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Guide on access to unpublished documents

Access to Documents Service

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Second revision *Further clarification of the queuing system including measures in place to prevent the possible circumvention of the access to documents queuing system (revised Q14).*	5 December 2019
Third revision *- Residence/registered office(s) in Northern Ireland (revised Q2)* *- Each access-to-documents request not to exceed 2 documents and a maximum of 5 access-to-documents requests to be submitted per requester/affiliation (revised Q6). See also new Q17 and Q18* *- Further clarification of the queuing system (revised Q14)* *- New Q16: Why are some requests placed in the 'chronological queue' and what is the difference to the Queuing system which is explained in Q14?* *- New Q17: Why, since March 2021, does the Agency require each access-to-documents request not to exceed 2 documents and a maximum of 5 access-to-documents requests to be submitted per requester/affiliation?* *- New Q18: What is considered 1 document?*	31 March 2021

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Sixth revision Phased lifting of EMA's business continuity plan: *- Minor revision of Q16* *- Minor revision of Q17*	24 May 2023
Seventh revision *Removal of maximum of 5 requests to be submitted per requester / affiliation following business continuity plan linked to Covid-19* *- Revision of Q17*	25 April 2024

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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 Access to Documents 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 would like to receive.

- If you know which document(s) you would like to request, please select the corresponding radio button under '*Please select your type of enquiry*' in the web form. Please click the button '*I want an unpublished document (maximum 2 documents per request)*.'
- If you are unsure which document(s) you would like to request, please select the radio button '*I want help identifying which unpublished document I need.*' 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 the following information:

- 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). EMA also grants access to documents to natural or legal persons residing or having their registered office in Northern Ireland.

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, Q10 and Q18). 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, please select the corresponding radio button under 'Please select your type of enquiry' in the web form. Select the button 'I want help identifying which unpublished document I need.' In addition, we advise you to indicate it and 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.

More information on what is considered one document is provided in Q18 below.

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 provided in the annex of this Guide.

- 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 ATD 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 ATD Service can only process clear requests.
- As detailed in our answers to Q17 and Q18, the Agency requires each access-to-documents request not to exceed 2 documents and a maximum of 5 access-to-documents requests to be submitted per requester/affiliation.
- 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.
- Depending of the volume of requested document, the Agency may need to process it in one or more batches (e.g. Clinical Study Report including all its appendix(es)). 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 ATD 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, such as 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 ATD Service will do its best to process your request on time.

However, workload and complexity may lead to some delay. The ATD 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 ATD 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 (e.g. 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?

The Agency applies a queuing system for access to documents requests, in line with the principle of proportionality as set out in its Policy 43, in order to avoid that the core business tasks of the Agency and its performance would be jeopardised by the workload related to activities conducted by the Agency in accordance with Regulation (EC) No 1049/2001.

This queuing system may be applied to a requester who submits one or more additional access to document requests while his/her earlier request is being processed. This mechanism is applied if the ATD Service is already working at full capacity. Of the requests that are put in a queue, the ATD Service deals with one at a time, while putting the other requests from the same requester on hold. The same queuing mechanism is applied when several requests are received from different individuals working in the same company or stating the same affiliation, as well as when several requesters submit requests in cooperation, with reference to each other or on behalf of each other.

The requests are treated in the order in which they arrive unless a different priority order is indicated by the requester. The requester is also invited to indicate the urgency (if any) into receiving their request. The processing of the next request in the queue starts once the processing of the 'active' request is finished, when a ATD Service team member becomes available, or when another requester requests access to the same document.

When a request is placed in a queue, the ATD team informs the requester. The ATD team then deals with one request at a time either in chronological order or in order of priority suggested by the requester/affiliation who has the queue of requests. Each time a request ends, an ATD coordinator will contact the requester/affiliation to inform that the next ATD request starts.

As mentioned above, the queuing mechanism serves the purpose of ensuring that EMA can simultaneously fulfil its core tasks and provide access to documents. It also ensures that every requester will have their requests fulfilled within a reasonable timeline in a consistent and fair way.

