EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Evaluation procedure for eligibility of patients', consumers' and healthcare professionals' organisations		
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1. Purpose

The purpose of this SOP is to ensure a consistent and efficient approach in the evaluation procedure for eligibility of patients', consumers' and healthcare professionals' organisations applying to be involved in the activities of the Agency.

2. Scope

This SOP applies to the Patients & Healthcare Professionals Department in the Stakeholders & Communication Division.

3. Responsibilities

It is the responsibility of each Head of Department to ensure that this procedure is adhered to within their own 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

Update of terminology following the new EMA organisational structure.

Step 11 deleted for simplification.

Minor editorial updates.

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5. Documents needed for this SOP

- Application/re-evaluation form for the involvement of patients, consumers and healthcare professionals in the activities of the European Medicines Agency (EMA/520442/2010) - available on the EMA external website: Partners & networks/Patients and consumers/Getting involved/How to apply.
- Excel spreadsheet: 'Overview of evaluation_re-evaluation of PCOs (EMA/217271/2006) which is available in DREAM under: Cabinets/09. Relationship management and communication/09.1 Stakeholder liaison/06 Joint interaction PCOs & HCPs/Tracking & monitoring/Tracking Tables.
- Excel spreadsheet: 'Overview of evaluation_re-evaluation of HCPOs (EMA/670841/2012) which is available in DREAM under: Cabinets/09. Relationship management and communication/09.1 Stakeholder liaison/06 Joint interaction PCOs & HCPs/Tracking & monitoring/Tracking Tables.

Templates:

- Acknowledgement of receipt of application email.
- Evaluation clarification letter.
- Letter advising removal from our webiste as documents not received – named 'Removal of organisation from website'.
- Evaluation(re-evaluation) sheet.
- Evaluation positive outcome letter.
- Evaluation negative outcome letter.
- Request email for documentation from new organisation.

(note: all the above-mentioned templates are kept on the X Drive under: X Drive/Templates/Others/ Committees and WPs/H/PCO-HCP templates/PCO-HCP evaluation and re-evaluation templates.

Please note the following:

- The DREAM folder of each PCO is located under Cabinets/09. Relationship management and communication/09.1 Stakeholder liaison/05 Interactions with PCOs/Patient-consumer organisations/Eligible organisations. The DREAM folder of each HCPO is located under: : Cabinets/09. Relationship management and communication/09.1 Stakeholder liaison/04 Interactions with HCPOs/HCP organisations/Eligible organisations. Paper copies with wet signature are filed in ring binders kept in the Department called 'Organisations' and are filed alphabetically by the name of the organisation.
- The EMA webpage listing the eligible PCO(s) is located here: Partners & networks/Patients and consumers/Organisations involved.
- The EMA webpage listing the eligible HCPO(s) is located here: Partners & networks/healthcare professionals/Organisations involved.

6. Related documents

- Criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency (EMA/24913/2005 rev 2) - available on the EMA external website: Partners & networks/Patients and consumers/Getting involved.

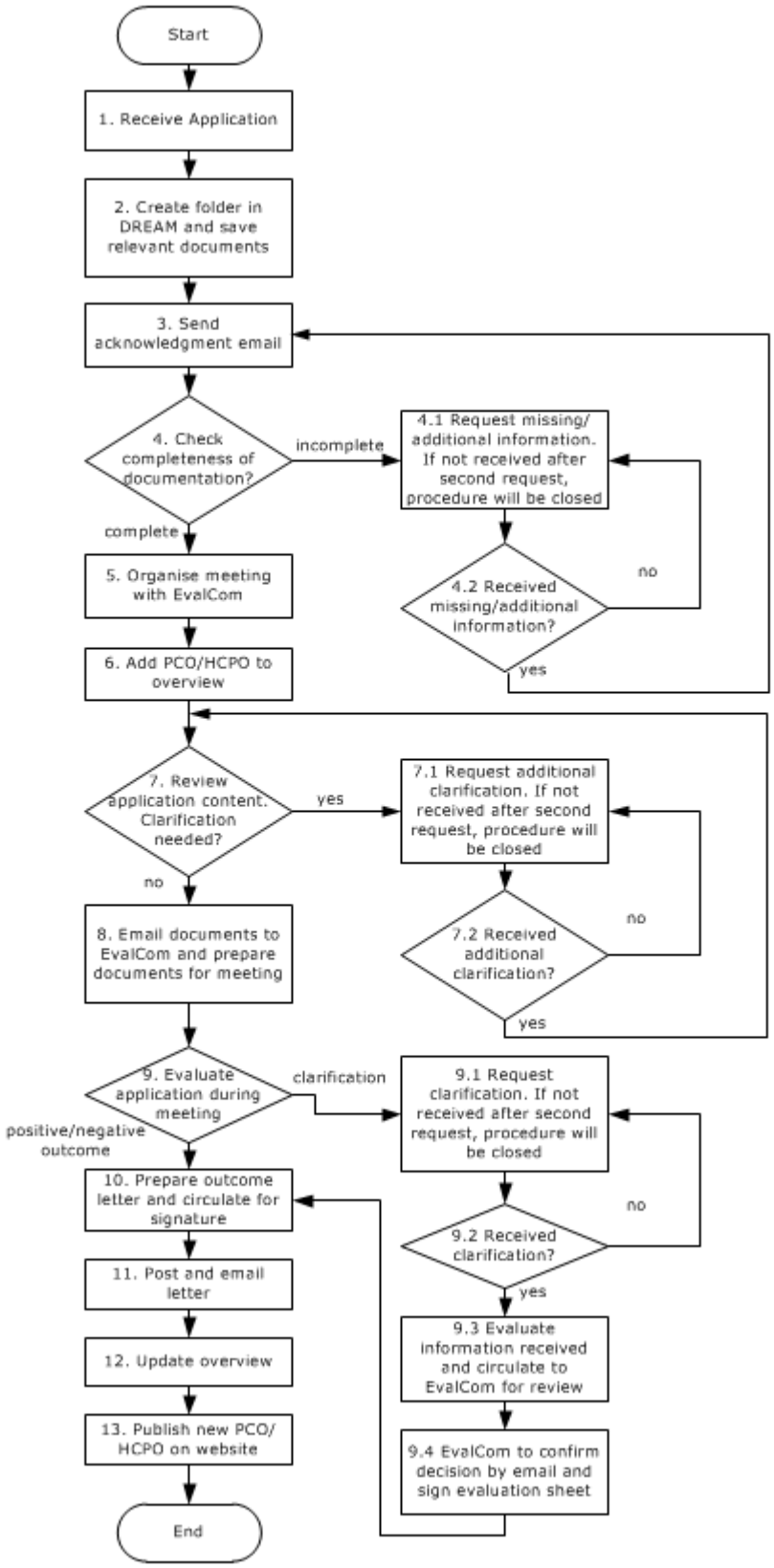
- Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency (EMA/161137/2011 rev 1) - available on the EMA external website: Partners & networks/ Healthcare Professionals/Getting involved.
- Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA 'eligibility' (EMA/566453/2012) - available on the EMA external website: Partners & networks/Patients and consumers/Key documents.
- DREAM user manual – available from IT service desk.

