Standard operating procedure

Title: Handling of requests for information		
Status: **PUBLIC**		Document no.: SOP/EMA/0019
Lead author	Approver	Effective date: 24-JUL-15
Name: Marketa Liskova	Name: Andreas Pott	Review date: 24-JUL-18
Signature: On file	Signature: On file	Supersedes: SOP/EMA/0019 (26-OCT-12)
Date: 24-JUL-2015	Date: 24-JUL-2015	TrackWise record no.: 4541

1. Purpose

The purpose of this SOP is to define the procedure for the handling of requests for information received at the Agency.

"Request for information" shall mean external requests requiring an answer from the Agency and not falling within the scope of "Access to documents" (covered by SOP/EMA/0041). These requests shall be handled in accordance with the European Medicines Agency Code of Good Administrative Behaviour.

2. Scope

This SOP relates to all general requests for information falling outside the mainstream business and procedures of the Agency.

This SOP does not relate to requests received via designated e-mail inboxes and which fall within the scope of responsibility of the Division/Department/Service/Office concerned.

Requests for information shall be submitted in writing via the webform:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0.

The Agency shall respond to requests for information “within a reasonable time limit, without delay, and in any case no later than two calendar months from the date of receipt” in accordance with Article 18 of the European Medicines Agency Code of Good Administrative Behaviour.

An acknowledgement of receipt shall be sent within two weeks. However, in accordance with Article 14, an acknowledgement of receipt is not required if a substantive reply can be sent within this period.

Requests for information should be distinguished from requests for access to documents (covered by SOP/EMA/0041). Requests for information may involve an explanation of the contents of the document or an answer to a specific query, whilst requests for access to documents will always encompass an existing document held by the Agency.

In cases where the distinction between requests for information and requests for access to documents may not be straightforward, the Agency shall always reply following the 'EMA Rules on Access to Documents' and comply with the deadline of 15 working days. Failure to do so may result in a legal challenge or a complaint to the European Ombudsman (see SOP/EMA/0041).

In cases where the distinction between requests for information and requests for access to documents (mixed requests) can be easily made, the request can be split and for each subset the respective procedure must be followed. Replies will be sent out as and when each subset has been finalised.

In cases where the request for information is of a complex nature, a stepwise approach will be taken, where necessary, and replies sent out as and when they have been finalised.

3. Responsibilities

It is the responsibility of each Head of Division, Head of Department, Head of Service and Head of Office to ensure that this procedure is adhered to within their respective Division, Department, Service, Office. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of **9. Procedure**.

4. Changes since last revision

The SOP was updated to reflect the reorganisation process 'Review and Reconnect' with respect to the establishment of the Access to Documents Service and the introduction of a new way to submit a Request for Information (RFI).

5. Documents needed for this SOP

All documents are located in Document Records Electronic Archive Management (DREAM) in Cabinets/09. Relationship management and communication/09.7 ATD & RFI/Requests for information/02 Reports and work reference documents.

- EMA/212834/2014 – Dispatch channels for RFIs (internal procedure document).

6. Related documents

All documents are published on the EMA public website:

- European Medicines Agency Code of Good Administrative Behaviour;
- EMA/385894/2012 – EMA Code of Conduct;
- 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;
- EMA/110196/2006 – POLICY/0043 - European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use);
- SOP/EMA/0041 – Handling of Requests for Access to Documents;

- EMA/45422/2006 – Principles to be Applied for the Deletion of Commercially Confidential Information for the Disclosure of EMA Documents;
- EMA/127362/2006 Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use.