EMA's queuing mechanism has been acknowledged by the European Ombudsman who concluded in case 1608/2017/MIG that "*EMA's queuing mechanism constitutes a fair and appropriate solution for cases in which EMA would otherwise have to refuse public access due to an excessive administrative burden. EMA applies this mechanism in a reasonable and proportionate manner*". Please refer to the following link for further details: https://www.ombudsman.europa.eu/en/decision/en/111254.

Preventing possible circumvention of the access to documents queuing system

The ATD Service seeks to treat all requesters fairly and equally and therefore aims to prevent requesters from circumventing the queuing system explained above.

Circumvention of the queuing system would arise if requesters whose requests should otherwise be queued in accordance with the queuing rules submit requests separately without acknowledging their relevant connection. For example, circumvention of the queuing system would arise if separate individuals requested access to documents for the single use of only one requester.

A possible circumvention may be detected based on the assessment of the links between requesters who are suspected of bypassing the queuing system. Such an assessment is based, amongst other things, on the following information: name of the requester, affiliation/employer, time of submission, content and subject matter of the request. The requesters will then be informed that their requests have been placed in the same queue due to a detected possible circumvention. At this point, should the requester(s) wish to provide further information, they are welcome to contact the ATD Service.

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

The ATD Service will do its best to release the requested document(s) in one transmission. Depending of the volume of requested document and as the Agency has to examine each document individually to ensure that no private or public interests are being compromised by the release, the ATD 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.

Q16. Why are some requests placed in the 'chronological queue' and what is the difference to the queuing system which is explained in Q14?

In early 2019, the Agency relocated from London to Amsterdam due to the notification by the UK of its withdrawal from the EU. The change of seat of the Agency entailed that resources needed to be re-allocated to ensure its smooth relocation. Further, in early 2020, the breakout of the coronavirus disease 2019 (COVID-19) was declared a pandemic. The Agency was operating within a business continuity plan to ensure operational continuity during the COVID-19 pandemic crisis of unprecedented scale which required EMA to dedicate resources specifically to transparency related to COVID-19 and other urgent issues.

While EMA was operating under a business continuity plan during the COVID-19 pandemic, the number of access to documents has been increased. EMA is making every effort to process all requests as soon as possible. However, you should be aware that not all requests can be processed expeditiously and will be dealt with in chronological order from the time they were received. These requests were placed in the 'chronological queue'.

The 'chronological queue' is distinct from the queuing system explained in Q14 [and in which each requester has one request handled at any given point in time (please see details in Q14)]. Requesters who do not have their own queue and that are not prioritised are placed in the 'chronological queue'.

With regard to prioritisation, it should be noted that certain access to documents requests such as confirmatory applications (appeals) in accordance with Article 8 of Regulation (EC) No 1049/2001 and safety-related documents regarding ongoing/soon to start regulatory procedures e.g. Risk Management Plans are not placed in the queue or chronological queue but are handled immediately.

This decision is in line with the principle set out in our policy which states that the Agency will apply the principle of proportionality in order to avoid jeopardising the performance of the core business tasks of the Agency by the workload related to activities within the Regulation (EC) No 1049/2001. This decision was made public on the EMA website in October 2019.

Regarding access to documents requests relating to COVID-19, please note that, since October 2020, EMA has been publishing clinical data for COVID-19 medicines submitted in support of marketing authorisation application(s) by the companies in line with its exceptional transparency measures for treatments and vaccines for COVID-19.

Documents published on the clinical data website concern clinical reports defined as clinical overviews (submitted in module 2.5), clinical summaries (submitted in module 2.7) and the clinical study reports (submitted in module 5, "CSR"), together with the following appendices to the CSRs: 16.1.1 (protocol and protocol amendments), 16.1.2 (sample case report form) and 16.1.9 (documentation of statistical methods). Please see the "European Medicines Agency policy on publication of clinical data for medicinal products for human use".

