EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Handling of information from external sources disclosing alleged improprieties concerning EMA activities on the authorisation, supervision and maintenance of medicinal products for human and veterinary use		
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1. Purpose

The purpose of this document is to establish a procedure providing for uniform, structured and confidential handling of information from external sources disclosing allegations of improprieties reported to the European Medicines Agency.

This procedure applies when an external source (as defined herein) provides or reports, irrespective of the mode of transmission, any "relevant information" (as defined hereafter) to the Agency or its staff.

2. Scope

This procedure addresses the **handling of information from external sources on alleged improprieties** in the area of the Agency's responsibilities and especially those that have an impact on the authorisation, supervision and maintenance of medicinal products for human and veterinary use. This procedure applies to all staff of the Agency, irrespective of their administrative position.

The following situations fall outside the scope of this SOP:

- the handling of allegations of internal or external misbehaviour covering in particular, but not only, any misbehaviour adversely affecting the financial interests of the EU. Please consult the EMA Anti-Fraud strategy (EMA/591051/2014).
- a staff member, acting in good faith, who reports facts discovered in the course of or in connection with his or her duties which point to the existence of serious irregularities. Please consult the EMA guidelines on whistle-blowing for its staff (EMA/182359/2014).

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- Private grievances, including complaints about individual employment matters and to complaints submitted under the EMA Code of conduct.
- This procedure does not replace normal reporting lines at the Agency.
- This procedure does not replace normal scientific and/or regulatory assessment procedures.

3. Responsibilities

The Head of the Committees and Inspections Department chairs the Infringement Action Group (IAG). It is the responsibility of the Head of the Legal Department and/or the Head of the Committees and Inspections Department to triage the incoming information from the external source and to decide whether this procedure or another Agency procedure should be followed.

A (Scientific) Administrator will be appointed for each case and will be responsible to coordinate the evaluation and processing of the information, the exchange with the external source and the conduct of the technical assessment. The (Scientific) Administrator must consult with the Head of the Legal Department and/or the Head of the Committees and Inspections Department. Additional staff members may be consulted according to the nature of the information to be assessed, on a need-to-know basis.

The External Information (EI) co-ordinator in the Committees and Inspections Department co-ordinates the handling of the cases, provides support to the Head of the Legal Department, the Head of the Committees and Inspections Department and the appointed (Scientific) Administrator and maintains the tracking table 'EI overview'.

The responsibility of each party to execute a particular part of this procedure is identified in the right-hand column of section 9, Procedure.

The information from an external source is to be kept confidential. All staff members who, on a needs basis, may receive such information shall not create a second copy, shall not further circulate the information, shall not further store it whether locally or on the Agency's server or shall not disclose personal data or the information from the external source to third parties, unless otherwise stated in this SOP.

It is the responsibility of each Head of Division to ensure that this procedure is adhered to within his/her own Division.

4. Changes since last revision

New SOP

5. Documents needed for this SOP

- Policy 0072 on EMA's handling of information from external sources disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products.
- Template for reporting an allegation concerning an impropriety in an area of EMA's responsibility (EMA/INS/GMP/201443/2016)
- Annex: Data Protection Notice (EMA/INS/GMP/190063/2016)
- Template 1: Acknowledgement of receipt to external source (EMA/200462/2015)
- Template 2: Communication to competent authority (EMA/200461/2015)

- Template 3: Communication to external source (EMA/200460/2016)
- Template 4: Closure communication to external source (EMA/625480/2016)

6. Related documents

- Regulation (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF
- Regulation (EC) No 45/2001, OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:008:0001:0022:en:PDF

7. Definitions

For the purpose of this procedure, the following definitions apply:

