EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA experience in supporting participation of patients and healthcare professionals in EU medicines regulation

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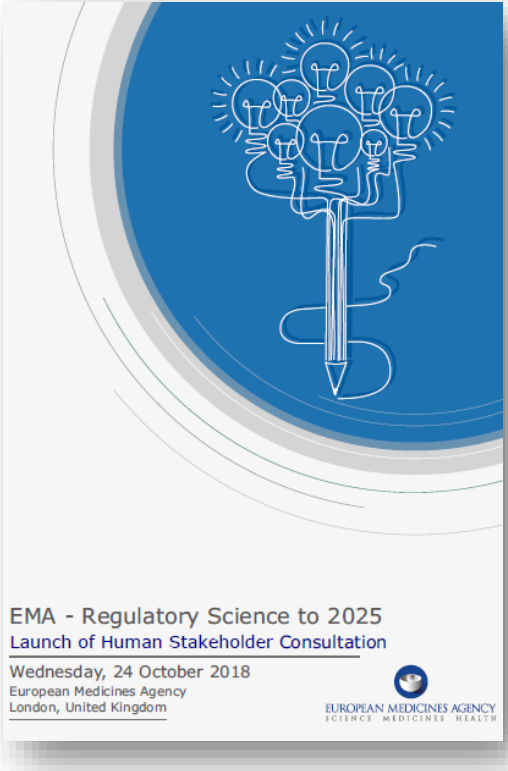
An agency of the European Union

Disclaimer

The presenter does not have any conflict of interests.

Vision - EMA Regulatory Science to 2025

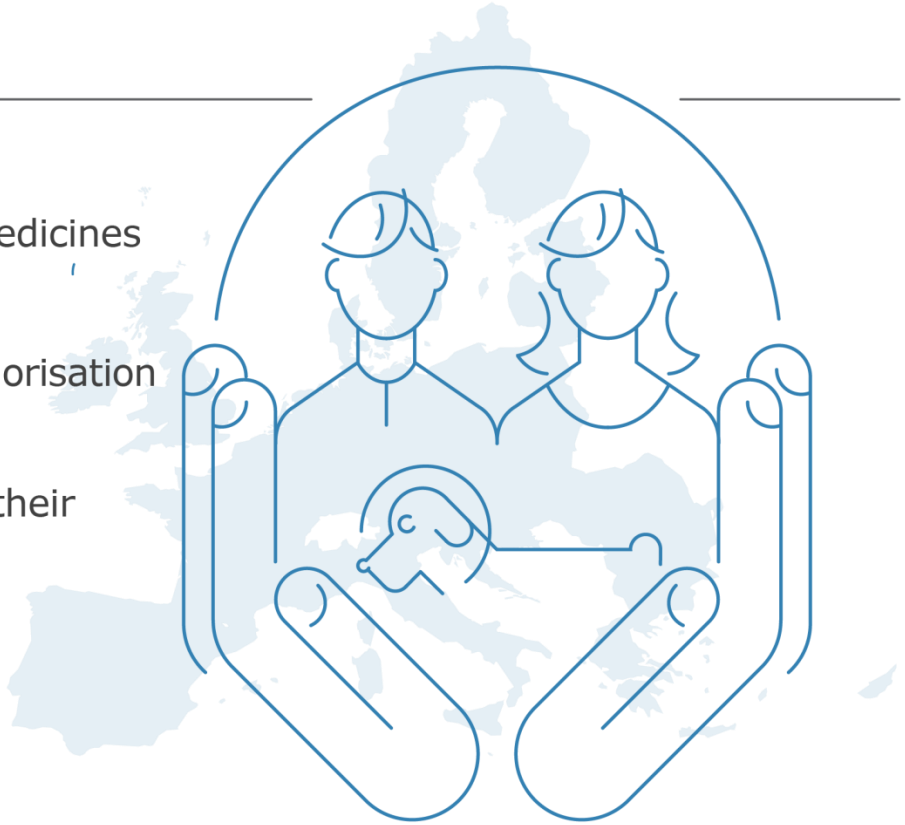
> To underpin its mission of protecting human health, EMA must catalyse and enable regulatory science and innovation to be translated into patient access to medicines in evolving healthcare systems.