If the scope of the access to documents request concerns document(s) planned soon to be published on the clinical data website, such request will not be prioritised in order to avoid duplication of work and potential delay in publishing on the clinical data website.

We would advise you to monitor the clinical data website and access the requested documents once published. Please take note of the Agency's website where you can find the background information to the clinical data publication policy, relevant documents as well as the clinical data website, where you will be able to search for the Clinical Study Reports published by the Agency.

Communication with the requester

An ATD coordinator sends the requester an acknowledgement of receipt of their application for access to documents. In the same email, the requester is informed that their request cannot be processed immediately and will be dealt in a chronological order from the time it was received, and that they will be informed when their procedure starts.

Q17. Why since March 2021 does the Agency require each access-to-documents request not to exceed 2 documents?

EMA makes every effort to process all requests as soon as possible, and deals with requests in a chronological order, based on time of receipt. An access-to-documents coordinator will inform you when your procedure starts.

In order to ensure a manageable flow of requests in a fair, timely and consistent way, each access to documents request cannot exceed 2 documents. There is no limit to the number of requests (maximum 2 documents) you can submit.

If a request exceeds 2 documents, an ATD coordinator will contact the requester to ask which 2 documents are the subject of this specific request. The requester can then submit another request for the other documents.

The current arrangements are in line with EMA's policy on access to documents. This states that the Agency will apply the principle of proportionality in order **not to jeopardise core business** tasks and its performance due to workload related to activities within Regulation (EC) No 1049/2001.

As mentioned above, this approach serves the purpose of ensuring that EMA can simultaneously fulfil its core tasks and provide access to documents. It also ensures that every requester will have their requests fulfilled within a reasonable timeline in a consistent and fair way.

Q18. What is considered 1 document?

Documents available at the Agency

You will find guidance on documents available at EMA in several sources such as:

- Output Table of EMA for product related documentation (EMA/127362/2006, Rev.1)
- Output Table of EMA for non-product related documentation (EMA/183710/2016)
- HMA/EMA Guidance on identification of CCI and PPD within the structure of a MAA
- Notice to applicants' (Vol 2B) where the procedures for obtaining a Marketing Authorisation in Europe are enshrined

What is considered one document?

You will find below a (non-exhaustive) list of what the Agency considers as one document. This list is based on the most commonly requested documents.

Please note that depending on the volume of the requested document, the Agency may need to process one document in several batches e.g. Clinical Study Report (body) including some or all of its appendices, if those are requested (for batch release please see Q15).

For all documents that contain annex(es) and/or appendix(ces), only the main part/body of the document will be processed by default (e.g. please see RMP format, structure of clinical study report). Specific annex(es) and/or appendix(ces) will be processed (batch release), only if requested.

Below is a (non-exhaustive) list of what the Agency considers as one document:

- Risk Management Plan (RMP) including its annex(es)
- The assessment report of an RMP
- Periodic Safety Update Report (PSUR) including its appendix(ces)
- The assessment report of a PSUR
- Clinical Study Report (CSR) including all its appendix(ces)
- Assessment Report as per the stage of a regulatory procedure [e.g. (Co-)Rapporteur Assessment Report at day 80 (overview, quality, non-clinical and clinical part, as applicable) of an initial Marketing Authorisation Application = 1 document, a List of Questions (LoQ) (overview, quality, non-clinical and clinical part, as applicable) for a regulatory procedure = 1 document, a List of Outstanding Issues (LoOI) (overview, quality, non-clinical and clinical part, as applicable) for a regulatory procedure = 1 document, Assessment Report at day 90 of a type II variation procedure = 1 document]
- Summary report of Paediatric Investigation Plan
- COMP Summary Report (orphan designation)
- COMP application form and Sections A-E
- Scientific advice/Protocol assistance (quality)
- Scientific advice/Protocol assistance (non-clinical)
- Scientific advice/Protocol assistance (clinical)
- Third Party/Marketing Authorisation Holder/Applicant response(s) as per the stage of the procedure (e.g. the responses at day 121 of an initial Marketing Authorisation Application on quality, non-clinical or clinical= 1 document).
- Agenda of a meeting
- Minutes of a meeting
- Correspondence (depends on type of correspondence e.g. letter= 1 document, email/track of emails on the same topic= 1 document)
- Modules of Marketing Authorisation Application (please see details in the table below):

