



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Handling conflicts of interest for patients' and consumers' organisations





- This document refers to conflicts of interest of **organisations, NOT individuals**
- For individuals, there is the '*EMA policy on conflict of interest*' in place



- Patients can participate in EMA activities as :
 - Individuals (experts, committee members)
 - EMA policy on COI applies
 - Representatives of their organisation (e.g workshops, product-related consultations)
 - Eligibility criteria applies (fit for purpose?)



Eligibility

- In order to work with the Agency, PCOs must comply with defined “eligibility criteria” – as adopted by EMA MB 2005, revised 2010.
- New organisations evaluated according to this criteria
- Eligibility is re-evaluated every 2 years
- Financial assessment is carried out every year
- 34 organisations are currently eligible



Financial assessment

- Organisations must disclose sources of funding (public & private)
- Names of individual providers with:
 - Absolute figures
 - percentage of overall budget
- Template used – to facilitate providing information
- EMA to request financial report each year



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,



- 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 does not currently include details on how financial information obtained from each organisations is used for assessment of eligibility



Purpose of this new document

- Explain how financial information is used to conclude whether that organisation is 'eligible' or not
- Identify and handle any potential conflict of interest that organisations may have when they are involved in a specific product-related evaluation or discussion



Assessment of eligibility

- As part of the information required for assessment of eligibility, it will be mandatory that each organisation provides:
 - Up-to-date information on funding sources (as per the table)
 - Copy of the latest financial report
- In addition, the Agency will ask for the following 'optional' information:
 - Proof that the organisation's accounts are annually audited
 - Any code of conduct/policy regulating the relations and financial independence of the organisation with the pharmaceutical industry
 - Information on the transparency of the organisation, in particular whether it makes public its funding information on its website



Assessment of eligibility 2

- The financial information received will be evaluated against the following set of parameters:
 1. Diversity of funding, where an organisation cannot be considered eligible if the majority of funding of such an organisation (>51%) is received from a single pharmaceutical
 2. Latest financial report made available to the Agency
 3. Annually audited accounts
 4. The existence of a code of conduct/policy
 5. Funding information is made public on website
- For eligibility:
 - the first two parameters must be met.
 - In addition, parameters 3 to 5 above, although not pre-requisites, will provide further evidence of the reliability of the organisation and will support its acceptability.



Conflict of interest when organisations are involved in product-related evaluation

- Organisation should provide 'standard' financial information or to update it (if already eligible)
- Information to be evaluated against parameters in view of the specific product under discussion
 - No involvement if organisation currently receives any funding from the marketing authorisation holder/applicant/sponsor of the medicinal product or competitor
 - Exceptions may apply in the case of rare diseases and where no other organisation in the field of interest may exist
 - Funding to be made transparent



Next steps

- PCWP to endorse proposal
- Further internal discussion with high management
- Present to Management Board