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



Who we are

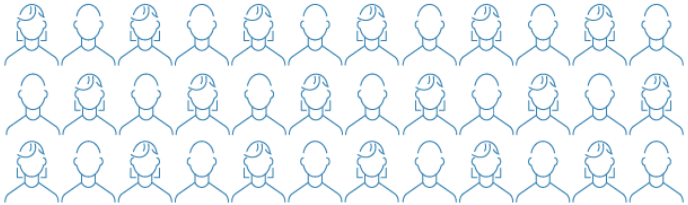
~4000 scientific experts from across Europe

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

The European medicines regulatory network

- ~50 national regulatory authorities
- European Medicines Agency
- European Commission

European experts

How EMA engages with stakeholders?

Patients, healthcare professionals, academia, industry

Inform
(announcement of review of policy or guidance; information days)

Consult
(written—public consultation on policies or guidance, surveys)

Consult and involve
(direct interactions—stakeholder meetings, workshops, conferences, public hearings)

Cooperate/participate
(direct interactions—technical expert groups, focus groups)

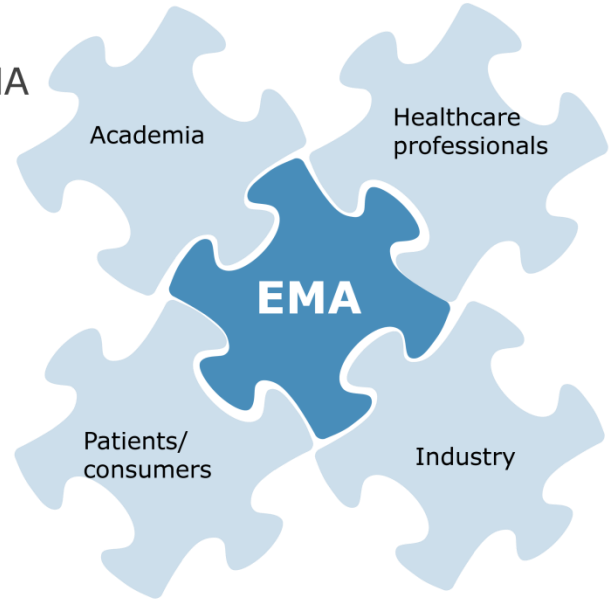
EMA stakeholder engagement

Promoting multi-stakeholder discussions

- Engage and involve stakeholders in EMA activities
- Enable stakeholders to share relevant issues with EMA

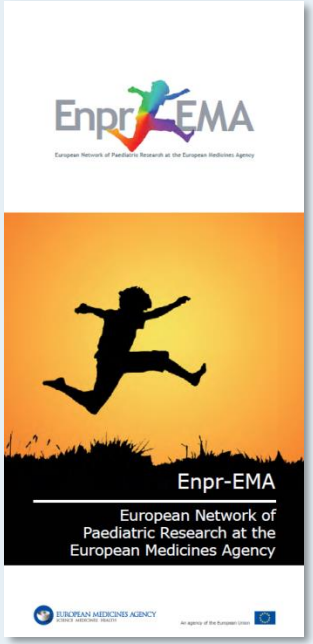
- Provide reliable, targeted and timely information
- Enhance understanding of EU medicines regulatory network
- Increase transparency and trust