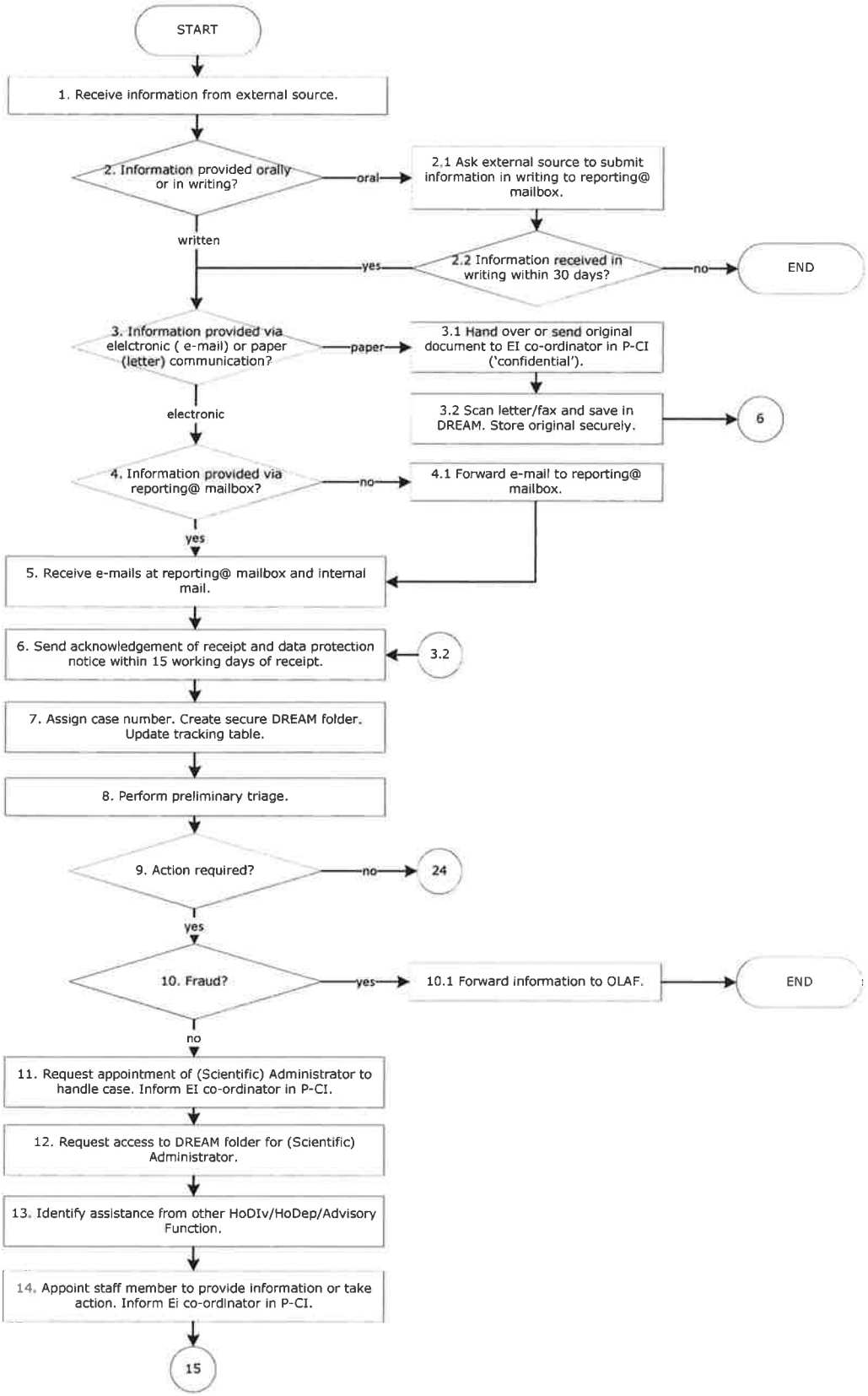
- "External source" is any external individual, i.e. other than an EMA staff member, who reports facts which point to the existence of improprieties.
- "External individual" shall mean any natural person who is not an EMA staff member.
- "Staff" and "Staff members" shall mean EMA temporary agents and contract agents.
- "Additional workers" shall mean national experts on secondment, interims and trainees working at the EMA.
- "Information from external source" shall mean any disclosure of relevant information to EMA by an external source as defined above.
- "Relevant information" shall mean information concerning any suspected, presumed or alleged impropriety concerning EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products.
- "Improprieties" shall mean irregularities concerning EMA activities on the authorisation, supervision and maintenance of human and veterinary medicinal products, i.e. any conduct or omission amounting to a violation of any legal provision governing the supervision, evaluation and maintenance of medicinal products for human and/or veterinary use.
- "Fraud" shall mean an intentional breach of any legal provision concerning the supervision, evaluation and maintenance of medicinal products for human and/or veterinary use with the aim of obtaining a gain. It may include misbehaviour that may not have a direct impact on the financial interests of the EU but only a reputational impact.
- "Personal data" are any information relating to an identified or identifiable person. An identifiable person is someone who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity (Article 2(a), Regulation No 45/2001).

