



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management & Business Support

Guide on access to unpublished documents

Access to unpublished documents

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Send a question via our website www.ema.europa.eu/contact

An agency of the European Union



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 documents that you are requesting. If you are unsure which document is needed, we advise you to give as much information as possible in the free text part of the [web form](#). 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.

In the [web form](#) you will be asked to provide your name, the name of your employer or organisation, contact details and the subject of your enquiry. You should type the full details of your query in the appropriate space.

Providing the reason for the request is optional. However, if you choose to provide the reasons for the request, it will help the Agency to identify the correct documents and to make an informed decision on the release.

Should you wish to request documents for several medicinal products it is recommended that you submit a separate request for each medicinal product.

Please give as much detail as possible when completing your request and be sure to 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.

In case of incomplete or incorrect data in the [web form](#), the request may not be processed.

Q2. Who can request a document?

Everyone may request a document.

Q3. What type of documents can I request?

You may request any type of document held by the Agency. Your request should clearly identify the documents that are requested.

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

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 an official language of the European Union, the correspondence between the requester and the Agency will be in the language of the request.

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

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

- European Public Assessment Reports (EPARs): the abstract, authorised presentations and the Commission Decision product information of all presentations are published in all EU languages. The scientific discussion and procedural steps are available in English only.

- Referral documents: background information and Annex I, II and III are published in all EU official languages.
- Annual Reports, Work Programmes and other statutory documents are published in all EU official languages.

All other published documents are therefore currently available in English only, including guidelines.

Q6. How will my request be processed?

- After submitting your query via the [web form](#), the ASK Reference number given to you must be used every time you contact us regarding the same query.
- You will receive an automated acknowledgement of receipt with a unique reference number (for example ASK-1234) which is to be used for all correspondence concerning your request.
- Your request will be placed in a queue.
- An Access to Document Coordinator may contact you if your request needs clarification, as we can only process clear requests.
- Each request for access to documents is carefully evaluated on a case by case basis by a dedicated team.
- Within 15 working days following the receipt of your request you will receive a decision letter or be informed that the timeline has been extended by 15 working days. If the deadline is extended, the Agency will provide you with a reason for this extension.
- When your request relates to a document that was provided by or concerns a third party, the Agency will consult them during the assessment of your request for access to documents.
- The Agency decision and the documents released will be sent to you via a secure system called EudraLink.
- If you submit a new query, you will receive a new acknowledgement of receipt with a new ASK reference number.

Q7. If access is granted how will I receive my document?

You will receive your document via a secure electronic system called EudraLink. You will have 50 days to download/open the link to the document. In the email sent to you, the expiry date of the package will be confirmed.

By clicking on the link, a new page will open where you will be able to see the document.

You will be asked to confirm that you have received the package by pressing on the “Confirm” button.

Please always confirm receipt.

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

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

If access to the requested document is not granted, you will receive a refusal letter within 15 working days from the receipt of your request (or 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” via the [web form](#). You are

kindly invited to provide your reasons for appealing against our decision to refuse access, which you believe should be taken into account by the Agency in adopting a final decision.

When sending a confirmatory application please ensure that the subject of the query contains the appropriate ASK number and mentions "Confirmatory Application" (i.e. Confirmatory Application ASK-1234).

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 a reason for this extension. You will also be informed of any further appeal routes open to you for consideration.

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 the individual, 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, produced or received by, and in possession of 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](#)).

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

Yes, documents submitted to the Agency are considered to be owned by the Agency. The entity which produces these documents is considered to be a "third party".

Prior to the release of such documents, the Agency will liaise with the third party to discuss potential steps necessary to protect commercially confidential information (CCI) and protected personal data (PPD).

Q11. Can I copy, publish or sell the documents that are obtained from the Agency?

According to current European Union and international legislation, the Agency is the owner of copyright and other intellectual property rights for documents published on the website of the Agency.

For more information please refer to the [Legal notice](#).

The Agency shall assume no liability for any unlawful or unauthorised use, disclosure or reproduction of the documents provided in response to requests for access to documents, in accordance with Article 16 of [Regulation \(EC\) No 1049/2001](#).

Q12. What if I do not receive the document I have requested on time?

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

However, workload and complexity may lead to a delay. The ATD Service will do its best to keep you informed of any such delay and you will be informed of the revised deadlines. For high volumes of documents you may be informed of a release in sequential batches over a longer period of time.

You may contact the ATD coordinator in charge of your request by e-mail, quoting the initial request reference number (i.e. ASK-1234).

If you have not been contacted by the Agency within 15 working days, you may send a Confirmatory Application.

If the Agency does not reply to your Confirmatory Application, 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](#)).

Q13. Flowchart of the ATD process

