EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

A viewpoint from EMA to UEMS session on '*A Holistic European and International Perspective on CME-CPD*'

Presented by Ivana Silva on 24 November 2018
Public Engagement Department, Stakeholders and Communication Division

An agency of the European Union

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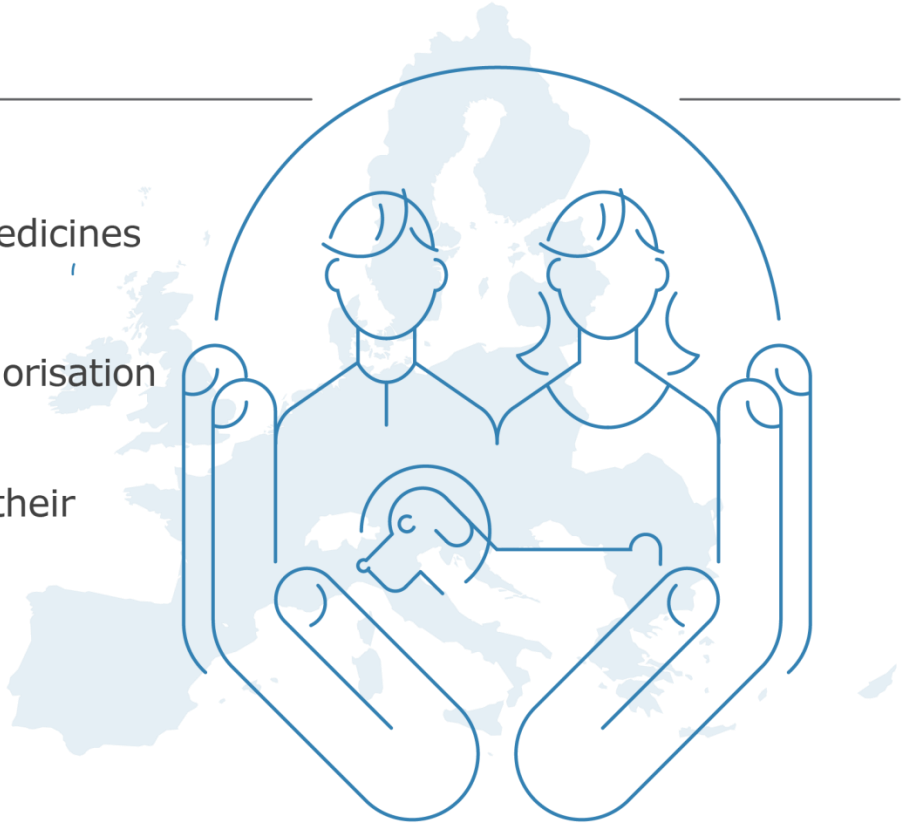
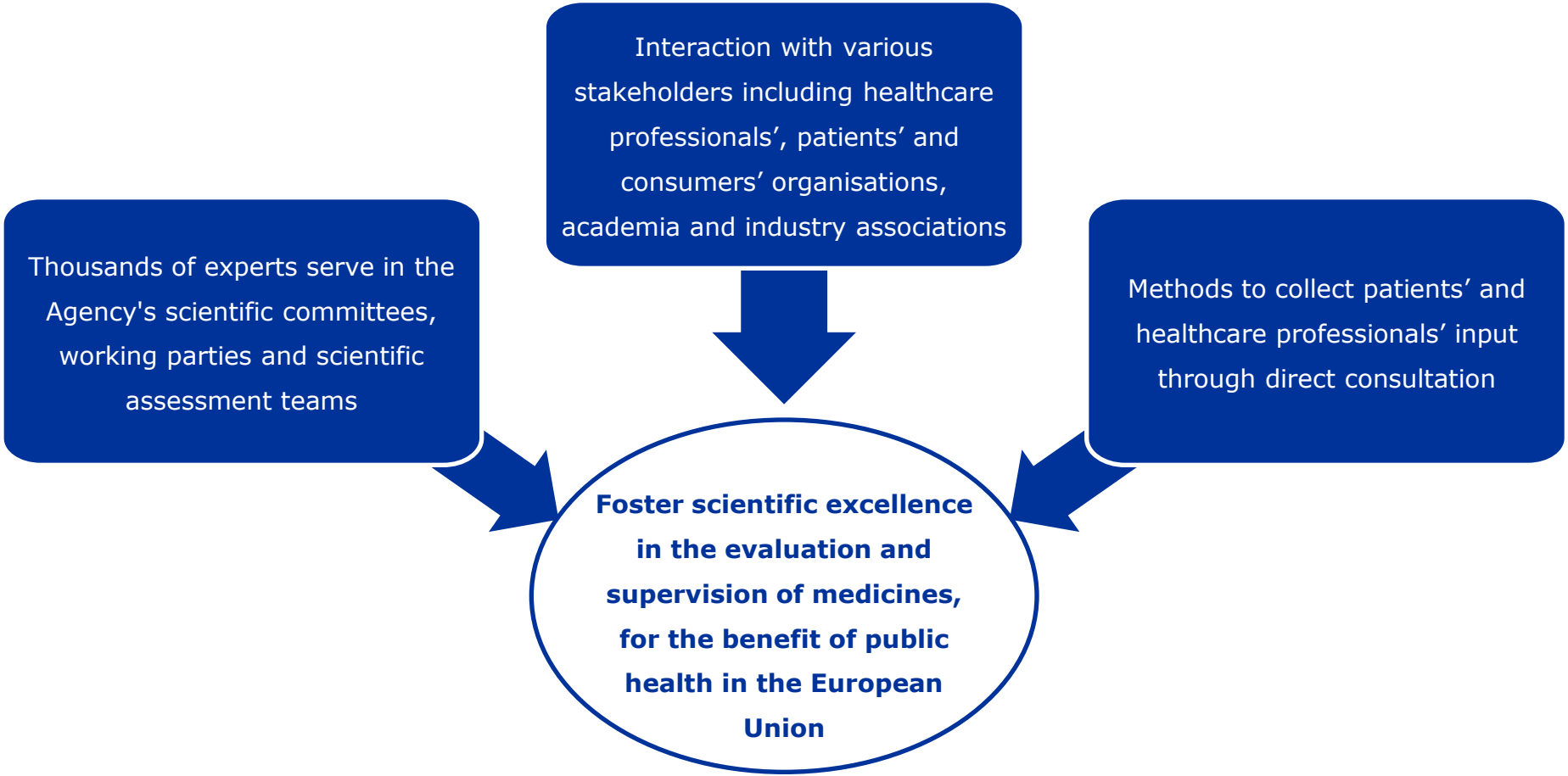
What we do