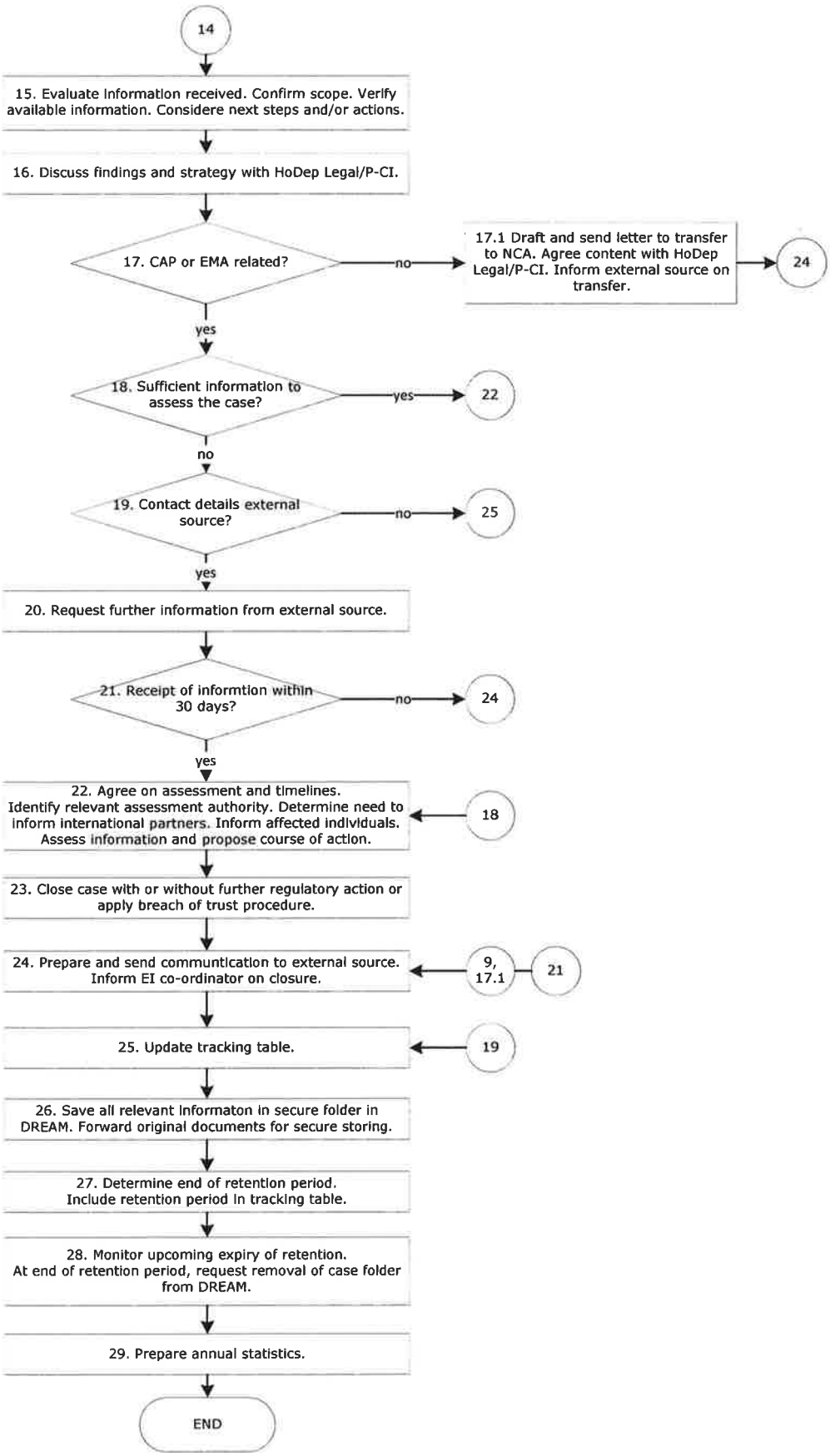
Abbreviations:

ACL:	Access Control List
AF-INT:	International Affairs Division

CAP:	Centrally authorised product
DED-MBN:	Management Board and HMA Office
DREAM:	Document Records Electronic Archive Management system
EI:	External source Information
EMA:	European Medicines Agency
EU:	European Union
HoDep:	Head of Department
HoDiv:	Head of Division
IAG:	Infringement Action Group
NCA:	National Competent Authority
OLAF:	European Anti-Fraud Office
P-CI:	Committees and Inspections Department
SOP:	Standard Operating Procedure

