



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

Criteria to be fulfilled by patient, consumer and healthcare professional organisations involved in European Medicines Agency (EMA) activities

1. Introduction

This paper defines the criteria that patient, consumer and healthcare professional organisations should fulfil in order to be considered 'EMA eligible organisations'

Organisations meeting the criteria defined herein become part of the Agency's network of European organisations listed on its website, and are the first point of contact for involvement in EMA activities, as and when appropriate. The initial assessment performed to confirm compliance with these criteria, as well as subsequent annual reviews, follows the steps detailed in the document "Assessment of patient, consumer and healthcare professional organisations compliance with EMA eligibility criteria" (EMA/566453/2012 – rev. 1)".

2. Definition of patient/consumer and healthcare professional organisations

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

These could be:

- General umbrella organisations (e.g. representing either European 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).

- b) 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.



- c) Healthcare professionals' organisations are defined as not-for-profit organisations that have an interest in patient care, and where healthcare professionals represent a majority of members in governing bodies.

The given definition ranges from those organisations mainly centred on patient care to other associations such as learned and academic societies, focused on research activities, but which may have an interest in medicines and in the Agency's work and which ultimately aim at a benefit for patients.

Relevant organisations include:

- European organisations representing national organisations or individual healthcare professionals (e.g. generalists or specialists in a specific disease area);
- European organisations that exist to promote a scientific discipline/profession; and
- General umbrella organisations (e.g. representing either European specific disease organisations and/or national umbrella organisations).

3. Criteria to be fulfilled

The organisations shall fulfil the following criteria:

- **Legitimacy:** the organisation should, in principle, be formally established in one of the Member States of the EU/EEA. Organisations not formally established in an EU/EEA Member State may apply to become 'EMA eligible organisations' if they provide additional information that they have specific focus and carry out activities in the EU.
- **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 or healthcare professionals 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 or healthcare professionals 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.

Organisations can also be considered for eligibility as long as they have a European focus and representation, including EU/EEA based office(s) and/or membership covering at least 50% of all EU/EEA Member States.

- **Structure:** the organisation should have governing bodies which are elected by their members, who shall be patients, or consumers, or their elected representatives or healthcare professionals.

- **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.

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

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

The organisation shall publish on its website the registered statutes, sources of funding, and information on their activities.

In addition, patient, consumer and healthcare professional organisations shall commit to take an active part in the interactions with the EMA.

To facilitate communication, a contact person shall be identified for each organisation.