EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Handling of external requests for access to information from patients, healthcare professionals, academia and the general public		
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Lead author	Approver	Effective date: 11-NOV-16
Name: Inga Abed	Name: Juan Garcia Burgos	Review date: 10-NOV-19
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1. Purpose

The purpose of this SOP is to describe the process for handling written external requests for access to information from patients, healthcare professionals, academia and the general public.

"Requests for access to 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.

Requests for information should 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

Requests for access to information submitted in other written format (letter, email or fax) will also be accepted.

Requests for access to information received from journalists, lawyers, pharmaceutical industry, national competent authorities or other similar origin or requests for access to information related to veterinary medicines will continue to be dealt with according to SOP/EMA/0019. Requests for access to documents will continue to be dealt with according to SOP/EMA/0041.

The Agency aims to respond to queries covered by this SOP (queries from patients, healthcare professionals, academia and the general public) within 15 working days, in line with the Agency's work programme.

The legal deadline to respond to requests for information is 2 calendar months.

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

2. Scope

This SOP applies to the Medical and Health Information service (S-CO-MHI), part of the Communication department in the Stakeholders and Communication division.

3. Responsibilities

It is the responsibility of the Heads of service and department to ensure that this procedure is adhered to within his/her own service/department. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

The SOP was updated to reflect the reorganisation process 'Review and Reconnect' with respect to the establishment of the Documents Access and Publication service (DAP) and the introduction of a new way to submit requests for information (RFI).

5. Documents needed for this SOP

EMA/464869/2010 - standard response templates – internal document

6. Related documents

EMA/264257/2013– Code of good administrative behaviour and dealing with public requests for information
(http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/09/WC500150730.pdf)

EMA/385894/2012 rev. 1 – EMA Code of Conduct
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf

EMEA/MB/203359/2006 – Rules on the implementation of Council Regulation (EC) No 1049/2001 on access to EMEA documents
(http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/02/WC500070829.pdf)

Regulation (EC) No 1049/2001 for the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents
(http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf)

Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters to Community institutions and bodies (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:264:0013:0013:EN:PDF)

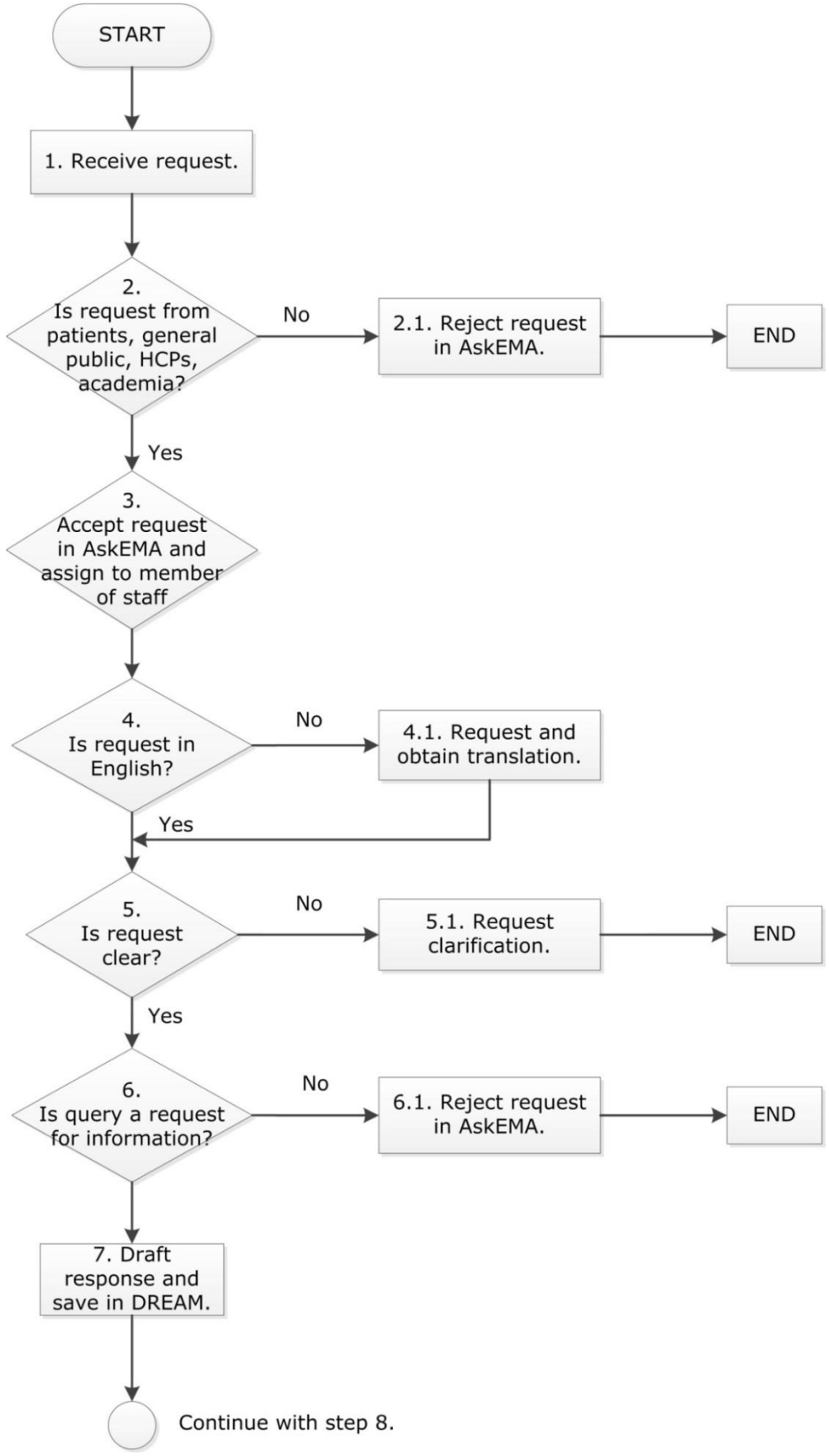
EMEA/127362/2006 – Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use
(http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/11/WC500099472.pdf)

