EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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# Mandate, objectives and composition of Industry Standing Group (ISG)

## 1. General considerations

The Regulation (EC) No. 726/2004 of the European Parliament and of the Council, in particular Article 78 of Regulation (EC) No 726/2004 calls for the Agency, its Management Board and its various Scientific Committees to develop contacts with the Agency's stakeholders, including industry stakeholders.

During its October 2015 meeting, the EMA Management Board endorsed a *"Framework of interaction between the European Medicines Agency industry stakeholders" (*EMA/591272/2014).

To further streamline interactions with industry stakeholders in accordance with this framework, the EMA is establishing an industry stakeholder forum to facilitate regular dialogue on topics of common interest.
The Industry Standing Group (ISG)'s mandate, objectives and composition are set out in this document.

## 2. Mandate and objectives

The ISG will provide a forum to regularly exchange views, promote dialogue and receive feedback from industry stakeholders on issues of common interest related to human medicines and medical devices within the European legal framework.

The forum focussed initially on implementation of EMA's extended mandate. The ISG will complement existing forums for interaction with industry stakeholders, such as the industry stakeholders' platform meetings which provide opportunities for post-implementation dialogue on operational aspects relating to *medicines development support*, the *centralised procedure* and *pharmacovigilance*. In addition topic- or project-driven (often multi-stakeholder) meetings, and (annual) bilateral meetings with industry stakeholder associations allow topics relevant to a particular sector of the pharmaceutical industry to be addressed.

The ISG's objectives are aligned with those outlined in the industry stakeholder framework:

1. Provide a platform to exchange views and promote dialogue with industry stakeholders on issues of common interest concerning medicines for human use in the context of EMA's extended mandate;

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

2. Facilitate discussion on the overall approach and plans for industry stakeholder engagement, at regular intervals;
3. Improve communication and provide efficient, targeted and timely information to industry stakeholders in a proactive manner;
4. Enhance stakeholders' understanding of the EU medicines Regulatory framework and the role of the regulators in the context of EMA's activities and enrich EMA's understanding of issues that are pertinent from the industry perspective;
5. Facilitate and foster efficient collaboration with interested parties (including patient organisations, healthcare professionals' organisations, learned societies, academia, etc) by identifying areas and topics where multi-stakeholder discussion would be of benefit;
6. Build on existing interactions between industry (including SMEs), academia and other stakeholders in the overall science, medicines, and healthcare arenas by co-operating with established networks and alliances;
7. Increase transparency of stakeholders engaging with the EMA in relation to EMA's activities and report on the interaction.

# 3. ISG Composition

ISG meetings will facilitate EMA's dialogue and exchange with representatives of relevant eligible human industry stakeholders organisations from innovative, SMEs, biopharmaceutical, generic, over the counter, clinical research organisations, medical devices, wholesalers and distributors, active pharmaceutical ingredient manufacturers, parallel distributors, nuclear medicine industries, radiotherapy, health ICT, electromedical industries, etc., as appropriate.

## *3.1 Members*

ISG will consist of:

- One (1) member and one (1) alternate industry representatives EU industry organisations secretariat following a call for expression of interest; in addition, each selected organisation shall appoint additional representative(s) depending on the agenda;
- One (1) Chairperson nominated from amongst the EMA Secretariat by the Executive Director;
- EMA Executive Director, Heads of Division, Head of Task Forces and relevant EMA staff will participate *as per* agenda topics;

### *3.1.1. Eligible Industry stakeholder organisations*

The industry stakeholders representatives invited to participate to ISG meetings will be selected following a call for expression of interest taking into account those identified as eligible (List of eligible industry stakeholder organisations (europa.eu).

The individuals nominated by the EU industry (trade) organisation secretariats will act as their representatives for the purpose of ISG meetings and activities and not on their own individual capacity.

Therefore, the appointed representative is responsible for liaising with their organisation in order to provide and represent the organisation's position on the topics to be addressed. In parallel, they should report back on the activities of the ISG meetings within their respective organisations.

ISG membership will be reviewed annually and confirmed by EMA secretariat.

### *3.1.2. Chairperson*

ISG Chairperson is responsible for the efficient conduct of the standing group meetings. The ISG Chairperson will be a representative of EMA secretariat and will be nominated by the Executive Director.

### *3.1.3. Observers*

Observer(s) from EMA Management Board, the European Commission, the Committees for Human (CHMP) and Coordination Groups for Mutual Recognition and Decentralised Procedures - Human (CMDh) may also be invited depending on the topics identified.

Relevant representatives of medical device notified body organisation will participate *as per* agenda topics.

Other *Ad hoc* observers may be invited to participate in ISG meetings and can include representatives of patients, consumers and healthcare professionals' organisations, other industry stakeholders organisations, national competent authorities, European agencies and any other relevant EMA stakeholders.

## 4. Meeting organisation, and transparency

- Four ISG meetings will be scheduled annually, in principle one per quarter.
- The frequency may be adapted further depending on specific needs and priorities, therefore it is important to mention the flexible and adaptable nature of the meetings. Also, specific topic-driven focus groups could be organised to advance on certain priorities. Any topic-driven focus groups would report back to ISG.
- The meeting schedule will be published in the EMA calendar of events.
- Meeting draft agenda will be circulated 2 weeks in advance to all participants, members and observers and will be published on EMA website.
- Summary reports will be made available and will be published on the EMA website.

The meeting secretariat and organisational support will be provided by EMA S-PH.