- Use stakeholder relations to further support EMA's strategic priorities

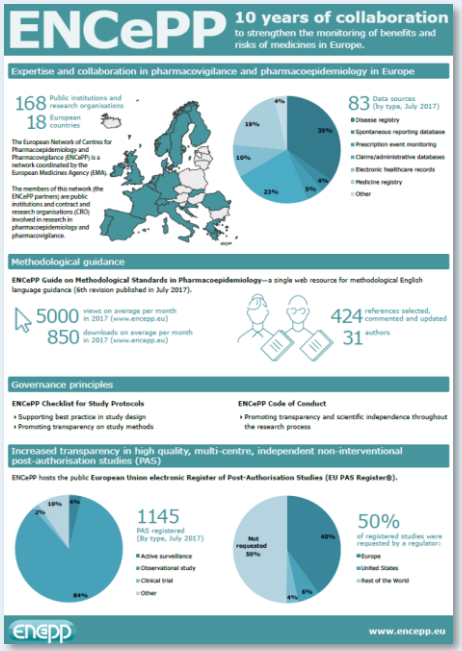


Participation in EMA-supported research networks

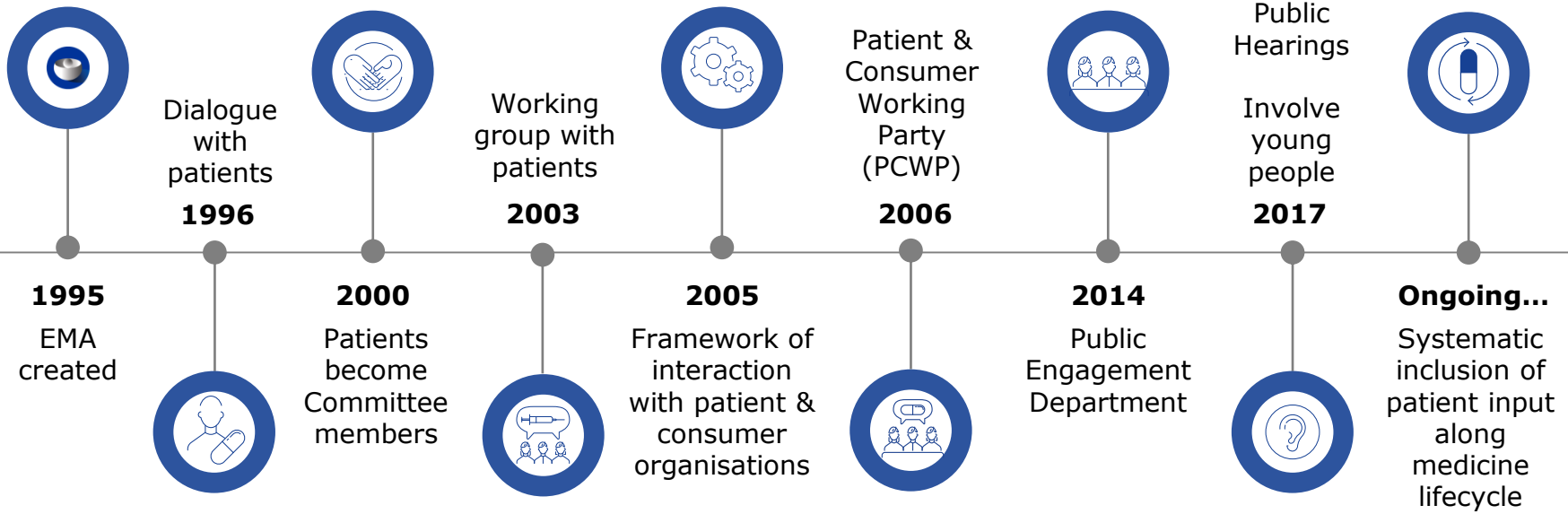
European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)



European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)



Interaction with patients
a progressive journey…



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
Dedicated Patients and Healthcare Professionals Department created

2016
Framework of interaction updated

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

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

Sources for reaching out to stakeholders

Individual expert database

Patients and Consumers Working Party (PCWP)