7. Definitions

In this procedure the following abbreviations are used:

AD	Administrator (in S-PH)
AST	Assistant (in S-PH)
AF-LD	Legal Department
DREAM	Document Records Electronic Archive Management
EvalCom	Evaluation committee (composed of AF-LD representative, AD, and Hdep)
EMA	European Medicines Agency
HCPO(s)	Healthcare professional organisation(s)
Hdep	Head of Department (of S-PH)
PCO(s)	Patient and consumer organisation(s)
S-PH	Patients & Healthcare Professionals Department

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



9. Procedure

Please note that active time excludes time taken by the organisation in responding to the EMA' requests (eg. for clarification/additional information).

Step	Action	Responsibility
	Initial evaluation of new application	
1	Day 0 Receive application submitted by email to the PCWPSecretariat@ema.europa.eu or HCPsecretariat@ema.europa.eu inboxes or by post to the European Medicines Agency's address.	AST
2	By day +5 Create a new folder in DREAM using the organisations' acronym and save all documents received in this folder (scan hard copies). Create evaluation sheet from template and enter organisation details.	AST
3	Send email acknowledging receipt to organisation's contact person and save electronic copy in relevant folder.	AST
4	Check application for completeness of documentation (i.e. that everything requested in the application form has been submitted). Confirm with AD. Is information missing/clarification needed? Yes: go to step 4.1 No: go to step 5.	AST/AD
4.1	Request missing/additional information from organisation to be provided within 1 month. Note: if this is the second request advise that if information/clarification is not received within a further month, the procedure will be closed.	AST
4.2	Reveived missing/additional information within 1 month? Yes: go to step 3. No: go to step 4.1	AST
5	By day +6 Send outlook meeting request to EvalCom, to take place within 21 days of receipt of complete application.	AST
6	Add the organisation's name on the excel spreadsheet 'Overview of evaluation_re-evaluation of PCOs/ HCPOs.	AST
7	By day +14 Review application content according to eligibility criteria and fill in evaluation sheet accordingly. Confirm with AD. Is clarification needed? Yes: go to step 7.1. No: go to step 8.	AST/AD
7.1	Request additional clarification from the organisation to be provided within 1 month. Note: if this is the second request advise that if clarification is not received within a further month, the procedure will be closed.	AST

Step	Action	Responsibility
7.2	Received additional clarification within 1 month? Confirm with AD. Yes: go to step 7. No: go to step 7.1.	AST/AD
8	By day +15 Email all documents to EvalCom ahead of the evaluation meeting and prepare hard copies for the meeting (include application form, evaluation sheet and all supporting documentation received).	AST
9	By day +21 Conduct meeting and evaluate application. EvalCom to sign evaluation sheet according to outcome: • Positive/negative outcome: go to step 10. • Pending clarification: go to step 9.1.	EvalCom
9.1	Request additional information/clarification to be sent within 1 month. Note: if this is the second request advise that if clarification is not received within a further month, the procedure will be closed.	AST
9.2	Received additional information/clarification within 1 month? Yes: go to step 9.3. No: go to step 9.1.	AST
9.3	Evaluate information received and circulate to EvalCom by email for review.	AD/AST
9.4	EvalCom to confirm positive/negative outcome by email and sign evaluation sheet accordingly. (A meeting may be requested to make final decision)	EvalCom
10	Prepare positive/negative outcome letter for signature by Hdep.	AST
11	By day +30 Post signed letter to organisation and inform them by email. Keep electronic copy in relevant folder.	AST
12	Update excel spreadsheet 'Overview of evaluation_re-evaluation of PCOs/HCPOs with the outcome and date of evaluation. End of procedure for negative outcome.	AST
13	Include the new organisation on the EMA webpage dedicated to the relevant eligible organisation. Send an email to the webteam with the following information: • name of organisation; • acronym of organisation (if applicable); • website address; • summary of the organisations's activities (to be obtained from "Mission/Objectives" on the application form.	AST

10. Records

When the process of evaluation is completed, the application form and supporting documentation; scanned copies of the signed letters sent to the organisation are kept in the appropriately labelled folder in DREAM and are identified as a record by the S-PH assistant (retention time 5 years).

Evaluation committee outcome evaluation sheet having wet signature should be kept in a ring binder folder in the Department.