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

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15. Evaluate information received. Confirm scope. Verify available information. Considere next steps and/or actions.
16. Discuss findings and strategy with HoDep Legal/P-CI.
17. CAP or EMA related?
no
17.1 Draft and send letter to transfer to NCA. Agree content with HoDep Legal/P-CI. Inform external source on transfer.
24
yes
18. Sufficient information to assess the case?
yes
22
no
19. Contact details external source?
no
25
yes
20. Request further information from external source.
21. Receipt of informtion within 30 days?
no
24
yes
22. Agree on assessment and timelines. Identify relevant assessment authority. Determine need to inform international partners. Inform affected individuals. Assess information and propose course of action.
18
23. Close case with or without further regulatory action or apply breach of trust procedure.
24. Prepare and send communtication to external source. Inform EI co-ordinator on closure.
9, 17.1
21
25. Update tracking table.
19
26. Save all relevant informaton in secure folder in DREAM. Forward original documents for secure storing.
27. Determine end of retention period. Include retention period in tracking table.
28. Monitor upcoming expiry of retention. At end of retention period, request removal of case folder from DREAM.
29. Prepare annual statistics.
END

9. Procedure

Step	Action	Responsibility
	RECEIPT OF INFORMATION	
1.	Receive information from an external source.	EMA staff member
2.	If the external source provides information in written format via a paper (e.g. letter, fax) or electronic communication (e.g. e-mail), go to step 3. If allegations are made via an oral communication (e.g. telephone call, in a meeting), go to step 2.1.	EMA staff member
2.1	Inform the external source that the Agency has a process in place to assess information from external sources on alleged improprieties. Ask the external source to review the EMA webpage (link) and to report the matter in writing within 10 working days to the dedicated mailbox reporting@ema.europa.eu, preferably using the reporting template.	EMA staff member
2.2	If the matter is reported in writing (paper or electronic communication), continue with step 3. If no information is received in writing within 30 working days, no further action is taken. End of procedure.	EMA staff member
3.	If information from the external source is received via an electronic communication (e.g. e-mail), go to step 4. If information is received via a paper communication (e.g. letter, fax), go to step 3.1.	EMA staff member
3.1	Hand over in person the original paper document(s), including the envelope (in case of a letter), to the EI co-ordinator in P-CI or send it in a closed envelope marked "confidential" in order to be processed. **No additional electronic version or paper copy of the document(s) should be made or kept.**	EMA staff member
3.2	Using the "my confidential folder" function, scan the document, including the envelope (in case of a letter), and save it in the appropriate DREAM folder. Store the original document securely. Continue with step 6.	EI co-ordinator in P-CI
4	If information from the external source is received through the dedicated mailbox reporting@ema.europa.eu, go to step 5. If information is received via another electronic communication (e.g. another e-mail address), go to step 4.1.	EMA staff member
4.1	Forward the communication to the dedicated mailbox	EMA staff member

Step	Action	Responsibility
	reporting@ema.europa.eu. **No additional electronic or paper copy of the document(s) should be made or kept.** *Note: For information received via AskEMA, request the Documents Access and Publication Service to delete the request from AskEMA.*	
5.	Review daily the e-mails received in the dedicated reporting@ema.europa.eu mailbox and internal mail and inform the HoDep Legal and/or HoDep P-CI on any new information received for triage.	EI co-ordinator in P-CI
6.	If the contact details of the external source are known, send an acknowledgement of receipt (template 1) with, if the reporting template was not used by the external source, the data protection notice in annex within 15 working days after receipt of the information.	EI co-ordinator in P-CI
7.	Assign a sequential case reference number to each new case, EI <year>-<reference number>. The number assigned has always to be reported in internal documents, including e-mails, related to the case. Create for each case a folder in the secure, dedicated area in DREAM and save the information in the folder, protected by a restricted ACL. *Note: It is crucial that all the information received on alleged improprieties is recorded and retained.* Include the case in the tracking table 'EI Chrono'.	EI co-ordinator in P-CI
	TRIAGE BY HEAD OF DEPARTMENT LEGAL AND/OR P-CI	
8.	Perform a preliminary triage without delay after receiving the report. *General points for consideration at triage stage:* • *Do the allegations appear to be from an external source acting in good faith, in the public interest and/or on reasonable grounds or do the allegations appear to be unreasonable?* • *Do the allegations concern fraud?* • *Do the allegations relate to a medicinal product or an activity falling under the pharmaceutical legislation and/or fall under the EMA's remit?* • *Do the allegations relate to regulated activities falling under EMA competence? Might the allegations have an international dimension?* • *Do the allegations refer to the misconduct of a named individual?* *Note: Should (a) particular individual(s) be the subject of the allegations, the HoDep Legal should be consulted to discuss the*	HoDep Legal and/or HoDep P-CI

