



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 July 2018

Stakeholders and Communication Division

Annual self-declaration form for eligibility

This form is a 'self-declaration' of compliance with EMA eligibility criteria, as defined by the Agency Management Board. Organisations are responsible for the information provided herein. If you require any clarification please email StakeholdersDB@ema.europa.eu

Organisation

Please note that this information will be published on the EMA website

Name:

Acronym:

Website:

Contact details of organisation's head office

Postal address:

Country:

Telephone number:

E-mail address:

Person with legal responsibility

Title:

First Name:

Last Name:

Position:

Address:



City:

Post code:

Country:

Telephone number:

E-mail address:

Contact person for EMA related activities.

Name:

Position:

Professional address:

Telephone number:

E-mail address:

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SAMPLE FORUM

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Definition

Patient organisation: the organisation is a non-profit, patient focused organisation

Consumer organisation: the organisation is a non-profit organisation which defends and promotes the general interests of European consumers as purchasers and users of goods and services

Healthcare professionals' organisation: the organisation is a non-profit organisation representing healthcare professionals and with an interest in patient care

Industry stakeholder organisations representing, operating in, or supporting the pharmaceutical industry are included, such as:

- Industry trade associations representing pharmaceutical companies;
- Associations of professionals or service providers operating in or supporting the general interests of industry, i.e. not including those representing the interests of a particular company based on a fiduciary mandate;
- Organisations engaged early on in the innovation life-cycle from development;
- Associations with multiple stakeholders including industry members;
- Stakeholders operating in domains related to pharmaceuticals such as medical devices or

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Definition (continued)

The organisation's registered statutes/bylaws/constitution/terms of reference is published on the organisation's website (include link below)

The organisation's non-profit status is clearly mentioned on the organisation's website (include link below)

Patients and/or carers represent the majority of members in governing bodies Yes No

1. Legitimacy

For organisations registered within the EU/EEA

The organisation is registered within the EU/EEA
The organisation has an EU wide representation and is registered as a European umbrella organisation within the EU/EEA (or incorporated into a legal entity registered as a European umbrella organisation within the EU/EEA) Yes No

For organisations not registered within the EU/EEA

The organisation has a branch or office operating within the EU/EEA Yes No

Information demonstrating the EU focus of activities and EU/EEA based operating branch/office or representation is available on the organisation's website Yes No

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2. Mission/objectives

The organisation's mission and objectives information (published on the EMA website under eligible organisations) is up-to-date
(Any updated information will be added where appropriate)

Yes No

3. Activities

The organisation's activities are linked to Medicines

Yes No

The organisation has an active interest in the work of EMA

Yes No

The organisation objectives and mission have an EU focus and outreach

Yes No

The annual activity report/or other form of reporting is published on the organisation website (include link below)

4. Representation

The organisation represents patients/consumers/ or healthcare professionals throughout the EU/EEA

Yes No

The list of member associations is available on the organisation's website (include link below)

The geographical distribution of individual members if any, is available on the organisation's website (include link below)

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5. Structure

Governing bodies are elected by their members
(members shall be patients, carers, or elected representatives in the case of patient/consumer organisations; or healthcare professionals, for healthcare professional organisations)

Yes No

A procedure is in place for electing members of governing bodies as representatives of the organisation

Yes No

Voting members are not employed by an individual company or association representing commercial manufacturers of medicines, healthcare products, medical devices; or distributors and wholesalers; or consultants providing services to a company or industry association

Yes No

6. Accountability and consultation method

The organisation statements and opinions reflect the views and opinions of its members

Yes No

An appropriate flow of information is in place to allow dialogue both ways: from and towards its members

Yes No

The policy and the decision-making procedures of the organisation are described on the organisation's website (include link below)

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7. Transparency

| | |
|--|--|
| The latest annual financial statement is available on the organisation's website (include link below) | <input type="checkbox"/> |
| <input type="text"/> | |
| The online list of all funding sources is up-to-date (include link below) | <input type="checkbox"/> |
| <input type="text"/> | |
| The overall proportion of industry and non-industry income is clearly mentioned on the organisation's website (include link below) | <input type="checkbox"/> |
| <input type="text"/> | |
| The percentage of the highest contribution from a single company is clearly mentioned on the organisation's website (include link below) | <input type="checkbox"/> |
| <input type="text"/> | |
| Funding received from pharmaceutical companies does not exceed 20% of the organisation's total funding | <input type="radio"/> Yes <input type="radio"/> No |
| Funding received from pharmaceutical companies exceeds 20% of the organisations total funding and is received from at least 3 separate companies | <input type="radio"/> Yes <input type="radio"/> No |
| The percentage of the highest contribution of a single company does not exceed 50% of the organisation's total income | <input type="radio"/> Yes <input type="radio"/> No |
| The organisation's accounts are annually audited | <input type="radio"/> Yes <input type="radio"/> No |
| The organisation has a code of conduct/policy regulating the organisation's relationship showing the independence from sponsors | <input type="radio"/> Yes <input type="radio"/> No |

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Undertaking

| | |
|---|--------------------------|
| We commit to take an active part in the interaction with the EMA and its activities | <input type="checkbox"/> |
| By completing this form the organisation confirms that all information provided herein is accurate and undertakes to advise the EMA immediately of any change | <input type="checkbox"/> |
| Full Name: | <input type="text"/> |
| Position: | <input type="text"/> |

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