EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

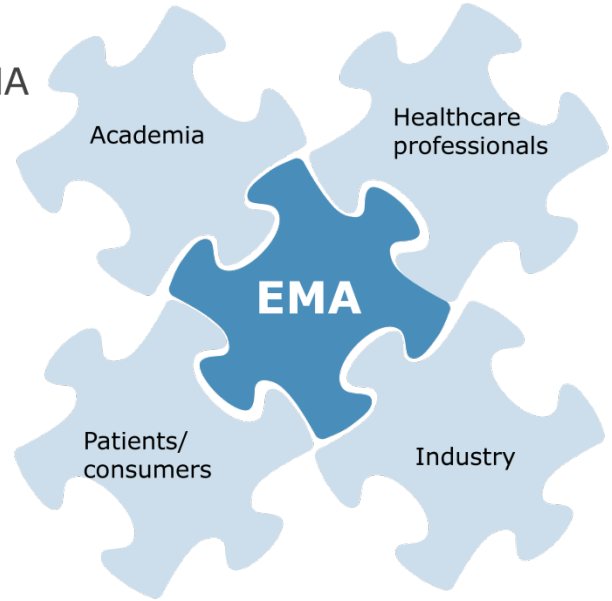
EMA stakeholder engagement

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)

Patients and Consumers Working Party (PCWP)

Act as filter and generator of activities at EMA

▼ Black triangle

Workshops / info session:

Personalised medicines

Antimicrobial resistance

Risk minimisation measures

Biosimilars

Topic groups:

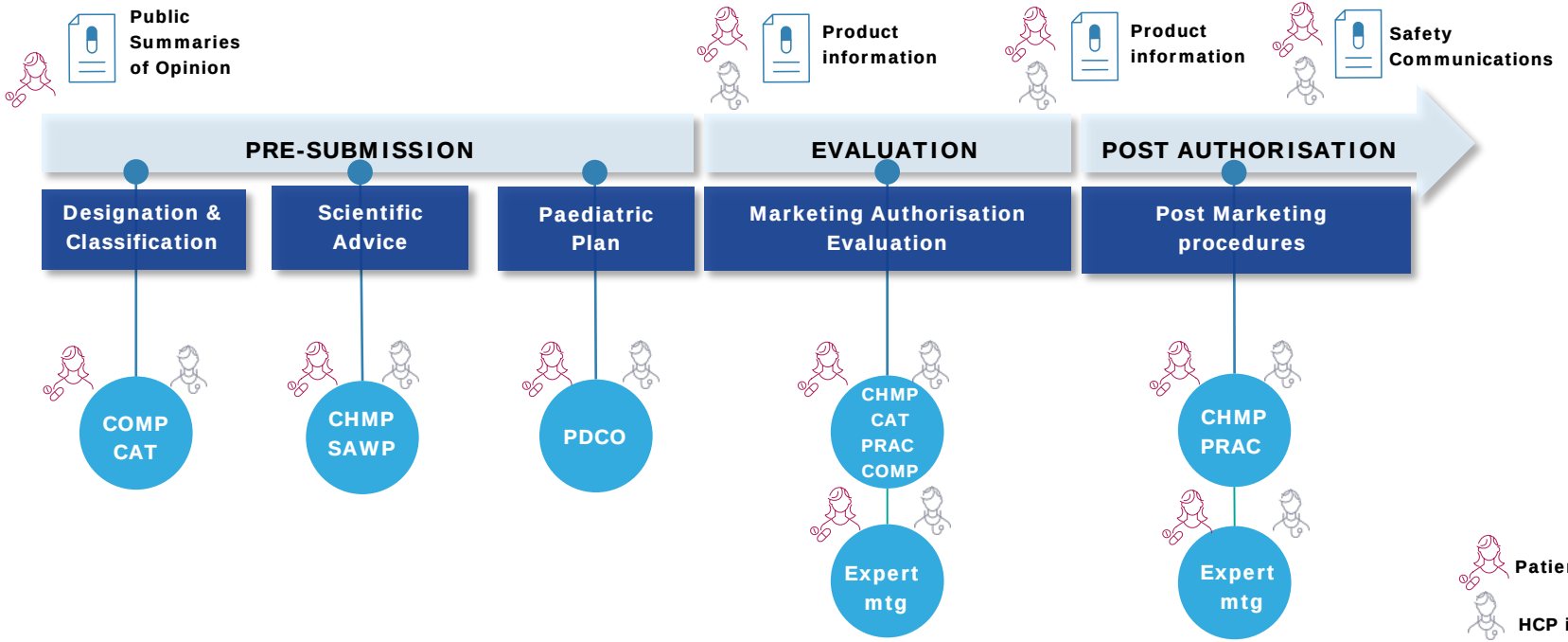
Digital Media and Health (joint)

Risk minimisation measures and assessment of their effectiveness (HCPWP)

Involvement of young people in EMA activities (PCWP)

