

Standard operating procedure

Title: Re-evaluation and financial re-assessment procedures for eligible patients', consumers' and healthcare professionals' organisations		
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Lead author	Approver	Effective date: 13-MAR-15
Name: Nathalie Bere	Name: Isabelle Moulon	Review date: 13-MAR-18
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1. Purpose

The purpose of this SOP is to ensure a consistent and efficient approach in the re-evaluation procedure for eligibility of patients', consumers' and healthcare professionals' organisations 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.

Minor editorial updates.

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

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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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:

- Evaluation-re-evaluation sheet.
- Financial re-assessment request email.
- Full re-evaluation request email.
- Re-evaluation or annual financial re-assessment positive outcome.
- Re-evaluation or annual financial re-assessment negative outcome.
- Reminder email financial re-assessment or full re-evaluation.
- Removal of organisation from the website letter – named 'Removal of organisation from website'.

(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 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 PCOs is located here: Partners & networks/Patients and consumers/Organisations involved.
- The EMA webpage listing the eligible HCPOs 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.

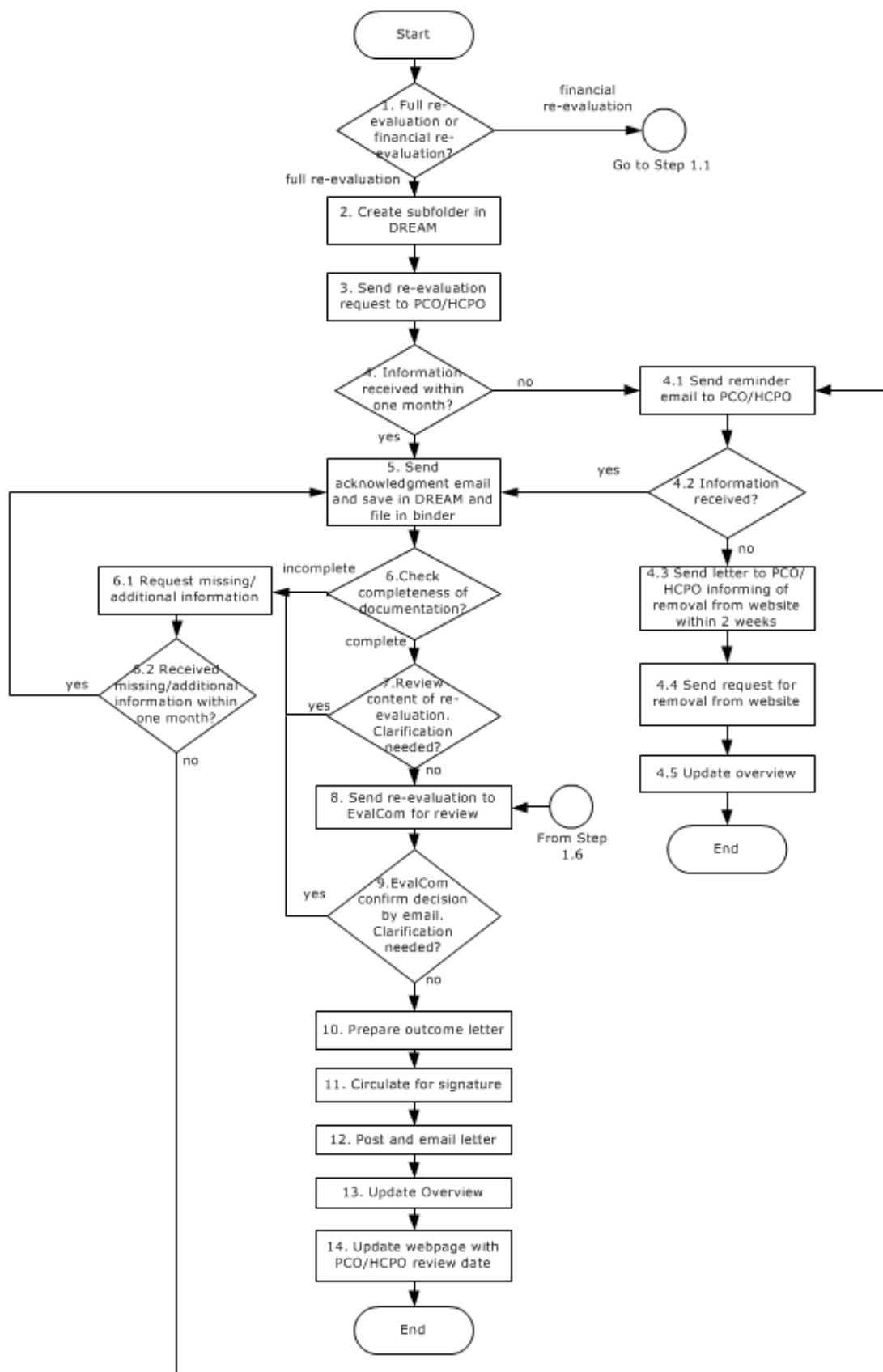
- Evaluation of financial information from patients', consumers' and healthcare professionals' organisations for assessment of EMA 'eligibility' (EMA/566453/2012) - available on the EMA external website: Partners & networks/Patients and consumers/Key documents.
- SOP/H/3390 Evaluation procedure for eligibility criteria of patients', consumers' and healthcare professionals' organisations.
- DREAM user manual – available from IT service desk.

