



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Breakout session 2 - Platform for stakeholders' consultation

Learnings Initiative for Optimal Use of Big Data for Regulatory Purpose

Presented by Dr. Marie-Helene Pinheiro on 30 November 2021
Industry Corporate Stakeholder Liaison, EMA

An agency of the European Union





Breakout session 2 - Platform for stakeholders' consultation

Using examples of existing platforms for collaboration, which mechanisms or fora could be put in place to support stakeholders' consultations on content, format and processes of submission of realworld data for regulatory purposes?

Introductory presentations: Elizabeth Vroom, Duchenne Parent Project; Álmath Spooner, AbbVie; Marie-Helene Pinheiro,
EMA Chair: Juan Garcia,
EMA Rapporteur: Carla Jonker, EMA

Discuss means and proposals to support effective consultation with stakeholders, including industry, academia, healthcare professionals and patients.

The webinar recommendations will be fed back HMA-EMA Big Data Task Force and Network Strategy to 2025 implementation activities and processes in relation to stakeholder consultations, support for individual product submission and ultimately [guidelines](#) for applicants and the regulatory network.

Goal & objectives

To engage with stakeholders to capture stakeholders' views and input in support of EMA's public health mission by:



facilitating implementation of EMA's priorities and new legislation, ensuring that EMA decisions are well informed and meet stakeholder's needs

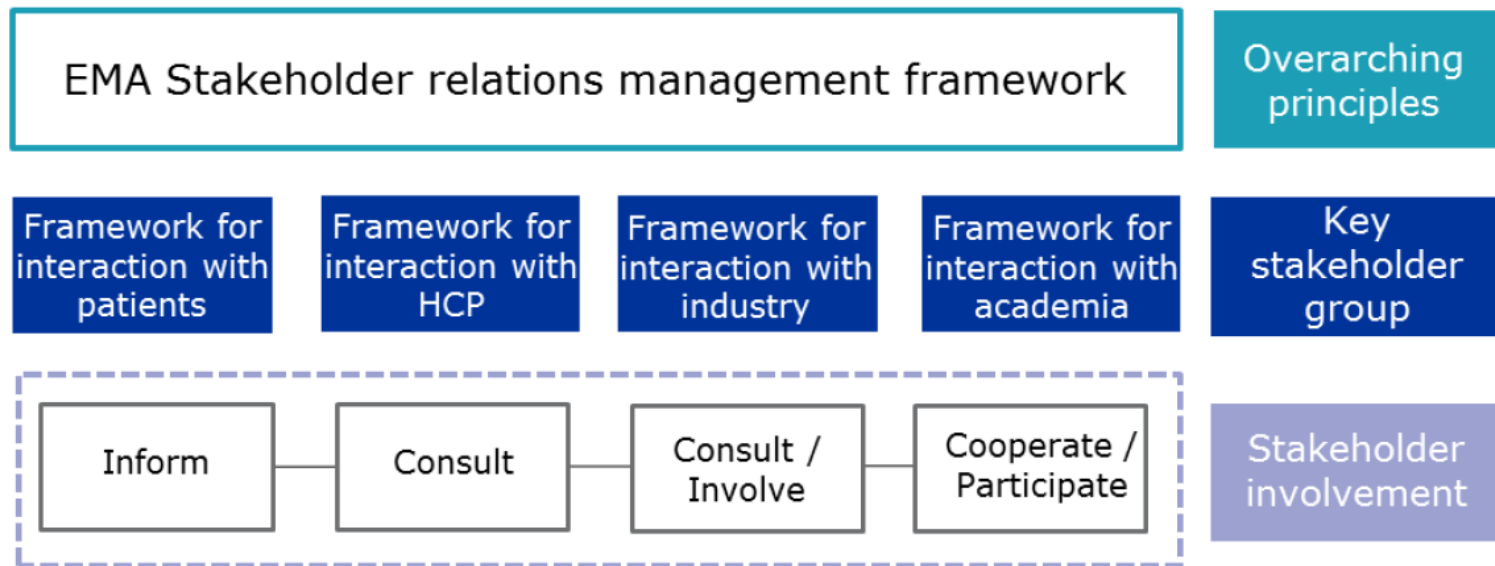


raising awareness and understanding of EMA's evolving role and its work



reinforcing legitimacy of EMA actions and trust in the scientific and regulatory outcomes and in the EU system

