EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patient engagement at the European Medicines Agency

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National Association of Patient Organisations (NAPO) Conference

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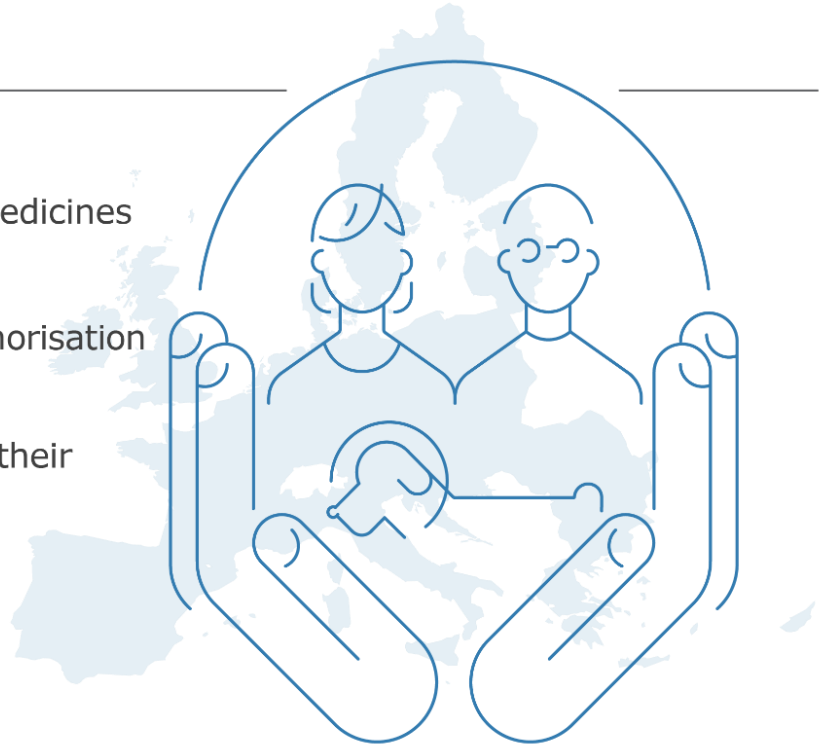
What we do

Protect human and animal health

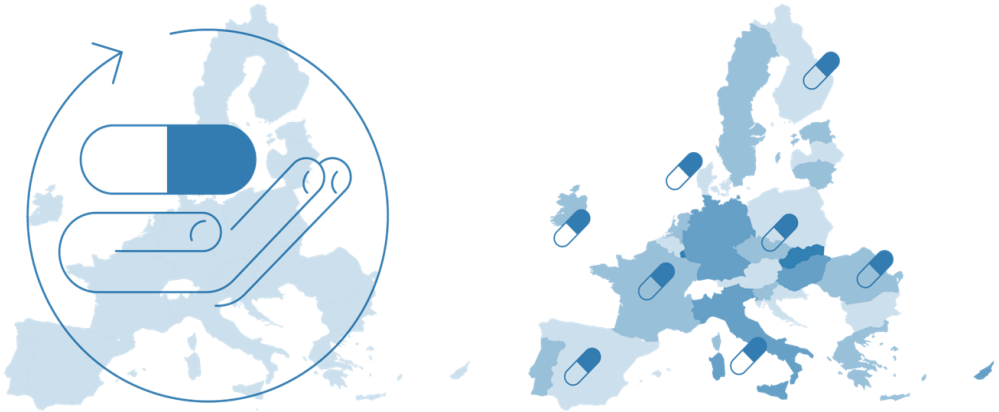
- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- ABC XΨΩ Provide reliable information on human and veterinary medicines to patients and healthcare professionals



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

How are medicines approved?

