



Criteria to be fulfilled by Patients' and Consumers' Organisations involved in EMEA Activities

I. Introduction

This paper has been developed to define the criteria patients' and/or consumers' organisations should fulfil in order to be involved in EMEA activities, such as the COMP or the CHMP/EMEA working group with patients and consumers' organisations.

These criteria do not apply to the procedure for external consultation on documents, since such external consultation is open to all external parties.

II. 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.

III. Criteria to be fulfilled

The organisations should be established at European Union (EU) level, and should fulfil the following criteria:

- **Legitimacy:** the organisation should have statutes registered in one of the Member States of the EU. If it is an international organisation not registered in a EU Member State, additional information needs to be provided demonstrating EU focus and activities.
- **Mission/Objectives:** the organisation should have its mission/objectives clearly defined and should agree to have it/them published on the EMEA website.
- **Activities:** the organisation should have, as part of its activities, a specific interest in medicinal products which should be documented (e.g. through a report published on the organisation website).

Public

- Representativity: the organisation should be representative of patients or consumers throughout the EU. Organisations already registered at Community level, e.g. in the EU Health Forum, the Council of Europe, are considered to adequately represent patients or consumers for involvement in EMEA activities.
- Structure: the organisation should have governing bodies which are elected by their members, who shall be patients, their carers, or their elected representatives.
- Accountability and Consultation Modalities: statements and opinions of the organisation should reflect the views and opinions of its members and adequate consultation procedures with those members should be in place. In particular, the organisation should ensure that the appropriate flow of information is in place to allow dialogue both ways: from and towards its members.
- Transparency: as a general rule, the organisation should be as transparent as possible, e.g. by regularly publishing, on its website, a report on the activities undertaken.
The organisation should also disclose its sources of funding both public and private 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. Any conflict of interest should be disclosed to the EMEA. In case of umbrella organisations the list of member associations should be publicly available.
The reference to private bodies does not include private individuals unless this presents a potential conflict of interest as referred to above.

In addition, Patients' and Consumers' Organisations shall be committed to take active part in the interaction with the EMEA. To facilitate communication, a contact person shall be identified.

In case of lack of European associations for a specific disease or treatment areas, 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.

In case of several associations existing in different Member States, a choice will be considered on a case-by case basis.

In order to further increase the transparency in this field, the EMEA will create a public registry of those patients' and/or consumers' organisations with whom it will interact, as a consequence of the fulfilment of the above criteria.