



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Session 3: Engagement with Stakeholders

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Academia Info Day

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An agency of the European Union





# Why is it important for EMA to engage with stakeholders?

- To **optimise the Agency's public service role** in improving human and animal health by systematically integrating multi-stakeholder engagement by design into EMA's key activities and strategic priorities.
- **EMA engages with stakeholders to:**
  - ensure that EMA decisions are well informed, meet stakeholders' needs and reach them
  - harness the widest expertise available
  - raise awareness and understanding of EMA's evolving role and its work
  - reinforce confidence and trust in the scientific and regulatory outcomes and in the EU system



# Who are our stakeholders?

- Over time EMA developed frameworks formalising its interaction with:
  - **Patients and consumers** (2005)
  - **Healthcare professionals and learned societies** (2011)
  - **Industry and EU trade organisations** (2015)
  - **Academia** (2017)
- **Other relevant stakeholders**
  - Media
  - HTA bodies and payers
  - Ethics committees
  - CROs
  - Tech developers

## Multi-stakeholder engagement by design

- Develop and implement a **streamlined and coordinated approach** to multi-stakeholder engagement at EMA to support implementation of EMA's strategic priorities and new legislation
- Support cross-Agency **implementation of EMAN and RSS strategies to 2025** and multi-stakeholder engagement in new areas under EMA's Extended Mandate
- Support targeted or multi-stakeholders **training and education on EMA activities** in cooperation with EMA partners (EC, EU Network, ICH)
- **Monitor, evaluate and report** on multi-stakeholder engagement to ensure optimal public service, continuous improvement and transparency

## Do we also interact with other European and international agencies?

EMA **partners** – with whom there are operational links – encompass:

### **Within the European regulatory network:**

- National competent authorities
- European Commission
- European Parliament
- Other European Institutions

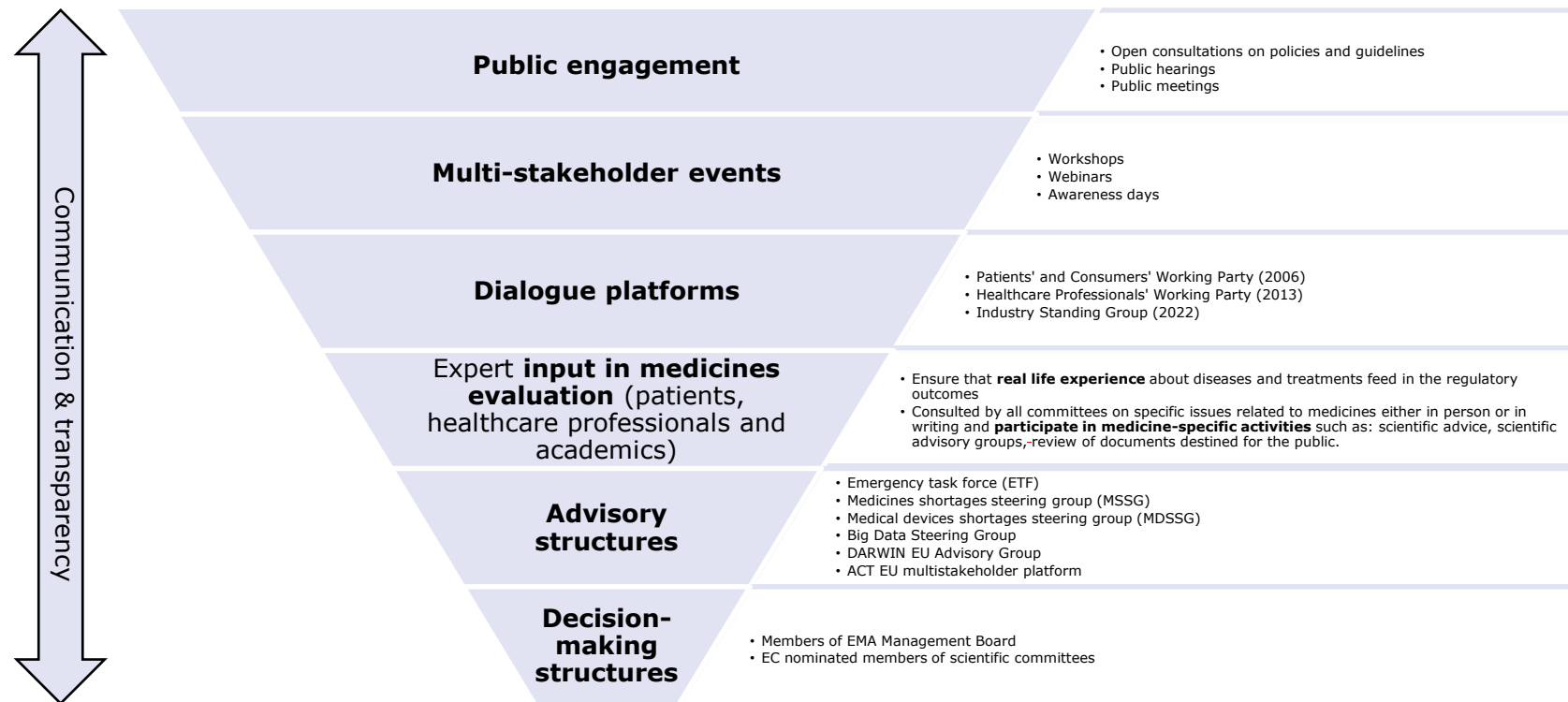
European Centre for Disease Prevention and Control (ECDC);  
European Food Safety Authority (EFSA); European Chemicals  
Agency (ECHA); European Monitoring Centre for Drugs and Drug  
Addiction (EMCDDA); European Environment Agency (EEA)