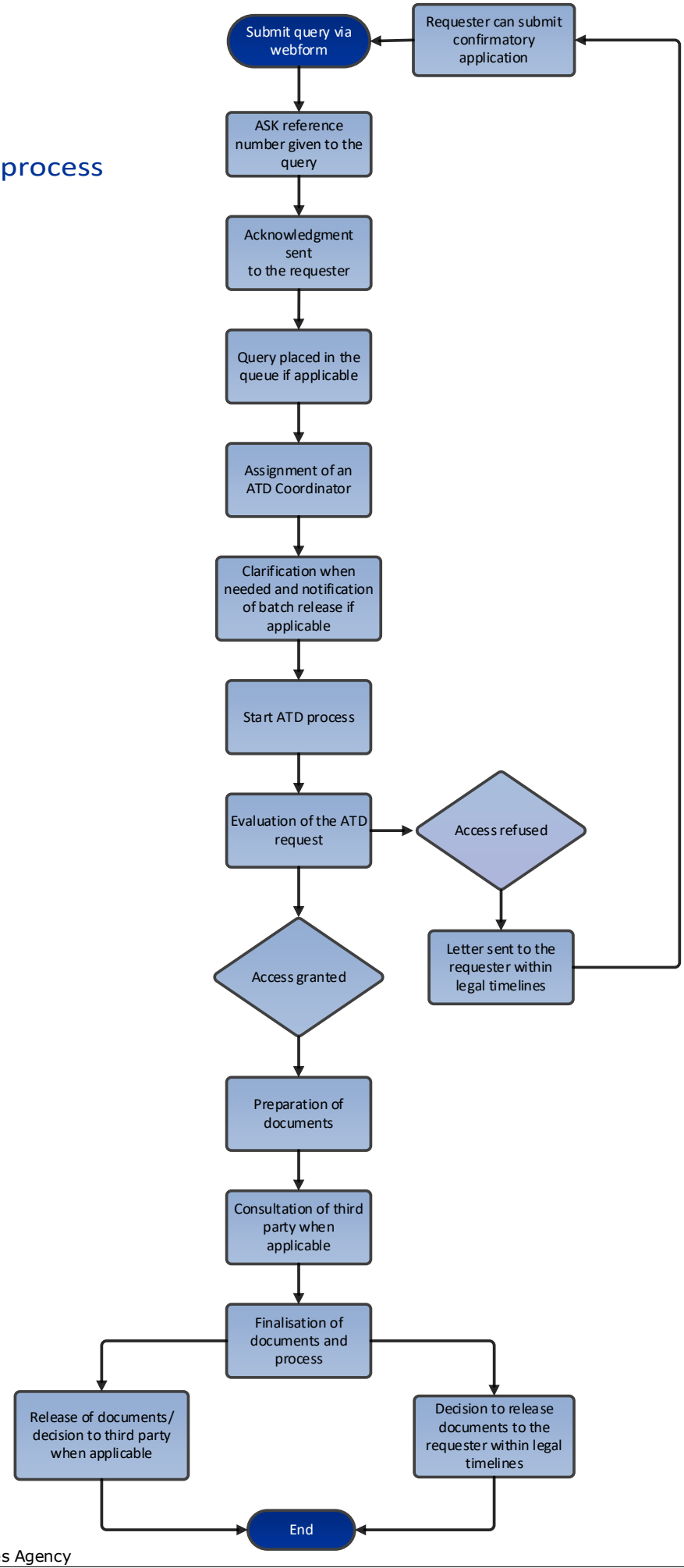
Modules		Document
Module 1:		
1.0	Cover Letter	1 document
1.1	Comprehensive Table of Contents	1 document
1.2	Application Form	1 document
1.3	Product Information	1 document
1.3.1	SPC, Labelling and Package Leaflet	
1.3.2	Mock-up	
1.3.3	Specimen	
1.3.4	Consultation with Target Patient Groups	
1.3.5	Product Information already approved in the Member States	

