EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

Assessment of patient, consumer and healthcare professional organisations' compliance with EMA eligibility criteria

1. Introduction and purpose

As defined within the frameworks for interaction, the Agency endeavours to establish and maintain a network of European patient, consumer and healthcare professional organisations to foster consistent and targeted interactions with a broad range of organisations across Europe with diverse expertise and interests.

'Eligibility criteria' for selection of organisations (*link to be added*) have been established to ensure that the Agency works with the most appropriate organisations.

Organisations may submit an application for eligibility at any time and, provided the criteria defined herein are met, they become part of the Agency's network of European organisations listed on the Agency website, and are the first point of contact for involvement in EMA activities, as and when appropriate.

The purpose of this document is to explain how information obtained from each organisation during the Agency's assessment of 'eligibility', is assessed to conclude whether that organisation is eligible.

2. Scope

This policy applies to patient, consumer and healthcare professional organisations. It does not apply to individual patients, consumers and healthcare professionals when they act as experts or committee members. Participation as experts and committee members is ruled by the EMA policy on conflict of interests (link).

3. Assessment of criteria for new applications

3.1. Pre-assessment

When a new organisation applies for eligibility, a pre-assessment is undertaken to confirm that the organisation has a not-for-profit status and fits within the definitions set out for patient, consumer or healthcare professional organisations:

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- *Patient organisations* are defined as not-for profit organisations which are patient focused, and in which patients or carers (the latter when patients are unable to represent themselves) represent a majority of members in their governing bodies.
- *Consumer 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.
- *Healthcare professional 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 their governing bodies.

Definition	Requirement	Mandatory website information	How information is evaluated by EMA
• Not-for-profit status • Focus of the organisation • Governing bodies	• Completed application form • Registered status/ bylaws/ constitution/ terms of reference, etc.	• A clear reference to the non-profit status • Registered status/ bylaws/ constitution/ terms of reference, etc.	Official document(s) and available information on the organisation's website are assessed to confirm that: • non-profit status is justified, and • focus of the organisation and representation in governing bodies comply with the definition

If these conditions are met a full assessment is carried out as highlighted below.

3.2. Fulfilment of criteria

The following table outlines how each criterion is assessed for compliance:

Criterion	Requirement	Mandatory website information	How information is evaluated by EMA
Legitimacy	• Statutes registered in a Member State of the EU/EEA OR • If statutes registered outside EU/EEA, – there is a branch or office operating within EU/EEA	• Registered status/ bylaws/ constitution/ terms of reference, etc.	Official document(s) and information on the organisation website are assessed to confirm that: • The organisation has registered status within EU/EEA and/or

Criterion	Requirement	Mandatory website information	How information is evaluated by EMA
	– and/or membership covers at least 50% of all EU/EEA Member States		• Has a branch or office operating within EU/EEA and/or • Has membership covering at least 50% of all EU/EEA Member States
Mission / objectives	• Mission and objectives are clearly stated in official documents/ website and are linked to patient care and/or medicines • Summary text for publication on EMA website is provided as part of application	• Mission and objectives	Official document(s) and information on the organisation website are assessed to confirm its mission and objectives include: • Patient care and interests • Activities with an interest in medicines and the Agency's work
Activities	• Specific interests in medicines documented as part of organisation activities • Annual activity reports and/or other forms of reporting /documenting specific interests in medicines included on organisation website • Activities have EU focus and outreach	• Annual activity reports and/or other forms of reporting/ documenting specific interests in medicines	Information on the organisation website is assessed in terms of: • How the scope of activities relates to its mission/objectives • Whether specific interests in medicines are documented as part of the organisation activities • EU focus and outreach • In the case of re-evaluation: – References to work with the Agency

