



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Streamlined procedure for evaluation of eligibility criteria of PCOs

EMA Patients' and Consumers' Working Party (PCWP)

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An agency of the European Union





- Eligibility criteria in place since 2005
- 33 organisations are eligible so far
- Evaluation procedure in place since criteria is in place



- Recent public attention to the way the EMA involves PCOs.
- Management Board discussion in 2010:
 - Revision of eligibility criteria
 - Strengthen evaluation procedure
 - Make it more transparent



Criteria

- Legitimacy
- Mission objectives
- Activities
- Representation
- Structure
- Accountability and consultation modalities
- Transparency



Standard operation procedure

Purpose:

- to ensure a consistent and efficient approach in the evaluation procedure for eligibility criteria of patients', consumers' (and healthcare professionals' organisations) applying to be involved in the activities of the Agency



Initial evaluation

- Application submitted ([website](#))
- EMA validation
- Evaluation Committee (including EMA Legal Sector)
 - Request for additional information
 - Final outcome



Negative outcome

- Communicated to PCO in writing
- Not made public
- PCOs may resubmit at any moment



Positive outcome

- Communicated to PCO in writing
- Made public:
 - Organisation published and acknowledged in EMA website ([website](#))
 - Link to organisation in EMA website



Re-evaluation

- Full eligibility evaluation – every 2 years
- Financial re-assessment – every year



Re-evaluation

- Updated application requested by EMA (using the basis of the previous application form)
- Evaluation committee



Re-evaluation - Outcome

- Communicated in writing to organisation
 - Positive
 - Update on website including date of last evaluation
 - Negative
 - Remove from EMA website



Re-evaluation – Outcome (2)

- Need for additional information/clarification/organisation non responding:
 - Reminder sent - *giving 1 month*
 - PCO is informed in writing on date of removal of organisation for EMA website
 - *Within 2 weeks*, organisation is removed from EMA website



Financial assessment

- Disclose source of funding (public & private)
- Names of individual providers
 - Indicate each individual contribution:
 - Absolute figures
 - percentage of overall budget
- Template to be used – to facilitate providing information
- EMA to request on December of each year - even if not yet finalised/confirmed



NAME OF ORGANISATION: _____

YEAR: _____

Industry related funding		
Name of company	Amount of funding	Percentage of overall budget
Subtotal:		

Non-industry related funding		
Source of funding *	Amount of funding	Percentage of overall budget
Subtotal:		
TOTAL:		

*e.g. membership fees,



Financial assessment

- EMA does not accept as eligible (i.e. cannot be involved in EMA activities) any organisation funded only by one single pharmaceutical company
- ***Is this enough?***
 - For eligible organisations:
 - When the organisation is involved in certain activities (e.g. product-related consultation) may require additional evaluation of any possible conflict of interest*
 - Specific threshold?
- Specific Ad-hoc group to be convened? (PCOs, EMA, legal Sector, etc)

* Related to the organisation and not to individuals, where the specific 'EMA policy of conflict of interest' applies



Open for discussion/comments