Step	Action	Responsibility
	appropriate action(s) to be taken, e.g. if and when the targeted individual(s) should be informed, whether this action should be taken by the EMA within its own assessment or when transferring the report to another competent authority. The HoDep Legal will give clear instructions to the (Scientific) Administrator who will deal with the case. *Note: Manifestly unfounded, improper and pointless reports and messages will not be handled.*	
9.	If no action is required, close the case and inform the external source. Go to step 24. If action is required, go to step 10.	HoDep Legal and/or HoDep P-CI
10.	If the allegations regard fraud, go to step 10.1 If the allegations do not regard fraud, go to step 11.	HoDep Legal and/or HoDep P-CI
10.1	Forward the information from the external source without delay to OLAF. End of procedure.	Anti-Fraud Office
11.	Request appointment of a (Scientific) Administrator from the relevant Head of Division/Department/Office/Service (depending on the nature of the information provided by the external source), to handle the case. Provide the name of the appointed (Scientific) Administrator to the EI co-ordinator in P-CI.	HoDep Legal and/or HoDep P-CI
12.	Request EMA Service Desk to provide the appointed (Scientific) Administrator access to the relevant DREAM folder by including him/her in the restricted ACL for that specific case. Provide support to the appointed (Scientific) Administrator, as appropriate.	EI co-ordinator in P-CI
13.	Identify, if applicable, other relevant internal functions to be involved and provide the respective Head of Division/Department/Advisory Function with the relevant information and request for assistance (on a need-to-know basis).	HoDep Legal and/or HoDep P-CI
14.	Nominate a manager and/or staff member in the Division/Department/Advisory Function who can provide information and/or take appropriate action in his/her field of responsibilities. Inform the HoDep Legal and/or HoDep P-CI and the EI co-ordinator in P-CI of the appointed person.	Respective Head
	INITIAL EVALUATION	
15.	Carry out an evaluation of the information received from the external source. Confirm the scope of the case and identify if the allegations are	Appointed (Scientific) Administrator

Step	Action	Responsibility
	related to a CAP or any other EMA activity. Verify information on the concerned product, company and/or topic available within the Agency, e.g. EudraGMDP, SIAMED, EudraCT. Consider, where applicable, whether further details should/could be requested from the external source and/or concerned competent authorities. Consider which next steps and/or actions should/could be taken for the evaluation or on the basis of the information.	
16.	Discuss findings and proposed strategy with the HoDep Legal and/or HoDep P-CI including the need to involve other internal staff members (always on a need-to-know basis).	Appointed (Scientific) Administrator and HoDep Legal/ HoDep P-CI
17.	If the preliminary evaluation concludes that the allegations concern a CAP or an EMA related activity falling within EMA's competences, go to step 18. If the preliminary evaluation concludes that the allegations are not within EMA's competences, but that a transfer to another competent authority is needed, go to step 17.1.	Appointed (Scientific) Administrator
17.1	Draft a letter to the concerned competent authority(ies) (using template 2) and agree the content of the letter with the HoDep Legal and/or HoDep P-CI in compliance with the principles of Policy 0072. Include the information received from the external source in its totality or only the relevant parts thereof. Consider the need to inform DED-MBN, AF-INT or other EMA Services/Offices on this case and/or the transfer. Send the letter to the authority(ies) via Eudralink. If the contact details of the external source are known, inform the external source within 15 working days of this transfer. *Note: If this notification to the external source could jeopardize enquires or investigations, it is deferred until it is no longer the case.* Close the case and go to step 24.	Appointed (Scientific) Administrator
18.	If the allegation concerns a CAP or EMA related activity and sufficient information is available to permit an assessment of the allegations, go to step 22. If more information is required from the external source before the assessment can start, go to step 19.	Appointed (Scientific) Administrator
19.	If the external source has provided contact details, go to step 20. If no contact details were provided, close the case and go to step 25.	Appointed (Scientific) Administrator