### **International (organisations) partners:**

- World Health Organisation (WHO)
- US Food and Drug Administration (FDA)
- Health Canada
- Japanese regulatory authorities (MHLW and PMDA)



# How do we engage our stakeholders in our work?





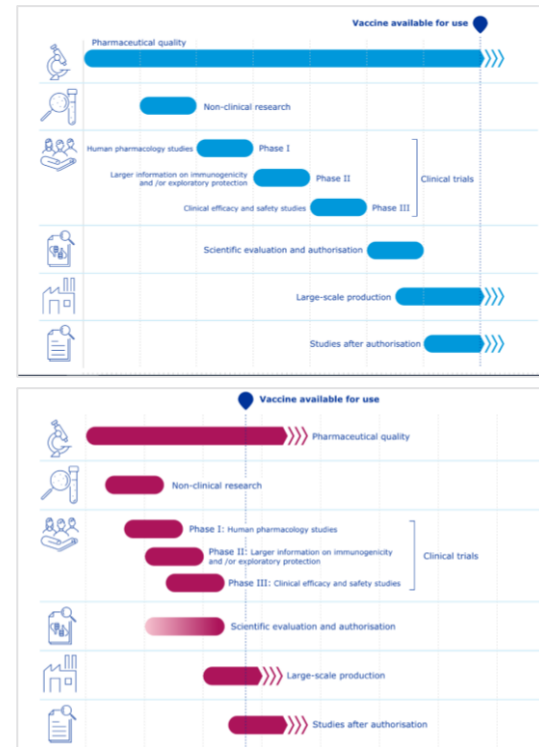
# Impact: examples of how stakeholders influence our work

- Medicine specific
- Strategic – EMAN and RSS strategies to 2025
- Policy wise – transparency of clinical trials; handling of competing interests
- Operational – CTIS; ePI and template review of product information
- Crisis management

# Stakeholder engagement during crisis management

## In crisis, engagement became more important than ever

- Voices of civil society in scientific committees
- Patients and HCPs on **EMA COVID-19 Taskforce** (ETF)
- COVID-19 communications review: key messages, channels
- Patient and healthcare professional organisations disseminated EMA's COVID-19 communications, advice
- Regular updates in PCWP/HCPWP meetings
- **EMA public stakeholder meetings:** Dec 2020, Jan/Mar/Nov 2021





# Added value and impact during crisis management

- Gather critical input into crisis-related activities in COVID-19 context
- Gain insight into concerns of specific groups of patients and healthcare professionals e.g. about vaccination
- Support specific information needs, e.g. discussions on vaccines, associated social challenges, hesitancy, review of safety communications to the public...
- Channel public health messages to communities of patients and citizens more effectively
- Reinforce legitimacy of actions, trust in scientific outcomes and EU system





# Any questions?

## Further information

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