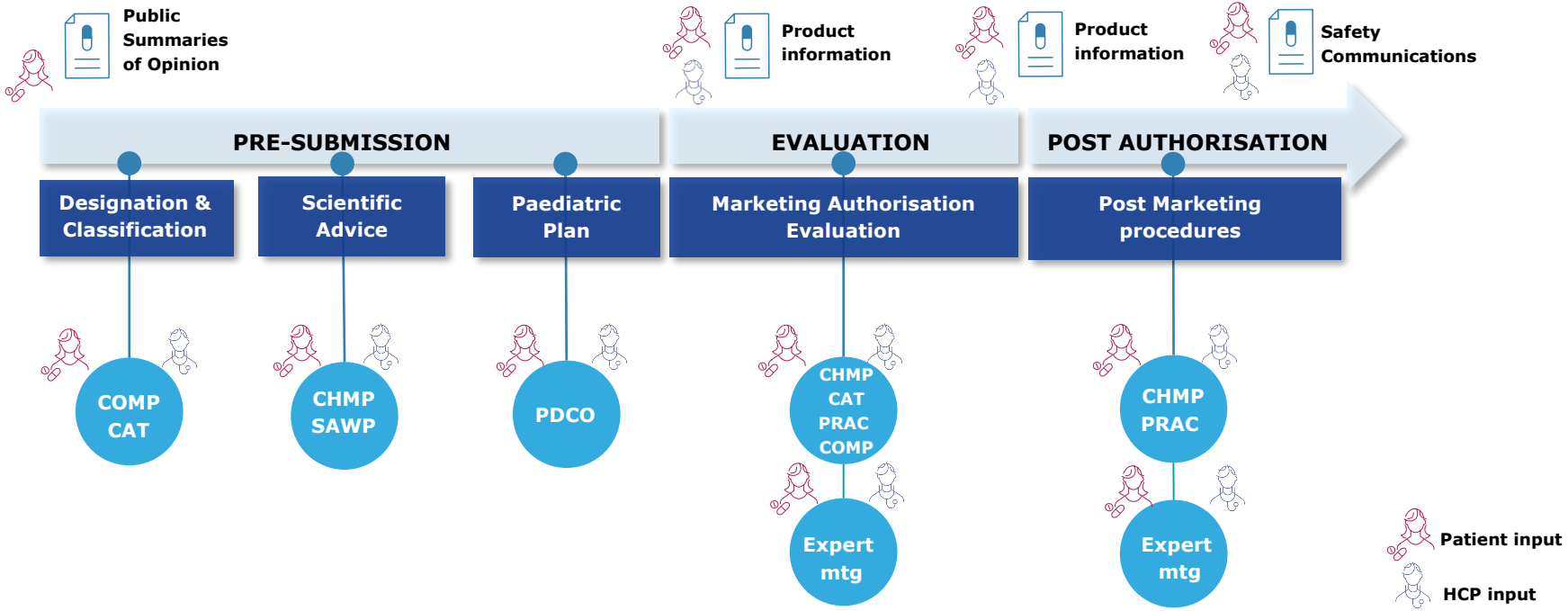
Healthcare Professionals Working Party (HCPWP)

Platforms for dialogue and exchange on relevant issues concerning medicines

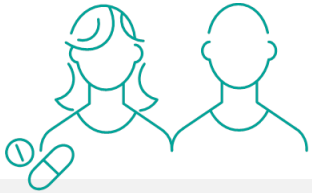
The Working Parties provide recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to patients and healthcare professionals

Bringing expertise into the EU medicines regulatory system

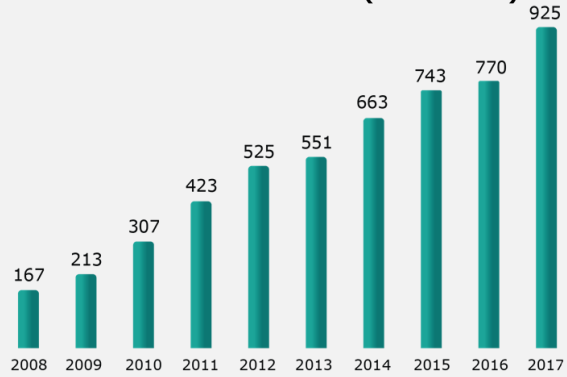
Involvement along the medicine lifecycle at EMA



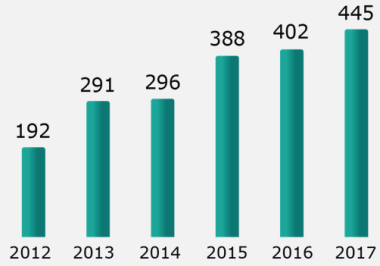
Increasing involvement in EMA activities



Patients and Consumers (2008-2017)