Protect human and animal health

- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- Provide reliable information on human and veterinary medicines to patients and healthcare professionals



Achieving EMA's mission



Collaboration with HCPs
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

2011
Framework of interaction with healthcare professionals and their organisations

2013
Healthcare professionals' Working Party (HCPWP) created

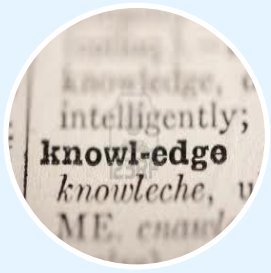
2014
Public Engagement Department

2016
Framework of interaction updated

Ongoing…
Systematic inclusion of real world clinical experience in EMA regulatory output

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**

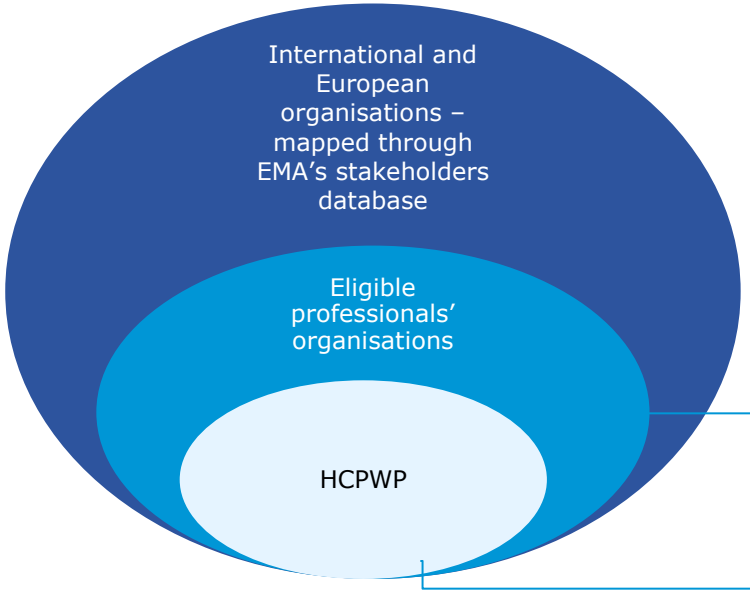
Contribute to a more efficient and targeted **communication** to healthcare professionals, to support their role in the safe and rational use of medicines



Enhance healthcare professional organisations' **understanding** of the role of the EU medicines Regulatory Network

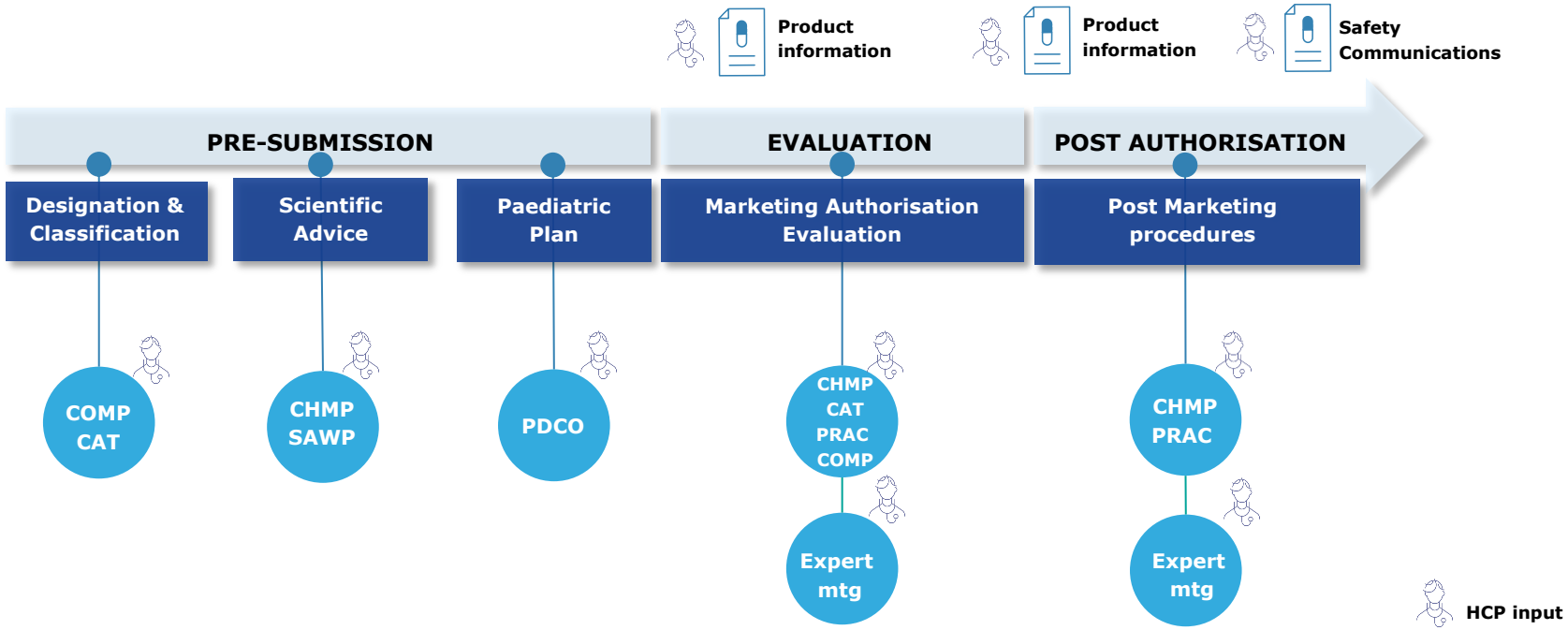
Network of European healthcare professional organisations

