16 June 2016
EMA/323235/2016
Corporate Stakeholders Department
Stakeholders and Communication Division

Criteria to be fulfilled by industry stakeholder organisations involved in European Medicines Agency (EMA) activities

1. Introduction

A 'Framework for interaction between the European Medicines Agency and industry stakeholders' was adopted by the EMA Management Board in October 2015, to formalise and structure interactions with this stakeholder group in line with principles of accountability, transparency and broad representation. As part of the Framework, the Agency was actioned to develop and publish the **criteria** to be fulfilled by industry associations **to be eligible for involvement in the Agency's activities**. This is in line with the approach taken for other EMA stakeholders, namely health care professionals' organisations and patients' and consumers' organisations.

For industry stakeholders, four levels of involvement in EMA activities have been identified, as follows:

1. Inform (to enable feedback e.g. news items, Q&As, information Day);
2. Consult (via written consultation e.g. guidelines development, public consultations on deliverables);
3. Consult & Involve (based on direct interactions e.g. focus groups) and,
4. Co-operate (jointly engaging towards a common technical goal e.g. technical expert groups).

The first 2 levels of stakeholder involvement referred to above are open to all external parties/stakeholders and do not require specific eligibility criteria to be applied. Any organisation can register with the EMA as an interested party to receive information and notice of written consultations in selective areas of interest (via StakeholdersDB@ema.europa.eu).

The eligibility criteria defined here will only apply where an organisation seeks **direct involvement** in EMA activities (at the latter 2 levels), i.e. where the industry stakeholder will be consulted and involved directly or co-operating with the Agency in specific areas. Industry stakeholder organisations will need to submit written declaration/confirmation that the eligibility criteria defined in this document are fulfilled (see further details on EMA website).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

These eligibility criteria are drawn up to ensure participating associations represent the broadest array of relevant pharmaceutical industry stakeholders. In accordance with the topics and type of interaction foreseen by the Agency, multi-stakeholder dialogue with all eligible organisations meeting criteria for participation will be encouraged to ensure representation of different views where they exist.

The criteria have been designed taking into account the general principles for stakeholder consultation outlined in the European Commission's Better Regulation package, the requirements pertaining to the European Commission's EU Transparency registry, as well as criteria defined by other EU Institutions, where relevant.

2. Definition of Industry stakeholder organisations

The Industry stakeholder framework defines **industry stakeholders** as organisations, associations or parties representing the pharmaceutical industry, which are affected or impacted by or have an interest in the actions and aims of the Agency and its partners, its projects or policies. This includes European umbrella organisations where they exist. In their absence, national or regional associations, and exceptionally individual entities (e.g. non-profit entities representing multiple stakeholders), may also be considered. It should also be acknowledged that the environment for pharmaceuticals along the life cycle from development to market access is nowadays global and operating at multiple levels. Therefore, extending the interaction beyond EU Industry Organisations to international industry organisations may occur if and when applicable.

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 HTA.

3. Criteria to be fulfilled

The organisation/association/party should fulfil the following criteria:

- **Legitimacy**: the industry stakeholder organisation should have an EU wide representation with interests of a specific constituency and be incorporated into a legal entity registered as a European umbrella organisation in one of the Member States of the EU/EEA. It should also be non-for-profit and have all of the above documented.

  If it is an international organisation not registered in an EU/EEA Member State, additional information needs to be provided demonstrating the EU focus of activities and EU/EEA based operating branch/office or representation.

- **Activities**: the industry stakeholder organisation should have its mission/objectives clearly defined and a legitimate interest in the areas of work of the EMA, stated when registering. As part of its activities, a specific interest in medicinal products for human or veterinary use should be documented (e.g. through a report or position papers in the area of medicinal products published on the organisation's website).

- **Entry in EU Transparency Register**: the industry stakeholder organisation should be registered in the European Commission EU Transparency registry.
- **Representation**: the industry stakeholder organisation should be representative of all its members/affiliations throughout the EU/EEA. It should not exclusively represent individual companies. Statements and opinions of the industry stakeholder organisation should reflect the views and opinions of all its members and adequate consultation procedures should be in place. In particular, the organisation should ensure that processes supporting information flow are in place, ensuring an effective two-way dialogue: from and towards its members.
- **Structure**: the industry stakeholder organisation should have governing bodies, which are elected by their members, where applicable.

In the spirit of increased transparency, the names of the industry stakeholder organisations deemed eligible to participate in EMA activities according to these criteria will be published on the EMA website.

The implementation of these eligibility criteria will be monitored and may be subject to review as experience is gained.

Finally, it should be noted that compliance with the Agency's conflicts of interest policy will continue to be pivotal to the Agency's accountability and governance for engagement with all of its stakeholders.