



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

## Criteria to be fulfilled by patients' and consumers' organisations involved in European Medicines Agency (EMA) activities

### 1. Introduction

This paper has been developed to define the criteria patients' and/or consumers' organisations should fulfil in order to be involved in EMA activities, such as those related to scientific committees, the EMA working party with patients' and consumers' organisations, and the review of EMA information. These criteria do not apply to the Agency procedure for external consultation on documents, since such consultation is open to all external parties.

### 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.



### 3. Criteria to be fulfilled

The organisations shall be established in a Member State of the European Union (EU) or of the European Economic Area (EEA), and shall fulfil the following criteria:

- **Legitimacy:** the organisation shall have statutes registered in one of the Member States of the EU/EEA. If it is an international organisation not registered in an EU/EEA Member State, additional information needs to be provided demonstrating EU focus and activities.
- **Mission/objectives:** the organisation shall have its mission/objectives clearly defined and should agree to have it/them published on the EMA website.
- **Activities:** the organisation shall 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).
- **Representation:** the organisation shall be representative of patients or consumers throughout the EU/EEA. 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 EMA activities.

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

If several similar associations exist in different Member States, a choice will be considered on a case-by case basis.

International organisations can also be considered for eligibility as long as they have a European focus and representation, including EU/EEA based office(s).

- **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:** the organisation shall disclose to the EMA its sources of funding both public and private by providing the name of the bodies and their individual financial contribution, both in absolute terms and in terms of overall percentage of the organisation budget. Any relationship with corporate sponsorship should be clear and transparent. This information shall be communicated to the Agency on an annual basis.

In the case of umbrella organisations the list of member associations should be made available to EMA.

The organisation shall publish on the organisation website the registered statutes, together with financial information including its source of funding both public and private, and information on their activities.

The organisation shall follow a code of conduct/policy regulating its relationship with and independence from the sponsors.

The EMA will evaluate the financial information according to the document “evaluation of financial information from patients’, consumers’ and healthcare professionals’ organisations” (EMA/566453/2012).

In addition, patients’ and consumers’ organisations shall be committed to take an active part in the interaction with the EMA.

To facilitate communication, a contact person shall be identified.

In order to ensure transparency in this field, the EMA will create a public registry of those patients’ and consumers’ organisations with whom it interacts, following fulfilment of the above criteria.