Stakeholder involvement in European Medicines Agency activities

HTA Network Stakeholder Pool - Health Providers Meeting

Presented on 21 March 2019
Public Engagement Department, Stakeholders and Communication Division
EMA stakeholder engagement
Promoting multi-stakeholder discussions

- Engage and involve stakeholders in EMA activities
- Enable stakeholders to share relevant issues with EMA
- Provide reliable, targeted and timely information
- Enhance understanding of EU medicines regulatory network
- Increase transparency and trust
- Use stakeholder relations to further support EMA’s strategic priorities
Patients and consumers and healthcare professionals: Representation within EMA

- **Representing their community**
  - Management Board
  - EMA Scientific Committee Members

- **Representing their organisations**
  - Working Party (PCWP or HCPWP)
  - EMA consultations
  - Workshops

- **Individual experts**
  - Scientific Advice / Protocol Assistance Procedures
  - Scientific Advisory/ad hoc expert Groups
  - Medicinal product assessments
  - Review of draft label/ product information documents

- All organisations must comply with EMA eligibility criteria
- All individuals must complete a competing interest declaration and confidentiality undertaking
Sources for reaching out to healthcare professionals and patients

International/European organisations – EMA stakeholders database

Eligible organisations
Working parties – HCPWP and PCWP

Healthcare professional working party (HCPWP)

Act as filter and generator of activities at EMA

Workshops/info session:
- Personalised medicines
- Antimicrobial resistance
- Risk minimisation measures
- Biosimilars

Black triangle

Patients and Consumers Working Party (PCWP)

Topic groups:
- Digital Media and Health (joint)
- Risk minimisation measures and assessment of their effectiveness (HCPWP)
- Involvement of young people in EMA activities (PCWP)
Bringing expertise into the EU medicines regulatory system
Involvement along the medicine lifecycle at EMA

- Designation & Classification
- Scientific Advice
- Paediatric Plan
- Marketing Authorisation Evaluation
- Post Marketing procedures

Public Summaries of Opinion
Product information
Safety Communications
Product information

COMP CAT
CHMP SAWP
PDCO
CHMP CAT PRAC COMP
CHMP PRAC
Expert mtg
Expert mtg

Involvement along the medicine lifecycle at EMA
Bringing expertise into the EU medicines regulatory system
Increasing involvement in EMA product-specific activities

- **Individual patient experts**
- **Individual HCP experts**

- **Scientific Advice / Protocol Assistance Procedures**
- **Scientific Advisory/ad hoc expert Groups**
- **Medicinal product assessments**
- **Review of draft label/ product information documents**
Engagement methodologies

Current:

- Invitations to meetings (1-2 individuals)
- Participation in committee meetings (1-2 individuals)
- Stakeholder meetings (up to 25 participants)
- Consultations in writing (depends on topic)
- Larger group consultation via surveys (depends on topic)

Future plan:

New methodologies will be incorporated to gather broader patient input (i.e. patient data) representing the wider community.
Collaboration with HCP: the EMA journey... so far

- **1995**: EMA created
- **1996**: HCPs as members of scientific committees
- **2004**: Doctors’ representative joins EMA Management Board
- **2006**: Working group with HCP organisations created/ HCP join PDCO as members
- **2011**: Framework of interaction with healthcare professionals and their organisations
- **2013**: Healthcare professionals’ Working Party (HCPWP) created
- **2014**: Public Engagement Department
- **2016**: Framework of interaction updated
- **Ongoing...**: Systematic inclusion of real world clinical experience in EMA regulatory output
How do we manage competing interests and confidentiality?

Level of involvement of expert in EMA activities is dependent upon the type of interest declared and the nature of the activity.

• **Scientific advice**
  - e.g. principle investigator of the medicine being assessed (0-3 years) = no involvement

• **Scientific Advisory/ad hoc expert group meetings**
  - e.g. principle investigator of the medicine being assessed (0-3 years) = involvement in discussions but not part of final deliberations

• **Stakeholder meeting consultation within a procedure**
  - Funding sources of organisations are assessed and individual representative also declares interest for transparency purposes
Support the Agency in order to access the best possible independent expertise and obtain information on the current use of medicines in real clinical practice.

Contribute to a more efficient and targeted communication to healthcare professionals, to support their role in the safe and rational use of medicines.

Enhance healthcare professional organisations’ understanding of the role of the EU medicines Regulatory Network.

Network of European healthcare professional organisations.
Opportunities to bring input in evaluation activities

- Input into Scientific Advice procedures in Scientific Advice Working Party
- Input in Scientific Advisory Groups (SAGs) and Ad-hoc expert group meetings
- Review of labelling aspects and additional risk minimisation measures including implementation
- Review of safety communications and DHPCs (including prevention of medication errors)
- Scientific Committees/Working Parties consultations (standard of care; risk minimisation measures; product information)
- Participation in EMA workshops leading to the development or update of regulatory guidance for medicine developers
Conclusion

- Healthcare professionals are systematically involved by EMA in activities linked with the assessment of scientific evidence generated during the development of a medicine and during its use in real life after its authorisation.

- Need to reflect on how best to recognise the contribution healthcare professionals provide to these activities.

- While EMA and HTA activities are specific, areas of synergy have been identified where we can work together to engage with HCP.

- Exchange of engagement practices between EMA and HTA is beneficial.
Thank you for your attention

Further information

Healthcare professional and academic relations coordinator:

European Medicines Agency

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