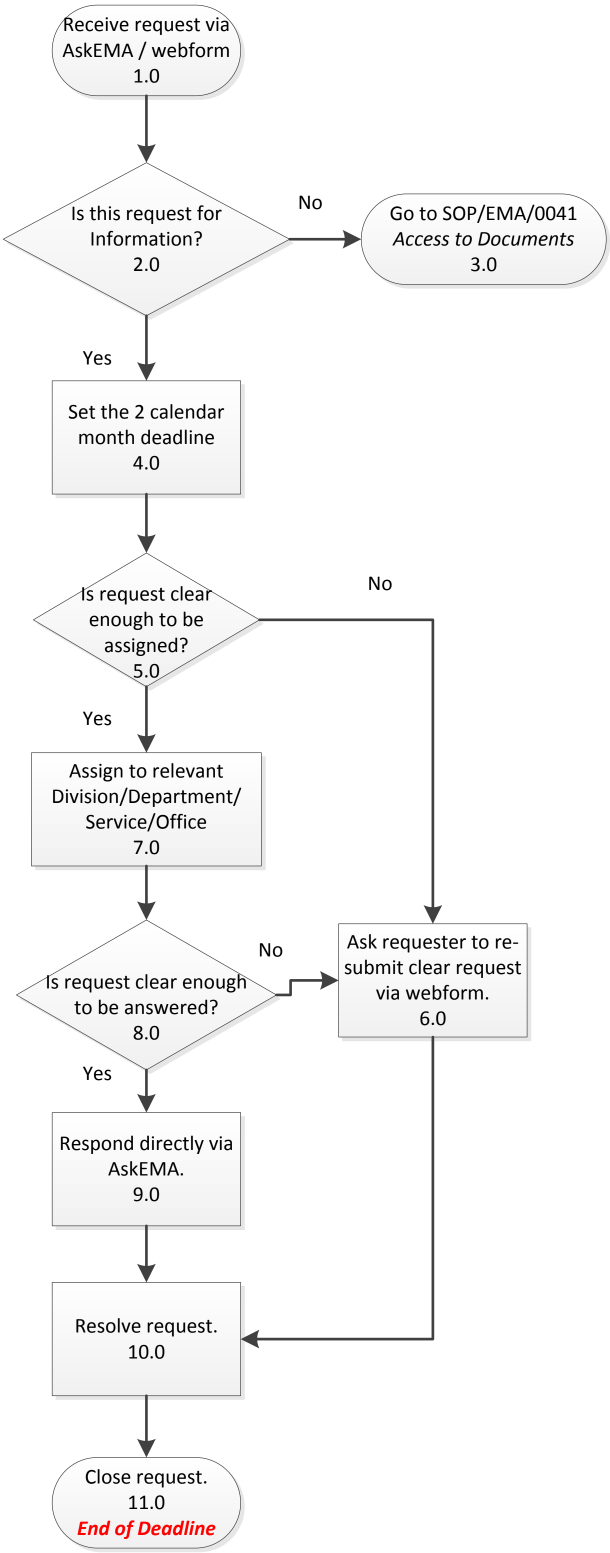
7. Definitions

Please note that the definitions below are those valid at the time of the effective date of this SOP. For the most up-to-date definitions please refer to the documents listed under **5. Documents needed for this SOP.**

Access to documents Management Team (ATDMT)	A group, appointed by the Executive Group on 15 July 2013, composed of EMA Staff- representatives from each of the Scientific Divisions in the Agency, the Legal Department and members of Access to Documents Service. The group holds weekly meetings and its aim is to ensure full consistency with the Agency policy framework, by identifying and managing the risks related to access to documents requests. The group is required to reach a decision, which should be taken by consensus.
AskEMA	The AskEMA management tool (JIRA) is used to record, manage and track all requests for information received via the web form[1]. Each request is allocated a unique reference number and the start date and deadline are recorded and tracked.
Assignee	Member of EMA staff responsible for replying to a request for information.
Document	Any content, whatever its medium (written on paper or stored in electronic form or as a sound, visual or audio-visual recording) concerning a matter relating to the policies, activities and decisions falling within the Agency's sphere of responsibility.
Public document	Documents not classified as confidential are considered public.
Requester	Any natural or legal person requesting general information from the EMA.
RFI Coordinator	Designated member of S-ATD responsible for the triage of Requests for information.
S-ATD	Stakeholders & Communication Division - Access to Documents Service.
Third Party	Any natural or legal person, or any entity outside the Agency, including the Member States, other Community or non-Community institutions and bodies, and third countries.

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1.0	*Start of Deadline* Receive request via AskEMA / webform. Then go to 2.0	RFI Coordinator
2.0	Is this a request for information? If yes, Automatic acknowledgment is sent and then go to 4.0. If no, go to 3.0 and to SOP/EMA/0041 for Access to Documents.	RFI Coordinator
3.0	Follow the steps described in SOP/EMA/0041 for Access to Documents. This is no longer a request for information and the responsibility passes to S-ATD.	RFI Coordinator S-ATD
4.0	Set the two calendar month deadline to respond to the request in AskEMA. Then go to 5.0	RFI Coordinator
5.0	Is this request clear enough to be assigned to the relevant Division/Department/Service/Office? If yes, go to 7.0 If no, go to 6.0	RFI Coordinator
6.0	Ask requester to re-submit clear request via the webform. Then go to 10.0	Assignee
7.0	Assign request to the relevant Division/Department/Service/Office. Then go to 8.0	RFI Coordinator
8.0	Is this request clear enough to answer? If yes, go to 9.0 If no, go to 6.0	Assignee
9.0	Respond directly to the requester using AskEMA *as soon as possible, in accordance with the EMA Code of Good Administrative Behaviour*. Then go to 9.0	Assignee
10.0	Resolve the request using AskEMA.	Assignee
11.0	Close the request using AskEMA. *End of Deadline*	RFI Coordinator

10. Records

Requests

All requests for information are logged electronically in AskEMA.

Replies

Electronic copies of replies are logged electronically in AskEMA.

Time spent

Records of time spent on requests for information are included in SAP-HR under chapter 17 – Transparency, Information and Communication - 03 Transparency/ Requests for information by all Agency staff members.