



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# The importance of stakeholders' engagement to support implementation of the European Medicines Agencies Network Strategy

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Healthcare Professionals' Working Party (HCPWP) meeting, 27 June 2023

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An agency of the European Union





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# Added value of regulators' multi-disciplinary engagement with HCPs

- Healthcare professionals provide a very valuable contribution to EMA's regulatory work
- Multidisciplinary expertise:
  - Primary care
  - Therapeutic area specialties
  - Community and hospital pharmacy
  - Nurses
- Input provided covers from detailed scientific or clinical care input to strategic/policy implications
  - Scientific assessment
  - Review of key communications
  - Policy and strategic topics

# HCP engagement at the interface with innovation

## Clinical research/clinical practice

Explore opportunities for engaging with healthcare professionals in the **interface of clinical research and clinical practice** on areas such as clinical trial design, personalised medicine, and use of real-world evidence

*Developers of innovative treatments can discuss the scientific, legal and regulatory aspects of their medicine with EMA early in the development through the **Innovation Task force**.*



Source: [https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorized-medicine\\_en.pdf](https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorized-medicine_en.pdf)





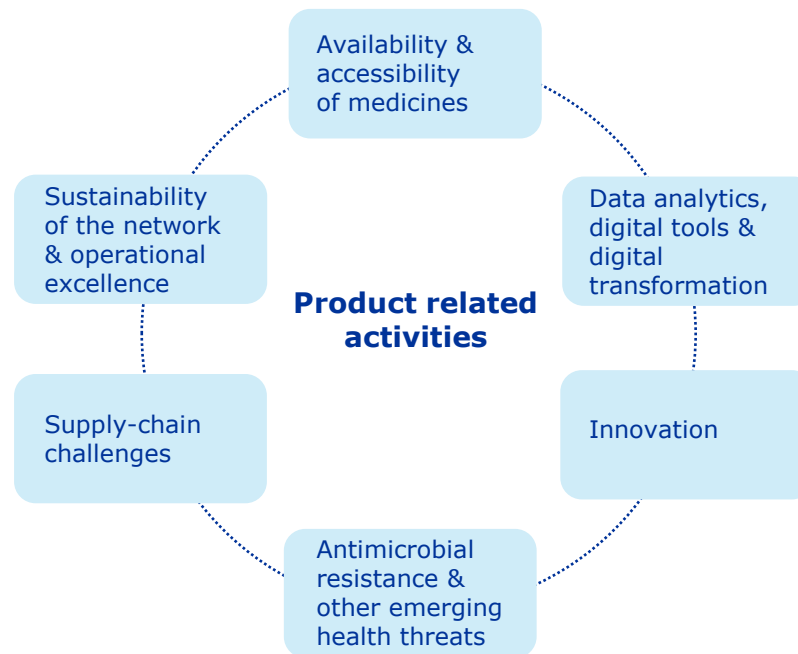
# Stepping up engagement with 'eligible' HCP organisations / Learned societies

## Map expectations & identify gaps

- Survey to eligible organisations
- HCP policy officers group
- Healthcare professionals working party (HCPWP)

## Learn & share knowledge

- Bilateral meetings
- Information loop



## Increase impact

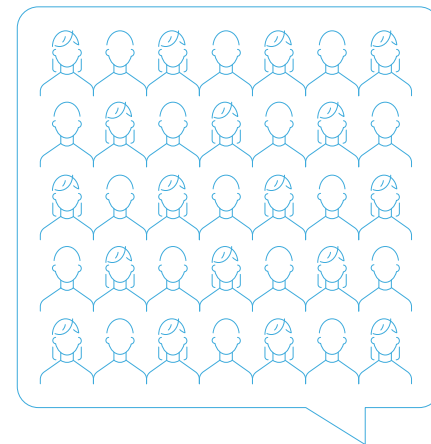
- Co-developed meetings
- Topic-driven multi-stakeholder platforms
- Training/ Participation in external events

## Create awareness

- Publications
- Audiovisual materials
- Annual reports

# Integrating multi-stakeholder engagement by design

- Stakeholder engagement is a key enabler of the EU Network's strategic priorities as reflected in the [EMAN strategy to 2025](#)
- Many stakeholders impacted by scientific advances and **external changes** that affect the Network and its upcoming work:
  - Strategies to 2025 (Regulatory Science, Network Strategy)
  - COVID-19 crisis and EMA Extended Mandate
  - New Pharmaceutical Legislation



**Goal:** 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

# Multi-stakeholder engagement – an enriched HCP perspective

- Engaging all stakeholders simultaneously offers new opportunities:
  - To achieve a common understanding and addressing needs and potential bottlenecks together
  - Enrich the regulatory work with the clinical practice perspective already taking into account other stakeholders' viewpoint
  - Transparency and collaboration fosters trust within stakeholders
- This will optimise regulatory outcomes and increase confidence in the regulatory system
- Where possible, need to integrate an earlier, multi-stakeholder approach with a multi-disciplinary HCP expertise
- Both bilateral and multi-stakeholder HCP engagement are complementary and needed in medicines regulation





# Multi –stakeholder engagement to deliver Network priorities

## Multi annual workplan priorities

### Public health priorities

#### EMANS/ RSS priorities :

- Availability/shortages
- Data Analytics / Big Data
- Clinical trials
- AMR and emerging health threats
- Patient Experience Data





# Conclusions

- EMA needs the multidisciplinary expertise from **healthcare professionals**, including **doctors, pharmacists and nurses** – **clinical care, scientific input and strategic/policy perspective**
- Access the best possible **independent expertise** in **clinical practice**, to **incorporate the real-world experience** of the full spectrum of healthcare (from primary, to secondary and tertiary care) into drug development, benefit/risk evaluation and monitoring
- Contribute to a more **efficient** and **targeted communication** to healthcare professionals
- **Innovative landscape** requires integration of **multi-stakeholder engagement by design**
  - Engaging with healthcare professionals in the **interface of clinical research and clinical practice** on areas such as clinical trial design, personalised medicine, AI and use of real-world evidence
- **Enhance** healthcare professionals' organisations' **understanding** of the role and activities of the EU medicines regulatory network



# Thank you for your attention

## Further information

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