7. Definitions

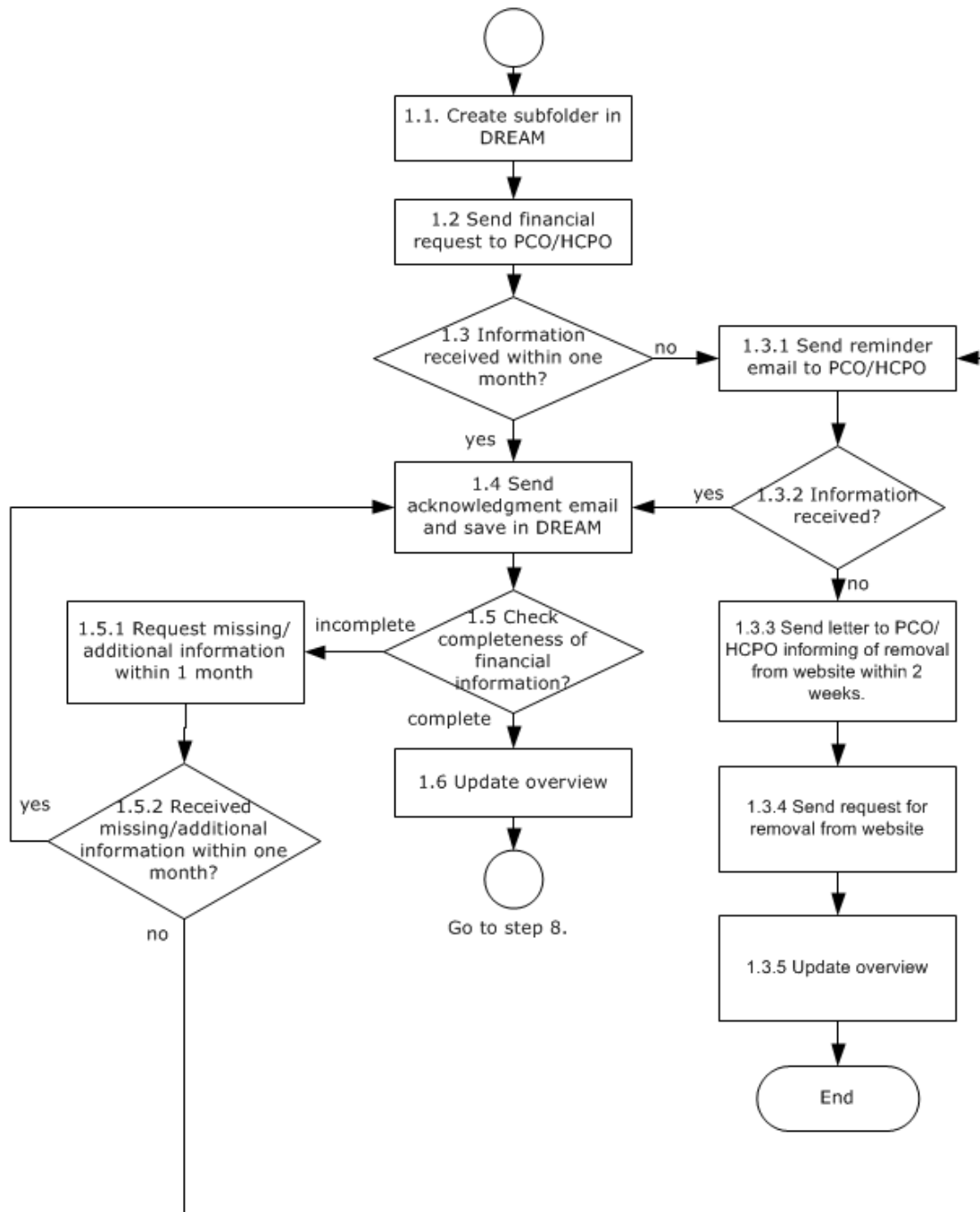
In this procedure the following abbreviations are used:

