' (CCI) refers to information the release of which might prejudice the commercial interests of individuals or companies to an unreasonable degree. Policy 43 has established that "*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*".

Q12. Can I copy, publish or sell the documents that are obtained from the Agency?

Please visit the Agency's public webpage 'Legal notice' to know more about the applicable copyright and limited reproduction notices in relation to the documents you have obtained from the Agency.

According to Article 16 of Regulation (EC) No 1049/2001, the release of the requested documents is without prejudice to any existing rules on copyright, which may limit your right to reproduce or exploit released documents. The Agency shall assume no liability for any unlawful or unauthorised use, disclosure or reproduction of these documents.

Q13. What if I do not receive on time the documents I have requested?

The DAP Service will do its best to process your request on time.

However, workload and complexity may lead to some delay. The DAP Service will keep you informed of any such delay and of the revised timelines. For requests concerning several documents or documents requiring extensive redaction before being disclosed, you may be contacted about a release in sequential batches over time. The DAP Service will do its utmost to respect the priority order in which you wish to receive the documents (see Q15).

If you want to know the status of your request, you may contact the ATD coordinator in charge of your request by e-mail, quoting the request reference number (i.e. ASK-12345).

If you have not been contacted by the Agency within 15 working days of the initiation of your request, you may send a confirmatory application (see Q8).

If the Agency does not reply to your confirmatory application or you are not satisfied with the response received, you may complain to the European Ombudsman or alternatively, you can institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU (see Article 8 of the Regulation (EC) No 1049/2001).

Q14. Why does the Agency apply a queuing system and can I influence the order in which my requests will be processed?

If you have submitted several requests for access to documents, you will receive an e-mail listing these different requests. In this communication, the DAP Service will remind you that the Agency applies the principle of proportionality set out in its Policy 43 in order to avoid the core business tasks of the Agency and its performance be jeopardised by the workload related to activities conducted by the Agency in accordance with Regulation (EC) No 1049/2001.

The DAP Service will plan to process the different requests in the order in which they were received; however you will be invited to suggest another order of priority, should you wish to do so.

The same queuing approach is applied when several requests are received from different individuals working in the same company.

Q15. Will I receive all documents I requested in one transmission?

The DAP Service will do its best to release the requested documents in one transmission. However, this is not possible if the request concerns a large number of documents. As the Agency has to examine individually each document to ensure that no private or public interests are being compromised by the release, the DAP Service may not be in a position to fulfil your request in one transmission. The Agency endeavours to provide you with sets of documents at regular intervals. This decision to release documents in batches is in line with the principle of proportionality set out in Policy 43. The Agency applies the principle of proportionality to prevent the core business tasks of the Agency and its performance being jeopardised by the administrative workload related to access to documents activities.

Annex

Flowchart of ATD process