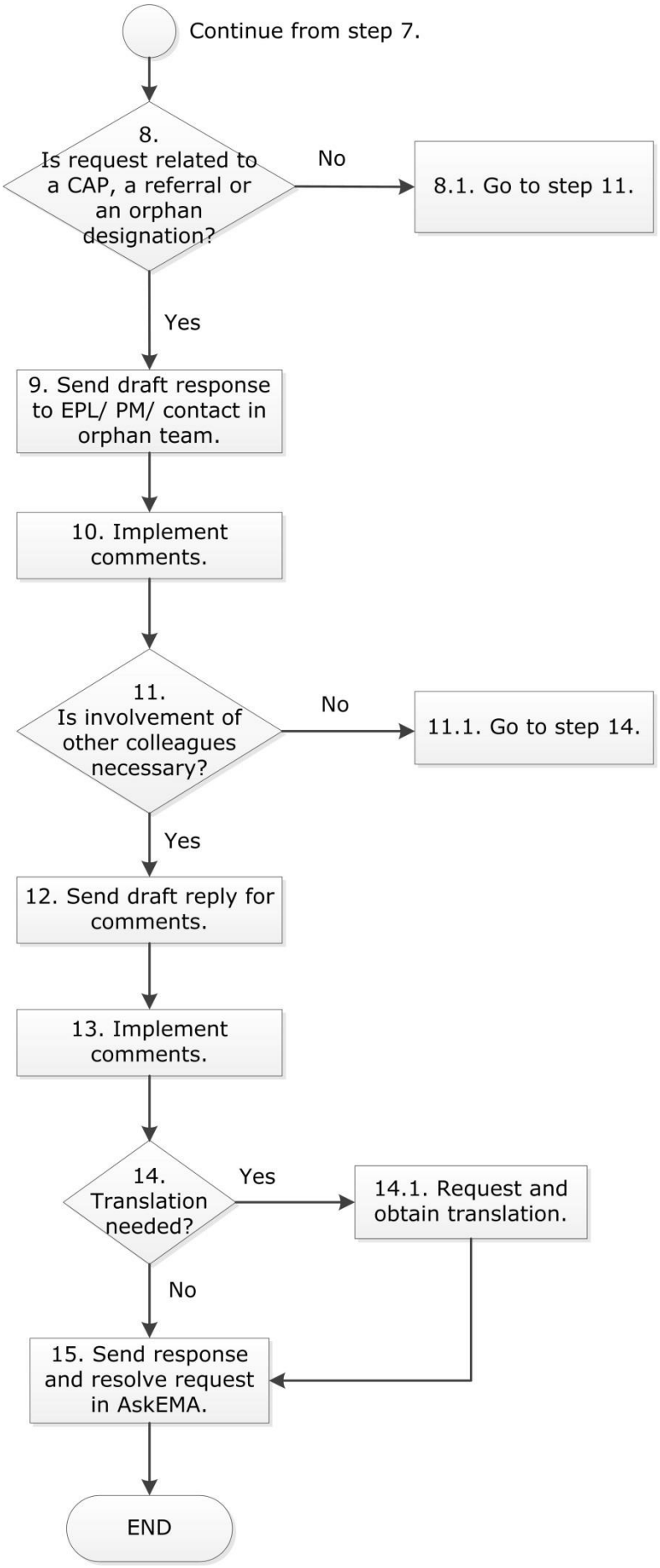
EMA/304162/2014 – Guide on access to unpublished documents
SOP/EMA/0041- Handling of Requests for Access to Documents
EMA/SOP/EMA/0019 – Handling of requests for Information
(http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2009/09/WC500002659.pdf)