Sources for reaching out to healthcare professionals



Bringing expertise into the EU medicines regulatory system

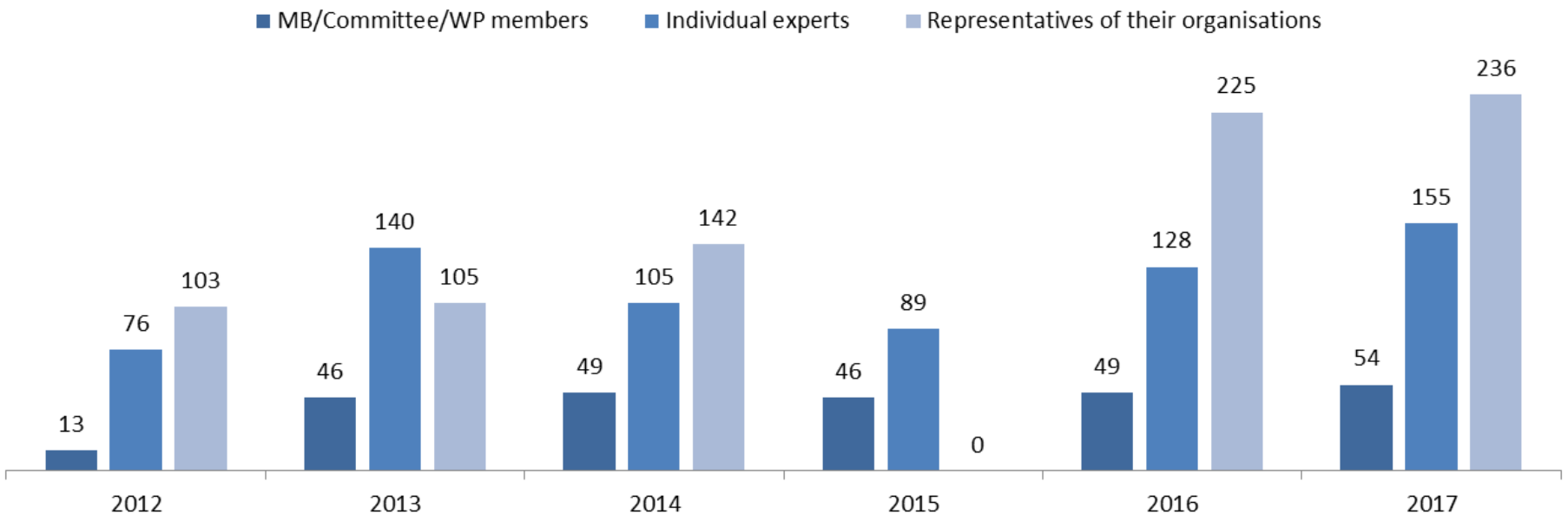
Involvement along the medicine lifecycle at EMA



Opportunities to bring on board input in evaluation activities

- 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

Increasing involvement in EMA activities



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 visibly recognise the contribution healthcare professionals provide to these activities

- Could EMA and UEMS explore together if and how these activities can be incorporated into healthcare professionals' CME-CPD?

