



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of new eligibility requirements

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Criteria to be fulfilled by patients, consumers and healthcare organisations for involvement in EMA activities

- The Agency has established 'eligibility criteria' in order to make sure that it only establishes dialogue with the most suitable organisations that act in the interests of European patients, consumers and healthcare professionals.
- Criteria revised in June 2014
- "Evaluation of financial information from patients, consumers and healthcare professionals organisations for assessment of EMA eligibility" adopted and published
- In order to allow current eligible organisations to adjust and implement any necessary changes, a transitional period of 18 months applies. All eligible organisations will be expected to **fully comply with the revised process by end of 2015.**

ATTENTION!



Criterion: Transparency

1. Organisation shall disclose to the EMA its sources of funding on a yearly basis
 - Completion of funding sources table with information on all sources of income; individualising each amount (both in absolute terms and in terms of overall percentage of the organisation's total income)
 - Disclosure of the official annual financial statement (approved by the organisation's governing bodies as per its status/bylaws) together with proof that the organisation's accounts are annually audited, if available



Completion of 'funding sources' table:

Industry related

This should include overall funding received from industry (used for overall internal operation of the organisation or any of its activities); e.g. fees for corporate memberships; sponsorship, donations and/or unrestricted grants for projects, conferences, training, etc.

Non-industry related

- This should include overall funding received from other sources (used for overall internal operation of the organisation or any of its activities); e.g. membership fees; sponsorship, donations and/or unrestricted grants from non-industry entities for projects, conferences, training, etc; royalties for publications; bank interests; sale of educational materials /guidelines; etc.

It is important that the 'funding sources' table reflects as much as possible the information included in the Organisation's official financial statement



Example

Industry related income		
Name of company/ funder	Amount of income	Percentage of overall budget
Company A	€1500	17.34%
Company B	€1000	11.56%
Company C	€700	8.10%
Subtotal:	€3200	37.00%
Non-industry related income		
Source of funding	Amount of income	Percentage of overall budget
Membership fees	€4000	46.24%
EU funded project XYZ	€1000	11.56%
Bank interests	€450	5.20%
Subtotal:	€5450	63.00%
TOTAL	€8650	100%



Evaluation of financial information

New: where industry-related funding exceeds 20% of the total income:

- this must be from at least 3 separate companies and
- the individual contribution from a single company should not reach the majority of the organisation's total income



Criterion: Transparency

- New: Organisation to publish on its website:
 - Registered statutes
 - Financial information including its source(s) of funding, both public and private
 - Information on the activities undertaken
- New: Organisation to follow a code of conduct/policy regulating conduct/policy regulating its relationship with and independence from the sponsors
 - Code of conduct/policy to be made available (web link if available)
- In case of umbrella organisations
 - List of member associations to be made available (web link if available)



Guidance

- [Guidance](#) has been prepared and published in May 2015:
 - more details on each criteria;
 - how it should be met;
 - how information is evaluated by EMA
- EMA staff always available to respond to questions, give guidance....
- Future streamlining: once new requirements have been fully implemented, experience gained will be assessed with the view to identify any possible simplification of the procedure