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)



Continued from Step 1 for financial re-evaluation



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
Re-evaluation		
1	Financial re-evaluation takes place every year and full re-evaluation only every second year. - For the 2-yearly full re-evaluation: go to step 2 - For the yearly financial re-evaluation only: go to step 1.1.	AST
Yearly financial re-assessment		
1.1	In the second quarter (ideally in May) of each year, create in DREAM a new subfolder under each organisation which is due for financial review only and name it "<year> financial evaluation".	AST
1.2	Day 0 Send template email to organisation's contact person requesting financial details for previous year to be sent within 1 month.	AST
1.3	Received information within 1 month? Yes: go to step 1.4. No: go to step 1.3.1.	AST
1.3.1	Day 31 Send email to contact person and inform if the organisation does not contact the EMA within 1 month, the organisation will be removed from the list of eligible organisations on EMA website.	AST
1.3.2	Received information? Yes: go to step 1.4. No: go to step 1.3.3.	AST
1.3.3	Day 62 Send letter to contact person, informing that the EMA will remove the organisation from the website within 2 weeks.	AST
1.3.4	Day 76 Send email to the webteam requesting the removal of the organisation from the website.	AST
1.3.5	Update the excel spreadsheet 'Overview of evaluation_re-evaluation of PCOs' with the outcome. End of procedure.	AST
1.4	Send acknowledgement email and save in DREAM.	AST
1.5	Check completeness of financial information. Confirm with AD. Is information missing/clarification needed? Yes: go to step 1.5.1. No: go to step 1.6.	AST/AD
1.5.1	Request missing/additional information to be provided within 1 month.	AST
1.5.2	Received information within 1 month? Yes: go to step 1.4. No: go to step 1.3.1.	AST
1.6	Go to step 8.	AST

Step	Action	Responsibility
2-yearly full re-evaluation		
2	In the second quarter (ideally in May) of each year create a new subfolder under the organisation which is due for full review in DREAM and name it "<year> re-evaluation".	AST
3	Day 0 Send template email to organisation's contact person requesting update of pre-filled re-evaluation application form within 1 month.	AST
4	Received information within 1 month? Yes: go to step 5. No: go to step 4.1.	AST
4.1	Day 31 Send reminder email to contact person and inform that if the organisation does not contact the EMA within 1 month, the organisation will be removed from the list of eligible organisations on the EMA website.	AST
4.2	Received information? Yes: go to step 5. No: go to step 4.3.	AST
4.3	Day 62 Send letter to contact person, informing that the EMA will remove the organisation from the website within 2 weeks.	AST
4.4	Day 76 Send email to the webteam requesting the removal of the organisation from the website.	AST
4.5	Update the excel spreadsheet 'Overview of evaluation_re-evaluation of PCOs' with the outcome. End of procedure.	AST
5	Send acknowledgement email to PCO/HCPO and save the information and supporting documentation in the DREAM folder.	AST
6	Check form for completeness of information. Confirm with AD. Is information missing/clarification needed? Yes: go to step 6.1. No: go to step 7.	AST/AD
6.1	Request additional information/clarification to be provided within 1 month.	AST
6.2	Received further information/clarification? Yes: go to step 5. No: go back to step 4.1.	AST
7	By day +14 Review re-evaluation content according to eligibility criteria and fill in evaluation sheet accordingly. Confirm with AD. Is clarification needed? Yes: go to step 6.1. No: go to step 8.	AST/AD
8	Circulate documents received to EvalCom by email requesting	AST/AD

Step	Action	Responsibility
	review.	
9	EvalCom to confirm positive/negative outcome by email and sign evaluation sheet accordingly. (A meeting may be requested to make final decision) • Positive/negative outcome: go to step 10. • Pending clarification: go to step 6.1.	EvalCom
10	Prepare positive/negative outcome letter.	AST
11	Circulate letter for signature by AD and Hdep.	AST
12	By day +30 Post signed letter to organisation and inform by email. Keep electronic copies in relevant folders including copy of outcome email from step 9.	AST
13	Update the excel spreadsheet 'Overview of evaluation_re-evaluation of PCOs/HCPOs with the outcome of re-evaluation. End of procedure for negative outcome. For positive outcome: go to step 14.	AST
14	Update the EMA webpage dedicated to the relevant organisation with last review date and any other updates as requested.	AST
	End of procedure.	

10. Records

When the process of re-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.