Healthcare professionals (2008-2017



Conclusion

- Providing **access to high quality medicine** is an objective which requires constant efforts and continuous improvement in drug development, evaluation and post-authorisation monitoring
- This objective can only be achieved through **close collaboration** between all partners, *i.e.* regulators, academics, industry, learned societies, patients, healthcare professionals and also payers
- Important to go deeper into areas of common interest and identify an **appropriate mechanism to channel input and feedback**

Thank you for your attention

Further information

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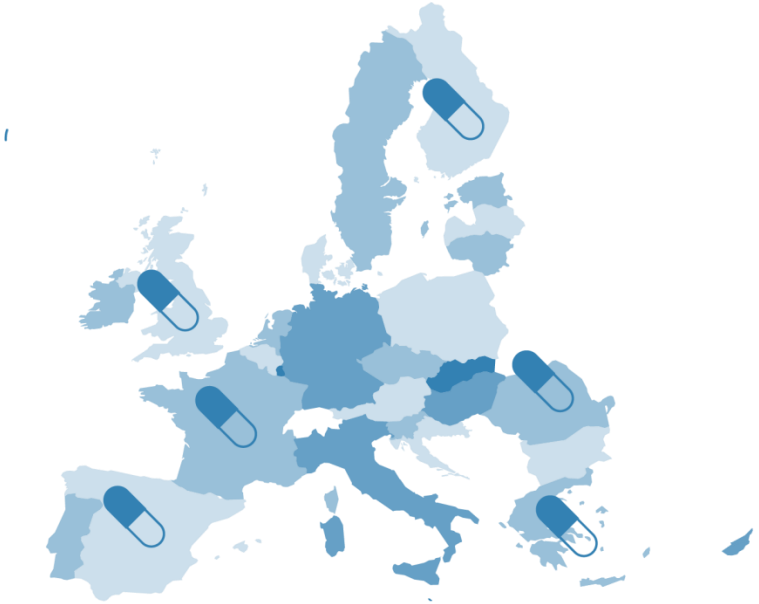
How are medicines approved?

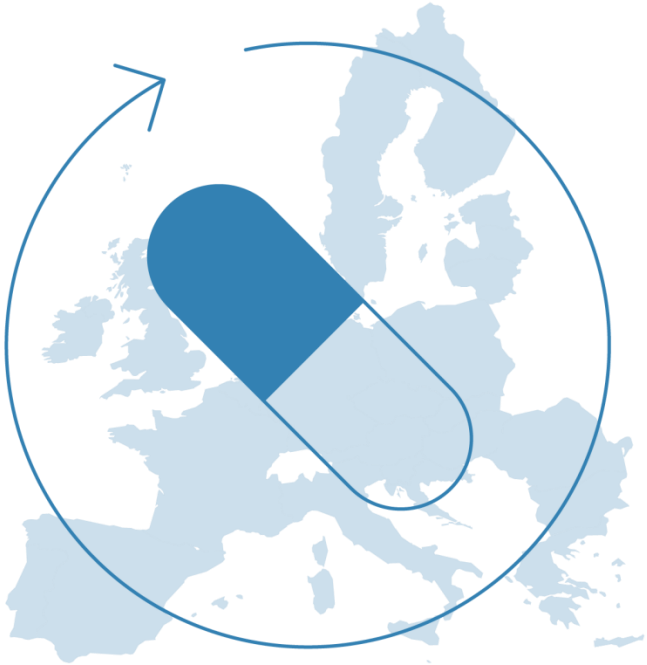
Different authorisation routes: one set of common rules

Centralised procedure (via EMA)



National procedures (via Member States)

Which medicines are approved through the centralised procedure?



- Human medicines containing new active substances for the treatment of HIV/AIDS cancer, diabetes, neurodegenerative diseases, auto-immune, and other immune dysfunctions, and viral diseases
- Medicines derived from biotechnology processes, such as genetic engineering
- Advanced therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines
- Officially designated 'orphan medicines' (medicines used for rare human diseases)
- Veterinary medicines for use as growth or yield enhancers

What is the benefit of the centralised procedure for EU citizens?

Medicines are authorised in all EU countries at the same time

Centralised safety monitoring

ABC
XΨΩ
Product information available in all EU languages at the same time

Access to the largest network of experts in medicines regulation