Step	Action	Responsibility
20.	Request further information from the external source to be provided within 10 working days (using template 3).	Appointed (Scientific) Administrator
21.	If further information is received from the external source, go to step 22. If no information is provided within 30 working days, close the case and inform the external source. Go to step 24.	Appointed (Scientific) Administrator
	ASSESSMENT OF THE ALLEGATIONS	
22.	Agree on the need and the strategy for an assessment and time lines with the HoDep Legal and/or HoDep P-CI. Forward the information from the external source in its totality or only the relevant parts thereof via Eudralink to the concerned EU national and/or third country competent authority for the purpose of their assessment and requesting that they provide the outcome of their assessment (using template 2). Include only personal data of the external source if authorisation for such disclosure has been requested and obtained from the external source or if requested by the competent EU authority as necessary for their assessment. In case of non-EU authority, personal data can only be transferred in accordance with Article 9 of Regulation (EC) 45/2001. Inform the external source of this transfer of information within 15 working days of the transfer. *Note: If this notification to the external source could jeopardize enquires or investigations, it is deferred until it is no longer the case.* If instructed by the HoDep Legal (see step 8), inform the affected individuals, i.e. persons against whom allegations are made, and/or request from them clarifications. Provide them, as appropriate, with the data protection notice. Determine the need to inform international partners on the case via the Head of International Affairs, in liaison with the HoDep Legal and/or HoDep P-CI. Assess all information received and gathered and propose an appropriate course of action.	Appointed (Scientific) Administrator
23.	The assessment may indicate that further regulatory action is necessary. The case may be closed with reference to the regulatory follow-up procedure necessary. The assessment may indicate that no further action is necessary. The case may be closed with a comment that no follow up regulatory procedure is needed. The assessment may indicate that a breach of trust procedure on conflicts of interests for scientific committees' members and experts may become applicable. In this instance, refer the case to Deputy	Appointed (Scientific) Administrator and HoDep Legal/HoDep P-CI

Step	Action	Responsibility
	Executive Director.	
	CLOSURE OF THE CASE AND INFORMING THE EXTERNAL SOURCE	
24.	If no contact details of the external source are known, continue with step 25. If the external source has provided contact details, prepare a communication to the external source (using template 4). Send the communication to the external source. *Note: The communication method with the external source mirrors the one by which the external source informed the EMA, e.g. if the external source informed the EMA by letter, the EMA replies by letter.* Inform the EI co-ordinator in P-CI on the closure of the case.	Appointed (Scientific) Administrator
	ARCHIVING	
25.	Update the tracking table 'EI Chrono' to record the closure of the external source case.	EI co-ordinator in P-CI
26.	When an action is required under this SOP, the staff member responsible for that action saves all the relevant information in the allocated, secure folder in DREAM and forwards any original paper document, if existing, to the EI co-ordinator for secure storing.	Appointed (Scientific) Administrator and EI co-ordinator in P-CI
27.	Determine the end of the retention period for the case based on the principles set out in section 10. Records, using the date of closure as the start of the retention period. Include the end of the retention period in the tracking table 'EI Chrono'.	EI co-ordinator in P-CI
28.	Monitor at regular intervals the tracking table 'EI Chrono' for upcoming expiry of the retention period of cases. At the end of the retention period of the case, obtain approval from the HoDep Legal and/or HoDep P-CI to instruct EMA Service desk to remove the case folder from DREAM and to destroy original documents of the case in a confidential manner.	EI co-ordinator in P-CI
	REPORTING	
29.	Prepare a statistical annual overview of all cases dealt with using this procedure.	EI co-ordinator in P-CI

10. Records

All documents on external source cases are saved in a restricted dedicated area in DREAM protected with a restricted ACL with the following retention period:

- 15 years: if the allegation falls within EMA's remit to examine the allegation and the outcome of the assessment includes a regulatory follow-up [in line with retention periods of OLAF]
- 8 years: if the allegation falls within EMA's remit to examine the allegations, but the outcome of the assessment does not include a regulatory follow-up [in line with retention periods of OLAF]
- 12 months: if the allegation does not fall within EMA's remit to examine the allegation, but the allegation is transferred to the concerned Member State or competent authority [to allow preparation of annual statistics, to ensure overview in case the same or similar report is made after closure of the case]
- 12 months: if the case was closed after triage with no initial evaluation or after initial evaluation with no assessment [to allow preparation of annual statistics]

Unfounded, improper and pointless reports and messages will be deleted immediately.

Original documents are stored securely in a locked cupboard or secure room.