



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2011
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Revised criteria to be fulfilled by patients' and consumers' organisations involved in EMA activities

Management Board meeting 6 October 2011

Background note

The Management Board adopted on 29 September 2005 criteria to be fulfilled by patients' and consumers' organisations in order to be involved in EMA activities such as the COMP or the CHMP/EMA Working Group with patients' and consumers' organisations.

Since the adoption of this document interaction with patients' and consumers' organisations has been further strengthened, hence the need for a revision of the 2005 document.

Matters for consideration

The main changes in the attached document relate to:

- A broadening of the involvement to (1) the EMA scientific committees (was limited to the COMP in 2005), and (2) the periodic review of information submitted to the Agency.
- A clarification that the organisation should be established in a Member State of the EU or of the EEA.
- A reference to the fact that in case of a lack of European associations for a specific disease or treatment area, the involvement of national organisations may be considered. International organisations also may be considered for eligibility as long as they have a European focus and representation.
- A revision of the transparency criterion whereby an annual provision of information to the EMA of the funding sources should be provided. The EMA also encourages organisations to publish financial information on their websites in order to further increase transparency in this field.

The revised eligibility criteria were adopted by the patients' and consumers' working party at the 23 February 2011 meeting.