Different authorisation routes: one set of common rules



Centralised procedure (via EMA)

National procedures (via Member States)

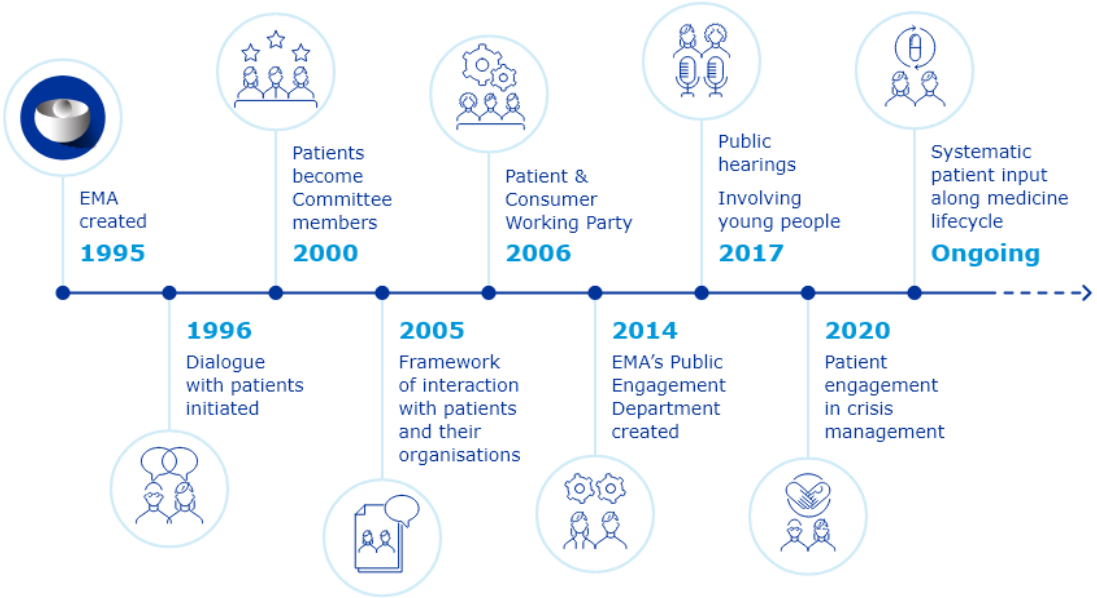
Medicines are authorised in all EU countries at the same time

Centralised safety monitoring

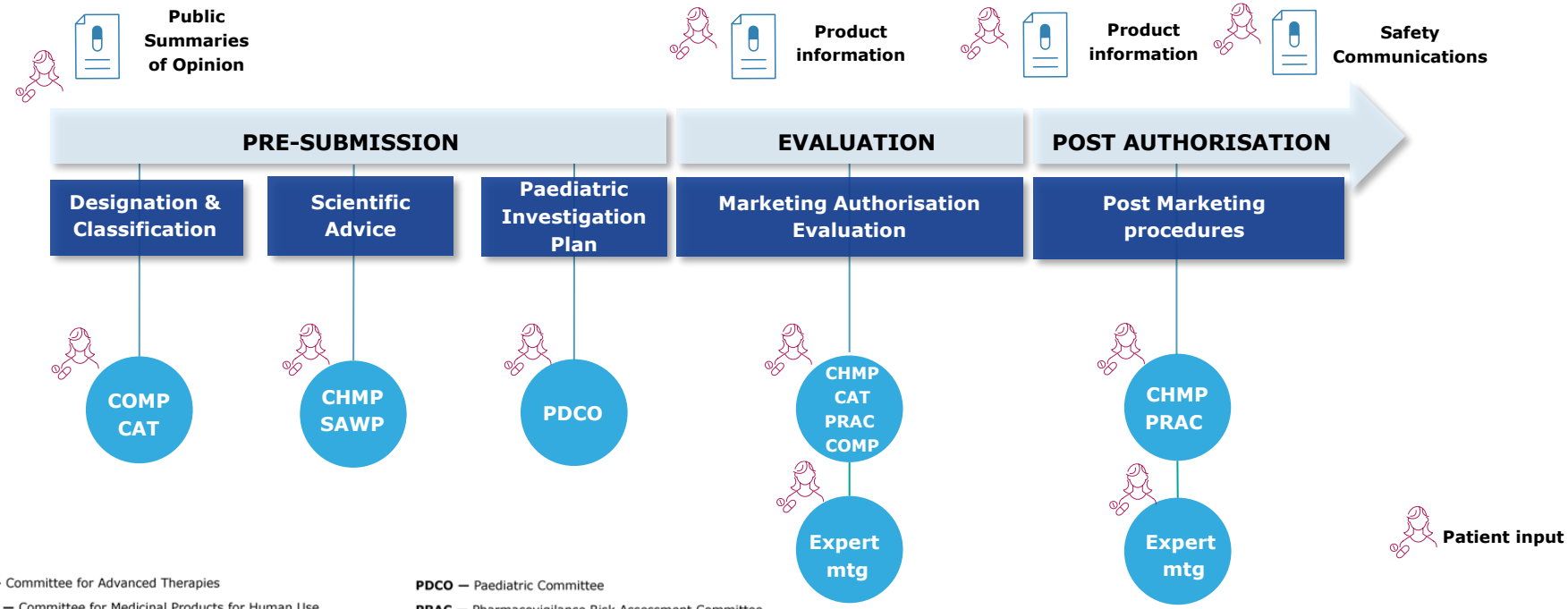
Product information available in all EU languages at the same time