Thank you for your attention

Further information

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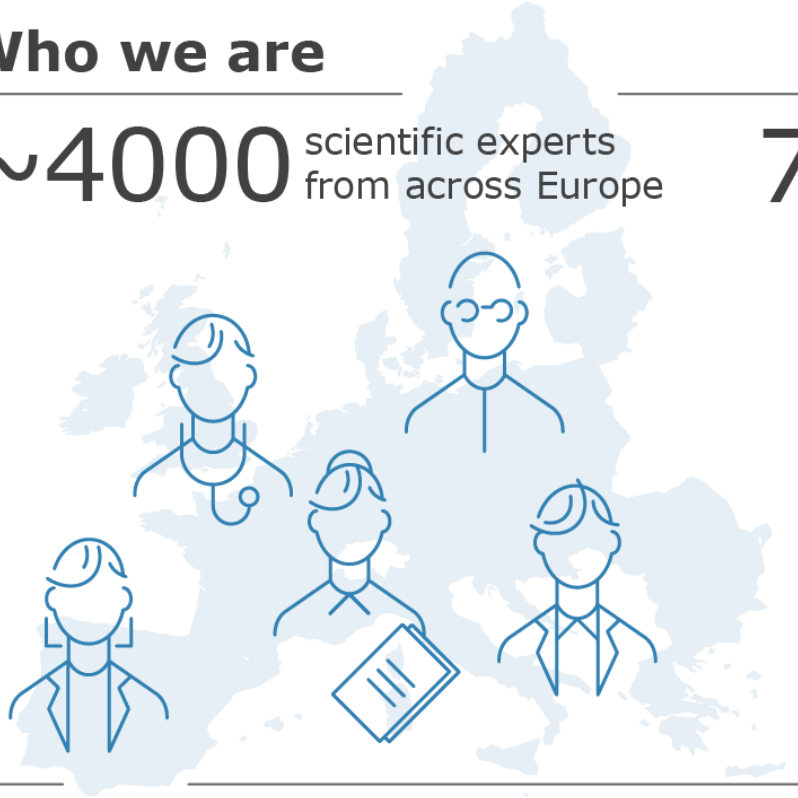
Who we are

~4000 scientific experts from across Europe

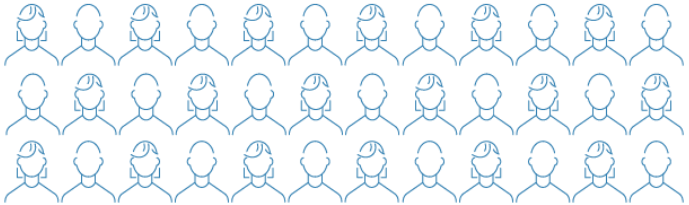


7 Scientific Committees

- CHMP
- CVMP
- COMP
- HMPC
- PDCO
- CAT
- PRAC

1 Management Board

- **28** Member States' representatives
- **4** Civil society representatives
- **2** European Commission representatives
- **2** European Parliament representatives



1995 EMA established

28 working parties

~900 staff members

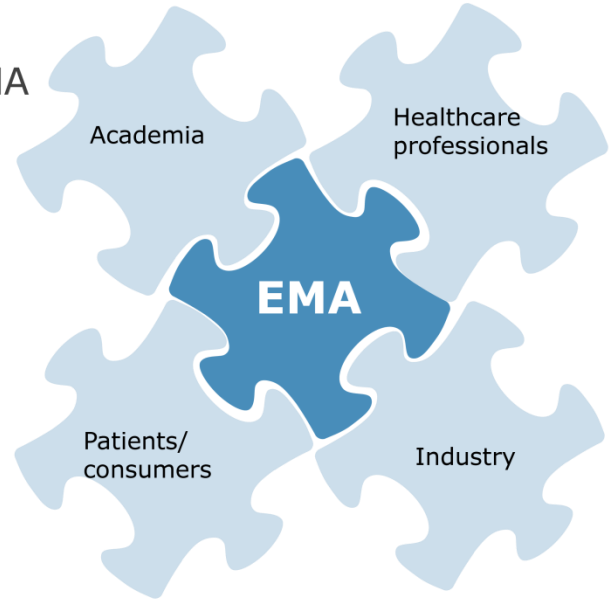
EMA stakeholder engagement

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



EMA Stakeholder engagement

Patients and healthcare professionals

Why?

- Experience of living with a disease and its treatment
- Reality of clinical practice

Who?

- European organisations, established representative groups
- Individual patients and healthcare professionals
- EC nominated members in scientific committees and management board

When? How?

- All along the medicines regulatory lifecycle (committees, medicines evaluation)
- Platforms for dialogue (PCWP and HCPWP)
- Workshops and public consultations on policies and guidelines

European experts

Healthcare Professionals Working Party (HCPWP)

Platforms for dialogue and exchange on relevant issues concerning medicines

The Working Party provides recommendations to EMA and its Human Scientific Committees on all matters of direct or indirect interest to healthcare professionals