



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2011
EMA/161137/2011
Patient Health Protection

Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency (EMA) activities

1. Introduction

This paper has been developed to define the criteria healthcare professionals' organisations should fulfil in order to be involved in EMA activities, such as those related to scientific committees, the EMA working party with healthcare professionals' 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 Healthcare Professionals' Organisations

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 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 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 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.

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 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.

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

EMA encourages organisations to be as transparent as possible, e.g. by publishing on the organisation website the registered statutes, together with financial information as specified above and information on the activities undertaken.

In addition, healthcare professionals' 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 healthcare professionals' organisations with whom it interacts, following fulfilment of the above criteria.