Industry Standing Group (ISG) – 1 year of experience

ISG meeting of 26th June 2023

Presented by Marie-Helene Pinheiro, EMA Corporate Industry Stakeholders Liaison

ISG MANDATE

- **First ISG meeting** in June (21) 2022 with initial focus on implementation of **EMA's extended mandate** (Regulation (EU) 123/2022) **as a pilot**.

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

- complement existing fora for interaction with industry stakeholders:

  - Industry stakeholders' platform meetings R&D, Centralised and pharmacovigilance
    - post-implementation dialogue on operational aspects of the centralised procedure

  - (Annual) industry bilateral meetings: EFPIA, Medicines for Europe, AESGP, Vaccines Europe, EuropaBio etc.
    - allow topics relevant to a particular sector of the pharmaceutical industry to be addressed

ISG – composition and Transparency

- **ISG Members** and **alternates:** one member and one alternate from selected group of EU eligible industry organisations relevant to the subject of discussion (following a call for expression of interest):
  - **AESGP, EFPIA, Vaccines Europe, Medicines for Europe, EUROPABIO, EUCOPE, Europharm SMC, EIGA, CEFIC/APIC, ECA Foundation/QP Association, IPFA and PPTA, Affordable Medicines Europe, GIRP, EALTH**
  - **ACRO, EUCROF**
  - **MPP, MedTechEurope, COCIR**
  - **EAAR and Notified Bodies**

  → **ISG membership will be reviewed annually and confirmed by EMA secretariat**

- One **EMA Chairperson** nominated by EMA's Executive Director

- **Observers**: from European Commission (DG-SANTE (B4, B5, D3, R4), HERA), CHMP, ETF, CMDh, SPOC WP, EU Network, Notified bodies, other EMA committees - depending on topics

- High level meetings **ISG summary report published** on EMA website with **EMA presentations**

ISG TOPICS DISCUSSED in 2022 and 2023

Industry Standing Group (ISG) mandate, objectives, composition

EMA extended mandate implementation

- Emergency task force: ETF formalisation/Submission requests/Industry EFT activities feedback ✅
- Medicine shortages and Medical Devices : i-SPOC registration, MAHs Reporting tools/guidance, ESMP Road Map ✅
- Medical Devices Expert Panels (EP): MD EP EMA transition from JRC/implementation, Transparency, SA and ✅
- HERA -EMA JICF joint working group on data collection update ✅

- **Strategic topics of common strategic and cross-Industry sectors interests**
  - Establishment of **the Quality Innovation Group** and Industry Stakeholder engagement (Key EMA strategic priority – New Group & pilot launch announcement)
  - Update on **EMA Agile governance implementation** clarifications/updates (Need urgent clarifications: Industry SME role/confidentiality)
  - **IT security at EMA** - update on additional measures in place (Key cross industry strategic topic information status sharing)
  - **CTIS implementation update** (Key cross industry strategic topic before/after Legal implementation)
  - **CTR implementation and ACT EU update** (Key EMA strategic priority: survey launch announcement)
  - **EMA COVID-19 Lessons Learned activities** (Key cross industry strategic topic – avoid unilateral EU industry Trade Associations discussions)
  - **Outcome from 2022 ISG Survey** and Key Industry stakeholder 2023 meeting (Feedback sharing)

ISG formalisation

- ISG Mandate scope updated beyond EMA Mandate extension topics
- Publication of ISG mandate on EMA website
- ISG Members and alternates nominations confirmation and publication
- 6th ISG meeting (remote) on 21st September 2023; Call for topics by July 20th 2023

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

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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