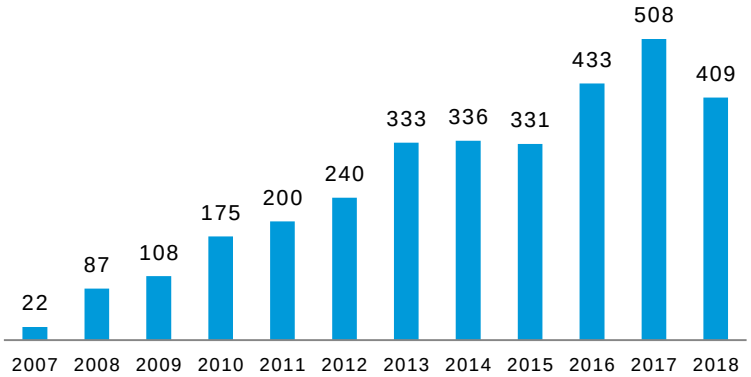
Bringing expertise into the EU medicines regulatory system

Involvement along the medicine lifecycle at EMA

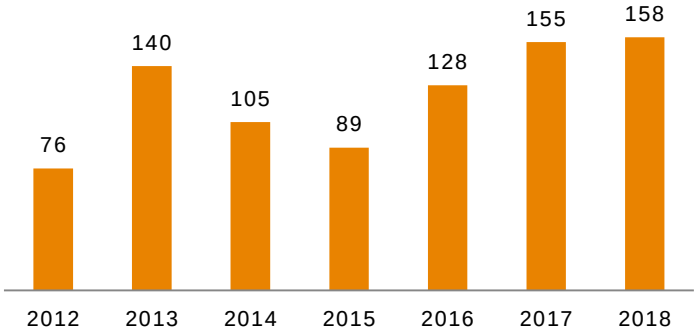


Increasing involvement in EMA product-specific activities

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

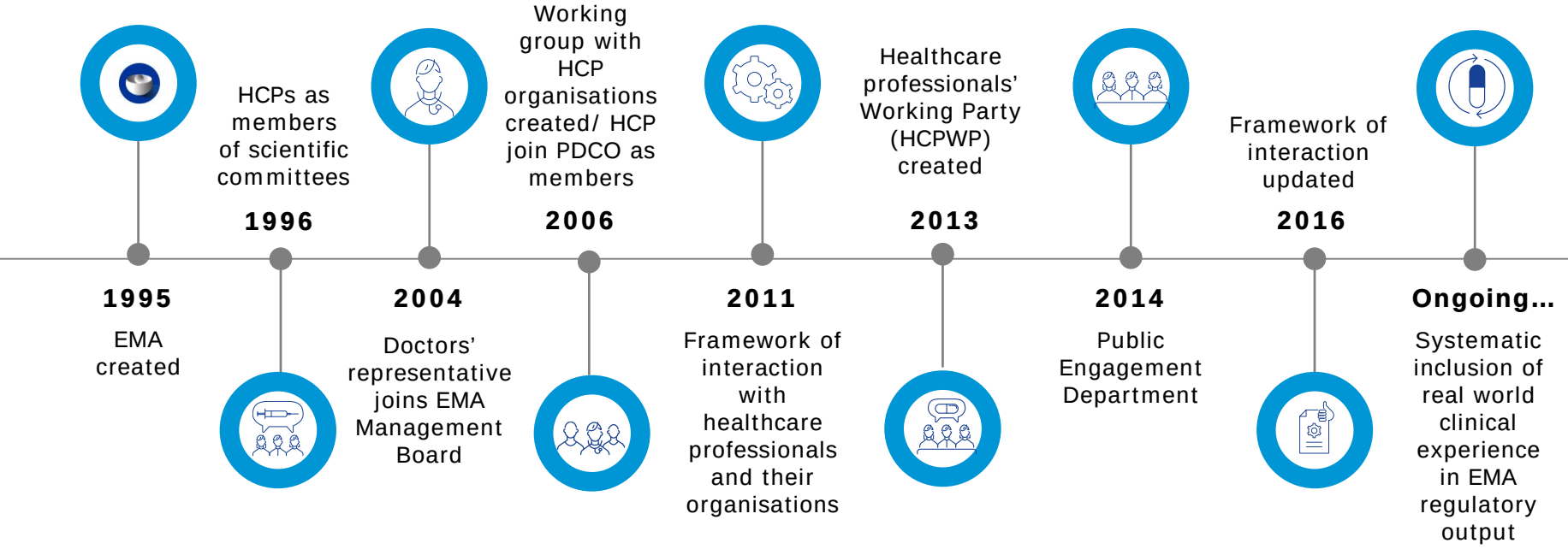
Current:

- 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



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

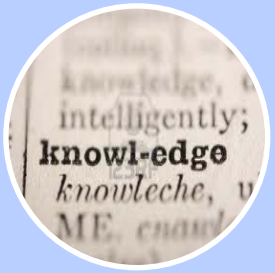
- **Scientific Advisory / ad hoc expert group meetings**
  - e.g. principle investigator of the medicine being assessed (0-3 years) = involvement in discussions but not part of final deliberations

- **Stakeholder meeting consultation within a procedure**
  - Funding sources of organisations are assessed and individual representative also declares interest for transparency purposes

Pillars of the framework of interaction with HCP

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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