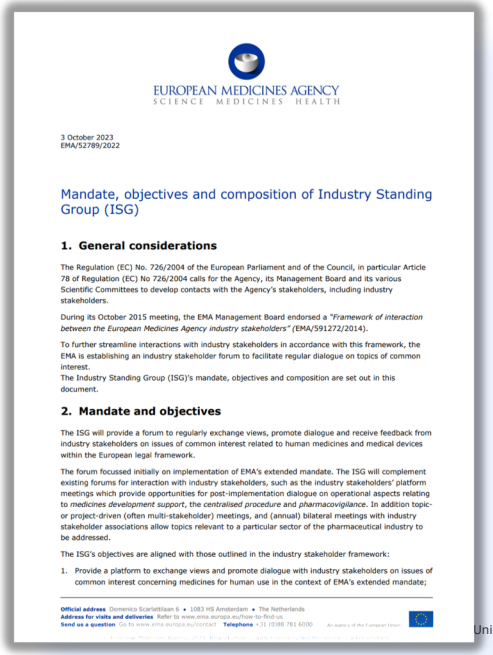
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Industry Standing Group (ISG) Mandate update

ISG meeting on 28 June 2024



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 October 2023
EMA/52789/2022

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;

Dr. Marie-Helene Pinheiro
EMA industry liaison – ISG Chair

Union

ISG Industry Standing Group

EUROPEAN MEDICINES AGENCY




Q1 2022

Industry Standing Group (ISG) created by EMA in Q1 2022

June 2022

- First meeting in June 2022 with initial focus on implementation of EMA's extended mandate (Regulation (EU) 123/2022) as a pilot
- **Focus on Human Medicines and MedTech sectors and NBs**

June 2023

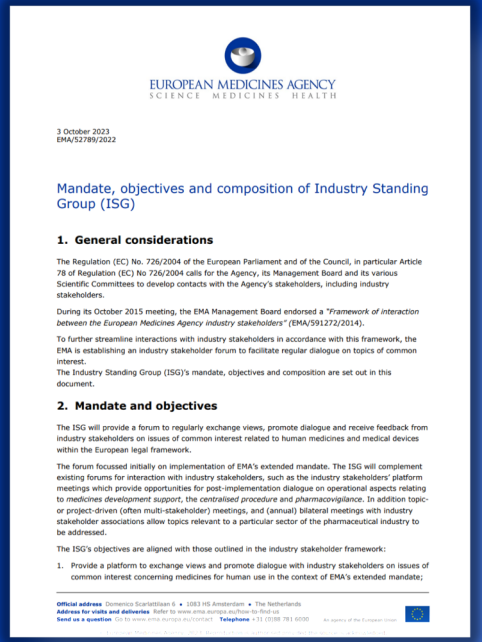
The ISG has now been extended to **other Strategic topics of common strategic and cross-Industry sectors interests e**.g. international activities, HTA regulation, EMA AGILE governance implementation, CTIS and Fee regulation

June 2024

Updated Mandate

- **Veterinary Industry Stakeholders** are now invited to the ISG meetings
- Observers from Committee for Veterinary Medicinal Products (CVMP) and Decentralised Procedures for veterinary medicinal products (CMDv) may also be invited depending on the topic

ISG updated mandate



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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;

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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 and veterinary use;

3. ISG Composition

ISG meetings will facilitate EMA's dialogue and exchange with representatives of relevant eligible human and veterinary 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.

3.1.3. Observers

Observer(s) from EMA Management Board, the European Commission, the Committees for Medicinal products for Human use (CHMP), Committee for Veterinary Medicinal Products (CVMP), Coordination Groups for Mutual Recognition and Decentralised Procedures - Human (CMDh) and Coordination Groups for Mutual Recognition and Decentralised Procedures for veterinary medicinal products (CMDv) may also be invited depending on the topics identified.

ISG – Industry Standing Group – UPDATED MAND

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2024
EMA/135119/2024

Draft agenda – 9th Industry Standing Group (ISG) meeting

28th June 2024, 09.00-13.30 CEST, Hybrid meeting room 1A and Webex

Chair: Marie-Hélène Pinheiro, EMA industry

Item	Preliminary draft agenda	
1.	**Medical Devices expert panels** (H + MD) *Silvy da Rocha Dias, Miguel Antunes (EMA)* 4.1 Expert Panels advice pilot updates 4.2 New guidance on the clinical evaluation of orphan medical devices update 4.3 Feedback on workshop with Notified Bodies of 22 April 2024 on clinical assessment alignment. Q&A session (all)	**10:25-10:55** 20'
2.	**Regulatory/HTA interface under the HTA Regulation** (H+MD) 5.1 Overview of implementation activities *Michael Berntgen (EMA)* 5.2 Operational aspects of the parallel procedure and joint clinical assessments *Joao Ferreira (EMA)* Q&A session (all)	 10' 10'
3.	**EMAN Strategy to** (H+V) *Juan Garcia Burg*	**11:25-11:30** 5'
	Coffee break	
4.	**Revised CTIS transp** and new v** **public portal** *(H)* *Peter Arlett (EMA)*	
5.	**Artificial Intelligence: Multi-annual AI workplan 2023-2028** (H+V) *Peter Arlett, Zaide Frias (EMA)* Q&A session (all)	**2:00-12:25**
6.	**Update on EU Network Portfol** f stra** **focus, including Regulatory** (ROG) (H+V) *Zaide Frias (EMA)* Q&A session (all)	 20' 10'
7.	**ICMRA collaboration pilots** (H) *Evdokia Korakianiti, Roberto Conocchia* (EMA)	**12:55-13:10** 15'

H+V+MD

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H+MD

H+MD

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H+V

H+V

H

Any questions?

Further information

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