



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of new eligibility requirements and working party mandates for 2016-2019

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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 will apply. As such, all eligible **organisations will be expected to fully comply with the revised process by end of 2015.**

ATTENTION!



Guidance and improvements

- [Guidance](#) has been prepared and published in May 2015:
 - more details on each criteria;
 - how it should be met;
 - how information received is evaluated by EMA
- **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
- Transparency = simplicity
- EMA staff always available to respond to questions, give guidance....



PCWP and HCPWP mandates for 2016-2019

- Current mandate ends in June 2016
- New 3-year mandate for 2016-2019 to be established by end May 2016
- Election of co-chairs will take place at the PCWP/HCPWP June meetings 2016

The PCWP/HCPWP is composed of the following members:

- Organisations **which fulfil the eligibility criteria** approved by the EMA MB (up to 20);
- EMA Human Scientific Committees (CAT, CHMP, COMP, HMPC, PDCO and PRAC);
- EMA secretariat.

ATTENTION!