Access to the largest network of experts in medicines regulation

Interaction with patients and consumers: a progressive journey…



Patient involvement in the medicines regulatory lifecycle



CAT — Committee for Advanced Therapies
CHMP — Committee for Medicinal Products for Human Use
COMP — Committee for Orphan Medicinal Products
PDCO — Paediatric Committee
PRAC — Pharmacovigilance Risk Assessment Committee
SAWP — Scientific Advice Working Party

Who does EMA interact with?

International/European organisations – EMA stakeholders database

Eligible organisations

Organisation representatives	Individual Experts
EMA 'eligibility' criteria	**Declaration / assessment of Interests**
Transparent on the funding of the organisation ▶ Legitimacy ▶ Mission/activities ▶ Representation ▶ Structure ▶ Accountability ▶ Transparency	**Confidentiality undertaking** Identification through European network of registered organisations and EMA database of individuals

Patients representing their community

7 Scientific Committees

1 Management Board

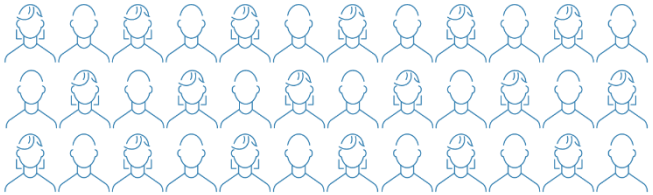
- CHMP
- CVMP
- COMP
- HMPC
- PDCO
- CAT
- PRAC

27 Member States' representatives

4 Civil society representatives

2 European Commission representatives

2 European Parliament representatives



~800 staff members

Management Board
EMA Scientific Committee Members

Patient membership

Patient engagement at EMA

Patients representing their organisations

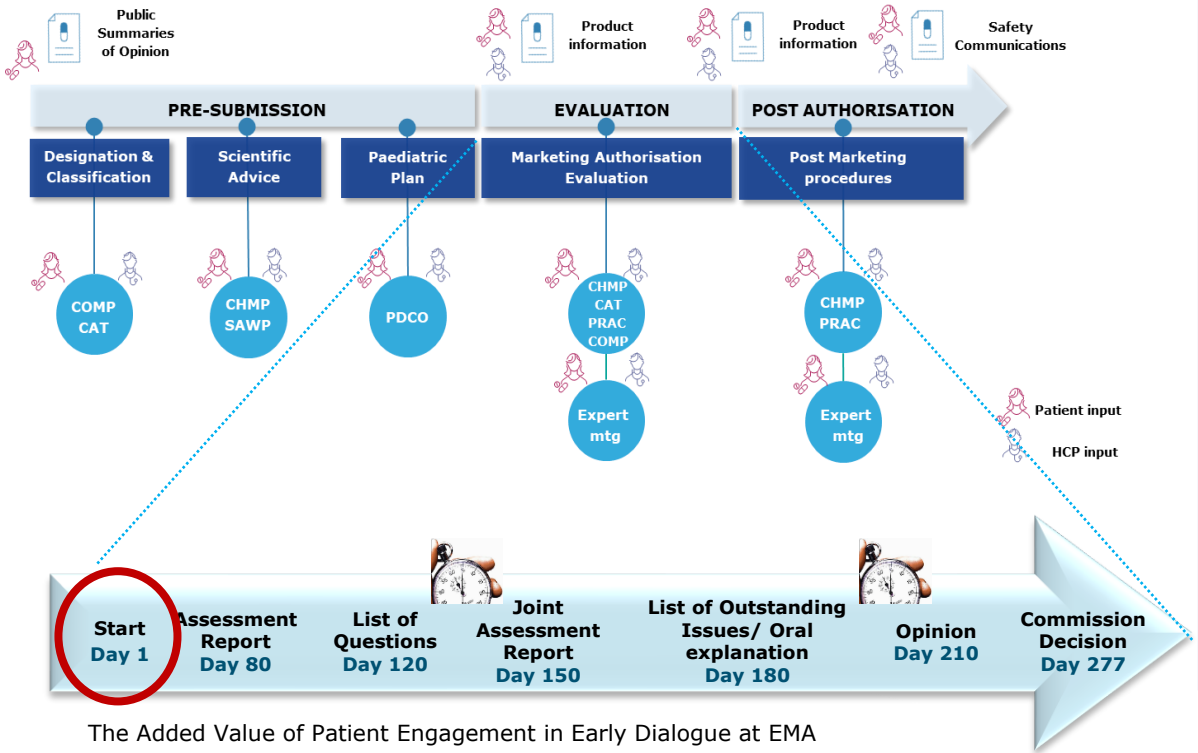
Patients and Consumers Working Party (PCWP)