Modules		Document
1.3.6	Braille	
1.4	Information about the Experts	1 document
1.4.1	Quality	
1.4.2	Non-Clinical	
1.4.3	Clinical	
1.5	Specific Requirements for Different Types of Applications	1 document
1.5.1	Information for Bibliographical Applications	
1.5.2	Information for Generic, 'Hybrid' or Bio-similar Applications	
1.5.3	(Extended) Data / Market Exclusivity	
1.5.4	Exceptional Circumstances	
1.5.5	Conditional Marketing Authorisation	
1.6	Environmental Risk Assessment	1 document
1.6.1	Non-GMO	
1.6.2	GMO	
1.7	Information relating to Orphan Market Exclusivity	1 document
1.7.1	Similarity	
1.7.2	Market Exclusivity	
1.8.1	Pharmacovigilance System	1 document
1.8.2	Risk-management System	1 document
1.9	Information relating to Clinical Trials	1 document
1.10	Information relating to Paediatrics	1 document
Module 2: Common Technical Document Summaries		
2.1	CTD Table of Contents (Module 2 – 5)	1 document
2.2	Introduction	1 document
2.3	Quality Overall Summary – Introduction	1 document
2.3.	A Quality Overall Summary – Appendices	
2.3.R	Quality Overall Summary – Regional Information	
2.3.S	Quality Overall Summary – Drug Substance	1 document
2.3.P	Quality Overall Summary – Drug Product	1 document
2.4	Nonclinical Overview	1 document
2.5	Clinical Overview	1 document
2.6	Nonclinical Written and Tabulated Summaries	1 document
2.6.1	Introduction	
2.6.2	Pharmacology Written Summary	
2.6.3	Pharmacology Tabulated Summary	
2.6.4	Pharmacokinetics Written Summary	
2.6.5	Pharmacokinetics Tabulated Summary	
2.6.6	Toxicology Written Summary	
2.6.7	Toxicology Tabulated Summary	
2.7	Clinical Summaries	1 document
2.7.1	Summary of Biopharmaceutic and Associated Analytical Methods	
2.7.2	Summary of Clinical Pharmacology Studies	
2.7.3	Summary of Clinical Efficacy	
2.7.4	Summary of Safety	
2.7.5	References	
2.7.6	Synopses of Individual Studies	
Module 3: Quality		
3.1	Module 3 Table of Contents	1 document
3.2	Body of Data	1 document
3.2.S	Drug Substance	
3.2.S.1	General information	
3.2.S.2	Manufacture	1 document
3.2.S.3	Characterisation	1 document
3.2.S.4	Control of drug Substance	1 document
3.2.S.5	Reference standards or Materials	1 document

Modules		Document
3.2.S.6	Container	
3.2.S.7	Stability	
3.2.P	Drug Product	
3.2.P.1	Description and Composition of the Drug Product	1 document
3.2.P.2	Pharmaceutical Development	
3.2.P.3	Manufacture	
3.2.P.4	Control of Excipients	1 document
3.2.P.5	Control of drug Product	
3.2.P.6	Reference standards or Materials	
3.2.P.7	Container closure system	1 document
3.2.P.8	Stability	
3.2.A	Appendices	1 document
3.2.R	Regional Information	
3.3	Literature References	1 document
Module 4: Nonclinical Study Reports		
4.1	Module 4 Table of Contents	1 document
4.2	Study Reports	1 study report and its appendix(ces) = 1 document
4.3	Literature References	1 document
Module 5: Clinical Study Reports		
5.1	Module 5 Table of Contents	1 document
5.2	Tabular Listing of All Clinical Studies	1 document
5.3	Clinical Study Reports	1 Clinical Study Report and its appendix(ces) = 1 document
5.4	Literature References	1 document

Annex

Flowchart of ATD process



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