



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Industry Standing Group (ISG) - Mandate, scope and composition

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ISG meeting on 21 June 2022

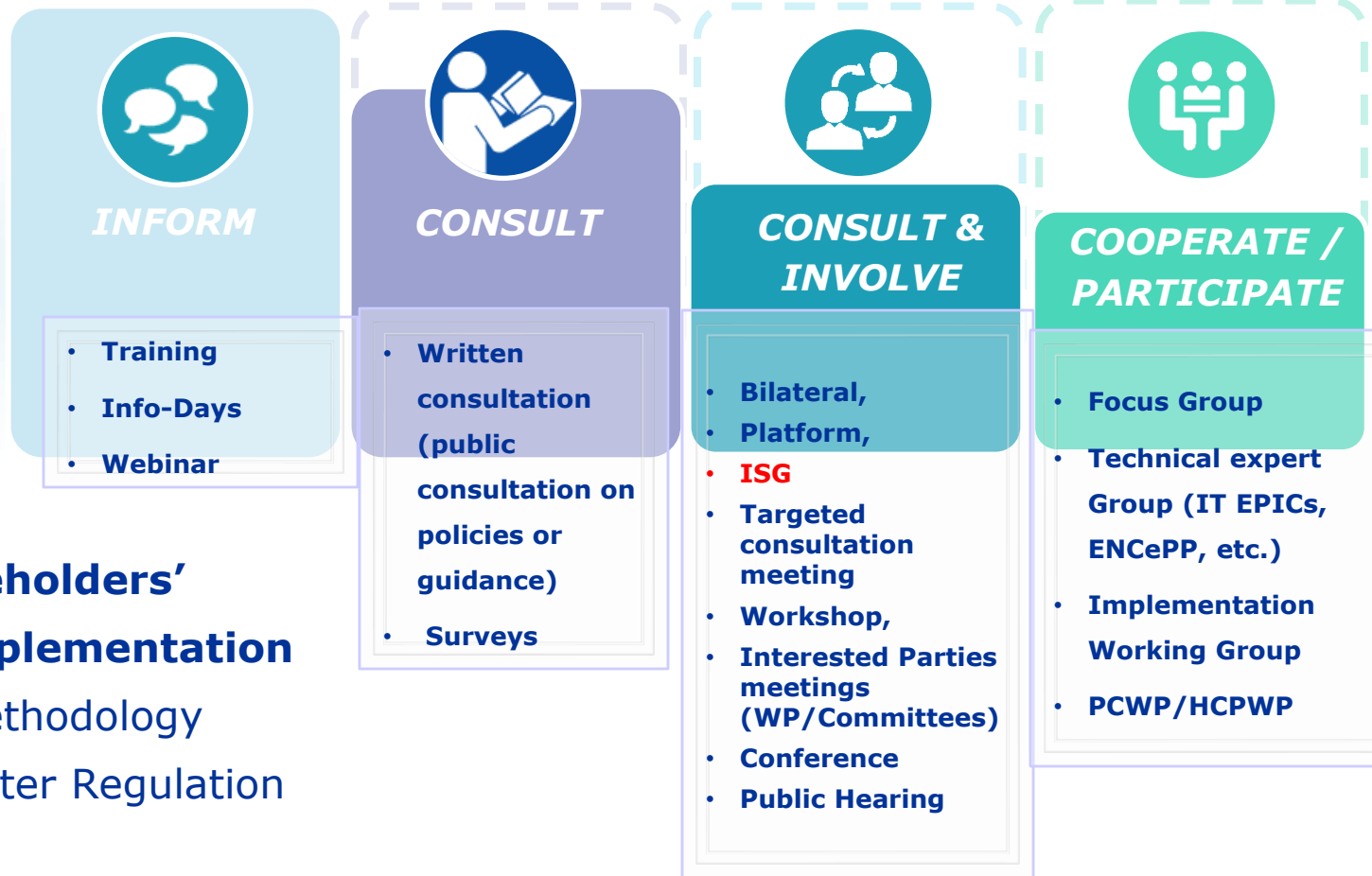
Juan Garcia Burgos  
Head of Public and Stakeholder Engagement – Stakeholder and Communication Division

An agency of the European Union



- A forum to streamline interactions with industry in accordance with EMA's framework of interaction to:
  - facilitate regular dialogue on topics of common interest during the implementation of **EMA's extended mandate**
  - exchange of views, promote dialogue and receive feedback from industry stakeholders on the implementation of new legislation
  - Complement existing fora for interaction, such as industry platform meetings, bilateral meetings, topic or project related meetings, etc

- Improve communication and provide efficient, targeted and timely information to industry stakeholders in a proactive manner
- Increase transparency and consistency of the approach to EMA stakeholder engagement in relation to EMA's extended mandate and allow better reporting on the interaction
- ISG to focus on human medicines
- Experience from ISG to be analysed with a view to explore extending its scope to other initiatives in future



- **Industry Stakeholders' Framework implementation** with working methodology based on EC Better Regulation

<sup>3</sup>Guidelines



- **Members** and **alternates**: one member and one alternate from selected group of EU industry organisations relevant to the subject of discussion (following a call for expression of interest)
  - ✓ Selected organisations can appoint additional representative(s) depending on the topics on the agenda
  
- One **EMA Chairperson** nominated by EMA's Executive Director as well as relevant EMA staff
  
- **Observers**: from European Commission, CHMP, ETF, CMDh, SPOC WP, SMMG, EU Network, Notified bodies, other EMA committees - depending on topics
  - ✓ Other ad-hoc observers may be also invited from MSs and stakeholder groups



- Members and alternates will represent their EU industry (trade) organisations for the purpose of ISG meetings and activities and will not act on their own individual capacity.
- Members and alternates will be responsible for liaising with their organisation to provide 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 industry organisations.

- Four quarterly ISG meetings to be scheduled annually
  - ✓ First meeting – 21st June 2022
  - ✓ 26 September (*proposed to be F2F*) & 22 November 2022
- Frequency could be adapted depending on specific needs and priorities
- Specific 'ad-hoc meetings' could be organised to advance on certain priorities.
  - ✓ Any 'ad-hoc meeting' would report back to ISG

- The meeting schedule will be published in the EMA calendar of events.
- Meeting agenda to be circulated 2 weeks in advance to all participants and will be published on EMA website
- Summary reports will be made available and will be published on the EMA website





- Proactive approach to streamline interactions with industry in accordance with Industry Stakeholder framework – focus on EMA’s extended mandate
- More structured and regular interaction (in view of the number of new activities) to exchange views and promote dialogue on new initiatives and implementation of EMA’s extended mandate.
- Facilitate monitoring of the interactions and improve transparency
- Explore potential usefulness and future extension to cover other initiatives and strategic priorities



# Any questions?

## Further information

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

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