Criterion	Requirement	Mandatory website information	How information is evaluated by EMA
Representation[1]	• Member associations are listed on the organisation's website • Information provided to EMA should include the geographic distribution (country coverage) of individual members, if applicable	• List of member associations ***Strongly recommended:*** • Geographical distribution of individual members, if applicable	Information on organisation website is assessed in terms of: • Organisation is representative of patients, consumers or healthcare professionals throughout EU/EEA • Organisations already registered at Union level, e.g. in EU Health Forum or Council of Europe, are considered to be representative
Structure	• Governing bodies are elected by their members, who shall be patients, or consumers, or their elected representatives or healthcare professionals • Governance structure clearly described in publically available information, including all categories of membership • Voting members of governing bodies or in executive functions are not employed by an individual company or association representing commercial manufacturers of medicines, healthcare products, medical	• Clear description of the Governance structure (e.g. via publication of status/bylaws) • List of corporate members, if applicable	Official document(s) and available information on the organisation website are assessed to confirm that: • A procedure is in place for electing members of governing bodies • Elected members of governing bodies are overall representative of the organisation • Corporate members, if part of governing bodies, do not have voting rights

[1] Applications from national organisations may be considered exceptionally in case of lack of European associations for a specific disease or treatment area; if similar associations exist in different MS, a choice will be considered on a case-by-case basis; Applications from international organisations can be considered as long as membership is representative of EU/EEA countries.

Criterion	Requirement	Mandatory website information	How information is evaluated by EMA
	devices; or distributors and wholesalers; or consultants providing services to a company or industry association		
Accountability and consultation modalities	• Statements and opinions of the organisations reflect the views and opinions of its members • Adequate consultation procedures are in place • Appropriate flow of information is in place to allow dialogue from and towards its members (e.g. announcements on the website; interactive on-line members' area; through email and meetings, etc.)	• Description of policy and decision-making procedures	Official document(s) and/or available information on the organisation's website are assessed to confirm that: • Procedures are in place for consultation and communication with all members of the organisation
Transparency	• Completion of EMA funding sources table with detailed information on all sources of income (both in absolute terms and in terms of overall percentage of the organisation's income). See 3.3 for full details of requirements • Disclosure of the latest official annual financial statement (approved by the organisation's governing bodies as per its status/bylaws) • Proof that the organisation's accounts are annually audited, if available • Full transparency is encouraged (and	The information below should be published following approval of annual accounts : • List of all funding sources (industry and non-industry) • Overall proportion of industry and non-industry funding • Percentage of the highest contribution from a single company (in terms of the overall income) ***Strongly recommended*:** • Latest official annual financial	Official document(s) and information on the organisation's website are assessed to confirm that: • The 'EMA funding sources' table reflects as much as possible the information included in the organisation's official financial statement • Organisation accounts are annually audited, if available • Financial information including source(s) of funding, both public and private is published in the organisation's

Criterion	Requirement	Mandatory website information	How information is evaluated by EMA
	minimum all the aforementioned publishing requirements must be met) • Code of conduct/policy[2] regulating its relationship with and independence from the sponsors is disclosed to the EMA or is made publically available	statement • Code of conduct/policy regulating its relationship with and independence from the sponsors	website • Where industry-related funding exceeds 20% of the total income: • This must be from at least 3 separate companies, and • The contribution from a single company should not reach the majority of the organisation's total income See 3.3 for full details of financial requirements The organisation should meet overall transparency requirements by ensuring that all information subject to publication is available on their website

3.3. Financial statements and completion of the 'funding sources' table

For the evaluation of financial information, organisations are asked to complete an EMA *template* table of funding sources (see completed example below) and also provide their official financial statement (and auditors' report if available) for the year covered by the assessment.

As part of the evaluation for eligibility, the Agency will assess the financial information received against the following set of parameters:

1. Diversity of funding; if funding received from pharmaceutical companies exceeds 20% of the organisation's total funding, this must be from at least 3 separate companies and the individual contribution from a single company should not reach the majority of the organisation's total funding (including non-pharmaceutical industry funding).
2. Latest official financial accounts/report made available to the Agency.