Healthcare professional working party (HCPWP)

- Act as filter and generator of activities at EMA
  - Workshops
  - Information sessions
  - Training
  - Topic groups

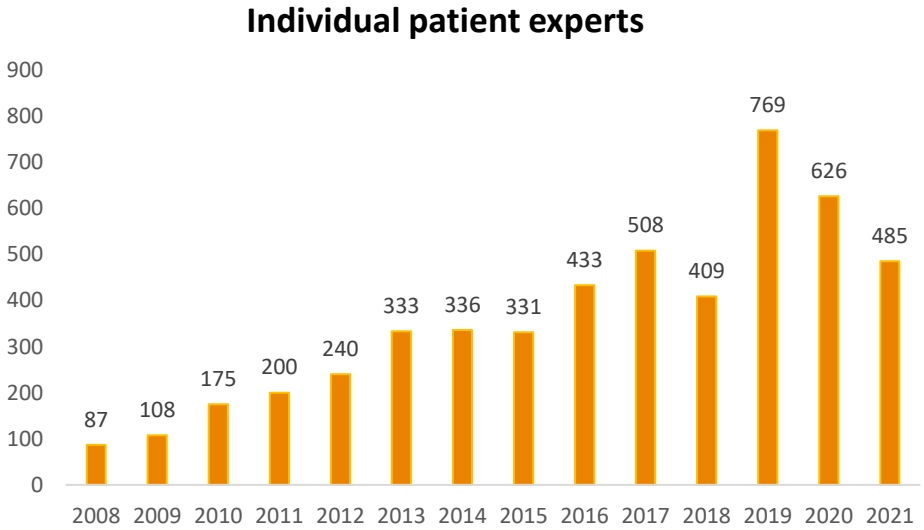
Working Party (PCWP or HCPWP)
EMA consultations
Workshops

Patient organisations in medicine-specific activities



- Relevant organisations contacted at start of orphan MAA's
- Patient organisations invited to share key aspects from their perspectives of living with the condition (3-4 weeks to respond) (in advance of first AR).
- Information shared with (Co-) Rapporteurs (and company for transparency) - Rapps decide if information provides added value, is useful for assessing the dossier, and if merits being included in AR.
- Value of patient input received during pilot assessed by short questionnaire

Patients as individual experts in medicine-specific activities



Scientific Advice / Protocol Assistance Procedures
Scientific Advisory/ad hoc expert Groups
Scientific Committee consultations
Review of documents

Challenges of patient engagement

- Finding suitable patients (e.g. language barrier, availability)
- Ensuring comprehensive, tailored training to facilitate and enhance participation
- Provide a clear definition of patients role in the different activities / committees to manage expectations from all angles
- Managing potential conflicts of interest
- Representativeness
- Measuring the value / impact of patients

Conclusions

- Engaging with patients and their organisations:
  - Brings **everyday aspects** of living with a disease **into scientific discussions**
  - Helps **bridge the gap** between clinical trial data and real world data
  - Increases **transparency, awareness and understanding: TRUST**
- Engage in a **stepwise approach; learn together** what format works best;
  - **Define roles** - manage expectations
  - Ensure engagement is **mutually beneficial**

Everyone has a role to play to ensure engagement happens

Engaging with patients leads to **more meaningful outcomes** for everyone!

Any questions?

Further information

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