



European Medicines Agency
Evaluation of Medicines for Human Use

London, 09 July 2008
Doc. Ref. EMEA/333929/2005

Questionnaire on criteria to be fulfilled by patients' and consumers' organisations prior to involvement in the emea activities

This questionnaire aims to collect all necessary information to allow the EMEA to evaluate whether a specific patients'/consumers' organisation fulfils the criteria as defined by the EMEA Management Board in its meeting on 28-29 September 2005, in order to be involved in EMEA activities.

NOTE: When filling in this questionnaire, you might feel it appropriate to provide the EMEA with relevant documents/specific sections of documents, to supplement and confirm the information provided in your statements and justifications. Please refer to the specific link of the website where each document is available. If a document is not published, justify the reason for it, and declare that it can be provided upon request by the EMEA.

1. Patients'/Consumers' Organisations contact details

Name of the organisation.....

Postal address.....

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E-mail address.....

Website.....

Organisation contact person.....

Public

2. Definition of Patients'/Consumers' Organisations

Patients' organisations are defined as not-for profit organisations which are patient focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies.

These could be:

- either general umbrella organisations (e.g. representing either European specific disease organisations and/or national umbrella organisations)
- or European disease specific organisations (i.e. representing national organisations or individual patients on acute and/or chronic diseases).

Consumers' Organisations are defined as not-for profit organisations which defend and promote the general interests of European consumers - citizens as purchasers or users of goods and services.

Justify and explain how your organisation complies with the given definition.

Document the "not-for profit status" of the organisation, and refer to the representation of its members in governing bodies.

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3. Criteria to be fulfilled

Legitimacy

Declare whether the statutes are registered in one of the Member States of the EU. If you are an international organisation not registered in the EU, please provide additional information demonstrating EU focus and activities.

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Mission/Objectives

Provide mission/objectives of the organisation.

Declare to be in agreement that these are published on the EMEA website.

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Activities

From your activities, please specify those with particular focus in medicinal products. Please document this information (e.g. through a report published on the organisation's website).

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Representativity

Provide explanation on how your organisation is representing patients or consumers throughout the EU. Please, specify if your organisation is already registered at Community level, e.g. in the EU Health Forum, the Council of Europe. ()*

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Structure

Explain the structure of your organisation, and explain how governing bodies are elected and who elects them.

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Accountability and Consultation Modalities

Explain which are the channels of communication within the organisation, (from and towards the members). Explain consultation procedures, and ways to consider all views and opinions from individual members.

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Transparency

Explain how the organisation ensures transparency with regard to funding and undertaken activities. Provide this information and also the location (e.g. organisation's website) where it can be found. Sources of funding (both public and private) must be made available by providing the name of the public and/or private bodies and their individual financial contribution in terms of percentage of the organisation budget. Any relationship with corporate sponsorship should be clear and transparent. Also declare any conflict of interest. In case of umbrella organisations the list of member associations should be publicly available (please provide link or location). The reference to private bodies does not include private individuals unless this presents a potential conflict of interest as referred to above.

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() In case of lack of European associations for a specific disease or treatment area, the involvement of national organisations may be considered even though preference will be given to European wide-associations. These associations will need to fulfil the same criteria apart from representativity, which will be at national level.*

4. Expected contribution to EMEA activities

Based on your activities and main areas of interest, please explain how you expect to contribute to EMEA activities (e.g. through a report published on the organisation's website)

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Date.....

Signature.....

Send this questionnaire together with relevant documents attached to:

European Medicines Agency (EMA)
Medical Information Sector
7 Westferry Circus, Canary Wharf
London E14 4HB
United Kingdom

Or via e-mail to: patients-consumers@emea.eu.int