[2] Such document should outline the basic principles governing relations between the organisation and industry (regardless of receipt of funds) when engaging in a dialogue, working partnership, joint initiative and/or sponsorship.

3. The organisation's funding sources are made public on its website.
4. The existence of a code of conduct/policy regulating the organisation relations with and independence from the pharmaceutical industry.

In order for an organisation to be considered eligible, all four parameters must be met.

Depending on the organisation's approval schedule, a final financial statement may not be available at the time of submitting the evaluation form. In this case, they should provide a draft financial statement, advising when the final official statement is expected to be approved and as soon as the final document is available forward it to the Agency which will then finalise the evaluation.

The table of funding sources is expected to reflect as much as possible the information contained in the official financial statement, as these documents are reviewed in conjunction.

This information, once assessed against the set of parameters identified above will remain valid throughout the year regarding participation in activities which do not involve specific product-related evaluation or discussion. Organisations must inform the Agency of any change at any time that could affect their eligibility.

Below is a description of what is expected to be included under the industry related and non-industry related sections of the table of funding sources:

Industry related income

- Income originating from:
  - Any individual company or association representing commercial manufacturers of medicines as well as healthcare products, medical devices and services;
  - Distributors and wholesalers;
  - Consultants providing services to a company or industry association, including PR firms.
- Should reflect the overall funding received from industry (used for overall internal operation of the organisation or any of its activities):
  - Fees for corporate memberships;
  - Sponsorship, donations and/or unrestricted grants for projects, conferences, or training; etc.

For organisations with an extensive amount of sponsors (e.g. > 50), the Agency may be prepared to discuss alternative methods of confirming the data.

Non-industry related income

- Income originating from:
  - All other sources not falling within the definition of industry-related income (e.g. public or private institutes/ bodies; banks).
- Should reflect the overall funding received from any other sources (used for overall internal operation of the organisation or any of its activities):
  - Membership fees;
  - Sponsorship, donations and/or unrestricted grants from non-industry entities for projects, conferences, training, etc.;

- Royalties for publications;
- Sale of educational materials/guidelines;
- Bank interests;
- Investment income (if managed by a third party, this should be stated and no further information is required; otherwise, the organisation will have to confirm in writing that the investment portfolio excludes pharmaceutical companies or include it under industry-related income);
- Income from congresses and other meetings (if managed via a professional congress organiser (PCO) and whereby the organisation receives a percentage of the net income), etc.

Example of a completed funding sources table:

Industry related income		
Name of company/funder	**Amount of income**	**Percentage of overall income**
Company A	€1500	17.34%
Company B	€1000	11.56%
Company C	€700	8.10%
Subtotal:	**€3200**	**37.00%**
Non-Industry related income		
Source of funding	**Amount of income**	**Percentage of overall income**
Membership fees	€4000	46.24%
EU funded project XYZ	€1000	11.56%
Bank interests	€450	5.20%
Subtotal:	**€5450**	**63.00%**

4. Annual re-assessment of eligibility

Annually each eligible organisation is required to perform a 'self-declaration of eligibility' to confirm that they remain compliant with the criteria.

The organisations complete and submit an electronic form (automatically sent to them via the stakeholder database) whereby they confirm compliance with each of the 7 eligibility criteria (series of tick boxes) as well as funding aspects.

Once submitted there will be a validation phase by EMA and if the organisation continues to comply with all criteria (as confirmed within the form) they will receive a confirmation of compliance and the organisation will continue to be part of the group of EMA eligible organisations as listed on the EMA website.

Each year a random selection of up to 20% of patient/consumer and healthcare professional organisations (up to 20% each category) will be performed using excel formula and the selected organisations will be subject to a full evaluation of compliance with the eligibility criteria.

Assessed organisations will be removed from the organisation assessment list during the following year

5. Related documents

“Criteria to be fulfilled by patient, consumer and healthcare professional organisations involved in European Medicines Agency (EMA) activities” (EMA/MB/24913/2005, Rev 3).