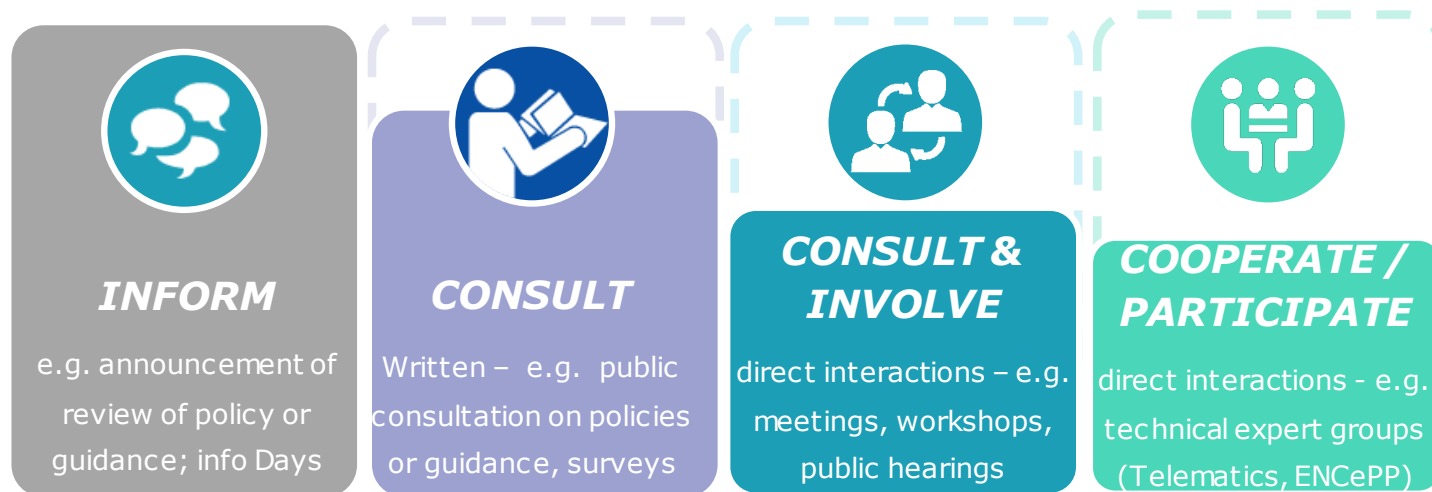
Using existing specific Stakeholders Frameworks



Together, these building blocks ensure a consistent approach to stakeholder relation management across a variety of stakeholder and interaction types.



Using the working methodology based on EC Better Regulation Guidelines





Engagement methodologies across stakeholder groups

	Patients Consumers	Healthcare professionals Learned societies	Academia ERNs	Industry SMEs
Training, webinar, info-days and awareness sessions	✓	✓	✓	✓
Working parties	✓	✓	✗	✗
Targeted consultation (meeting and in writing) & surveys	✓	✓	✓	✓
Workshop	✓	✓	✓	✓
Platform	✗	✗	✓	✓
Bilateral meetings	✓	✓	✓	✓
Interested parties meeting with Committees & Working Parties	✓	✓	✓	✓
Conference	✓	✓	✓	✓
Focus Group	✓	✓	✓	✓
Stakeholder Forum	✓	✓	✓	✓
Technical expert group	✓	✓	✓	✓
Implementation Working Group	✓	✓	✓	✓
Public hearing	✓	✓	✓	✓
Public stakeholder meeting	✓	✓	✓	✓
Public consultation and Surveys	✓	✓	✓	✓
Committee member, Expert involvement	✓	✓	✓	✓
Ad-hoc meeting or teleconference	✓	✓	✓	✓

Training and awareness: need for a long term approach



- Strengthen EMA-stakeholder interactions and facilitate participation in EMA processes through relevant tools, including training, info-days, awareness sessions, etc

- Provide a more strategic, structured approach

- Proactive outreach and educational efforts to key stakeholders



Monitoring, impact evaluation & reporting / transparency



Monitoring interactions



Measure impact of engagement
– defined outcomes



Reporting and transparency



- Avoid duplication and optimize best use of existing fora, tools and resources
- Planification and transparency of interactions engagement for better oversight of Stakeholders interactions
- Discuss format of industry interactions: F-2-F, Virtual, Hybrid (*COVID-19 LLs*)
- Foster the use/coordination of external EU Trade Associations representing EU

Questions:

- What aspects of RWE are critical for consultation for Stakeholders ?
- Need for additional mechanism, platform and tools ?



Thank you for your attention

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