7. Definitions

Academia	Public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest organisations.
Access to documents	Written request for access to any document produced or received and held by the Agency.
AskEMA	The AskEMA management tool (JIRA) is used to record, manage and track all requests for information received. Each request is allocated a unique reference number and the start date (the date when the query is received) and deadline (2 months from the day the query is received) are recorded and tracked.
CAP	Centrally authorised medicine
Patient	Individual who receives medical care, attention or treatment
S-CO-MHI	Medical and Health Information service, Communication department, Stakeholder Communication division
EPL	EMA Product Lead
Healthcare professional	A person with an appropriate qualification who professionally advises or delivers healthcare in his/her daily activity.
HoDiv	Head of Division
HoD	Head of Department
HoO	Head of Office
HoS	Head of Service
Medical and Health	dashboard dedicated to S-CO-MHI in AskEMA Information dashboard
Request for information (RFI)	"Request for information" shall mean external requests requiring an answer from the Agency and not falling within the scope of "access to documents".
Two months	Two calendar months from the date of receipt of a request for information at the EMA (regardless of whether request was received within or outside of opening hours). If the day of the deadline falls on a week-end/public holiday the previous working day shall be taken as the day of the deadline.
15 days	15 working days from the date of receipt at the EMA (regardless of whether request was received within or outside opening hours). If the day of the deadline falls on a week-end/public holiday the previous working day shall be taken as the day of the deadline.

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




Continue from step 7.
8. Is request related to a CAP, a referral or an orphan designation?
No
8.1. Go to step 11.
Yes
9. Send draft response to EPL/ PM/ contact in orphan team.
10. Implement comments.
11. Is involvement of other colleagues necessary?
No
11.1. Go to step 14.
Yes
12. Send draft reply for comments.
13. Implement comments.
14. Translation needed?
Yes
14.1. Request and obtain translation.
No
15. Send response and resolve request in AskEMA.
END

9. Procedure

Step	Action	Responsibility
1.	Receive request for information All requests should be received via AskEMA. Written requests sent by post/fax shall be scanned and sent to RFI@ema.europa.eu team who will enter these into AskEMA tool.	S-CO-MHI
2.	Is request within scope of S-CO-MHI? *(i.e. Is it a request for access to information from a patient, healthcare professional, academia or the general public?)* If yes - go to 3. If no – go to 2.1.	S-CO-MHI
2.1	Reject request in AskEMA tool with justification within 1 working day following receipt. The procedure ends here	S-CO-MHI Administrator
3.	Accept request in AskEMA and assign to member of the team	S-CO-MHI Administrator
4.	Is the request in English? If yes – go to 5. If no – go to 4.1.	S-CO-MHI
4.1	Send request for translation to internal volunteer On receipt of translation, continue and go to 5.	S-CO-MHI
5.	Is request clear? If yes – go to 6. If no - go to 5.1.	S-CO-MHI
5.1.	Ask enquirer for clarification through AskEMA tool *(this may require a translation of clarification request into language of enquirer).* If request is not clear due to poor English give option to submit request in another official EU language. When asking for clarification it should be pointed out to the enquirer that any clarification will have to be sent as a new request.	S-CO-MHI
6.	Is query a request for information? If yes – go to 7. If no - go to 6.1.	S-CO-MHI
6.1	Reject request in AskEMA tool with justification within 1 working day following receipt. The procedure ends here	
7.	Draft response using responses to similar previous requests and response templates where applicable and save in DREAM.	S-CO-MHI
8.	Is the request related to a CAP, orphan medicine or to a medicine that has been included in a referral procedure? If yes – go to 9. If no – go to 11	S-CO-MHI
9.	Email draft answer for comments to EPL/PM or colleague in orphan team. For any email communication with EPL/PM always copy the public folder external.queries@ema.europa.eu and product inbox. Give deadline for comments *(depending on urgency of request, usually*	S-CO-MHI

Step	Action	Responsibility
	2 working days).	
10.	Receive comments and implement as appropriate.	S-CO-MHI
11.	Would the request benefit from input from colleagues from other services/offices *(such as AF-LD for enquiries that involve litigation, C-PM-F)* or/and input from HoDiv/HoD or from the Rapporteurs? If yes – go to 12. If no – go to 14.	S-CO-MHI
12.	Email draft response to relevant colleagues for comments and copy "external queries". Give deadline for comments *(depending on urgency of request, usually 2 working days)*. Follow-up if needed. Continue and go to 13.	S-CO-MHI
13.	Implement comments and finalise as appropriate.	S-CO-MHI
14.	Does response need to be translated? If yes – go to 14.1 If no – go to 15.	S-CO-MHI
14.1	Send request for translation to internal volunteer On receipt of translation, save both versions in the same Word document. Continue and go to 15.	
15.	Send response through AskEMA tool To respond, copy answer into body of email and add name of responder before sending out. Bcc to Head of Service and external.queries@ema.europa.eu In case of translation, the translated version followed by the English version should be sent out including a disclaimer*: 'The message above is a translation from the original text in English, which is copied below for your reference.'* If request was received in letter or fax format, then send reply by letter or fax. A copy of the response shall be recorded in AskEMA. Press "resolve" and copy answer in the comment box.	S-CO-MHI

10. Records

REQUEST and RESPONSE

Electronic copies of the requests and responses are saved in the AskEMA tool and in DREAM in the folder corresponding to the year/month the enquiry was received (Cabinets/14. Working areas/14.06 S-Division/03. S-CO - Activities/4. S-CO-MHI activities/External queries/queries