



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Civil society members in EMA scientific committees: an overview

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Annual PCWP/HCPWP meeting with all eligible organisations

Presented by Maria Mavris on 24 November 2021  
Public and Stakeholders Engagement Department

An agency of the European Union



# EMA scientific committees and Management Board

**7** Scientific Committees

**1** Management Board

CHMP

27 Member States' representatives

CVMP

4 Civil society representatives 



COMP

2 European Commission representatives

HMPC

2 European Parliament representatives



PDCO



CAT



PRAC



**~800** staff members

Civil society members in EMA scientific committees

[CHMP](#): Committee for Human Medicinal Products

[CVMP](#): Committee for Veterinary Medicinal Products

[COMP](#): Committee for Orphan Medicinal Products

[HMPC](#): Committee on Herbal Medicinal Products

[PDCO](#): Paediatric Committee

[CAT](#): Committee for Advanced Therapies

[PRAC](#): Pharmacovigilance and Risk Assessment Committee

[SAWP](#): Scientific Advice Working Party



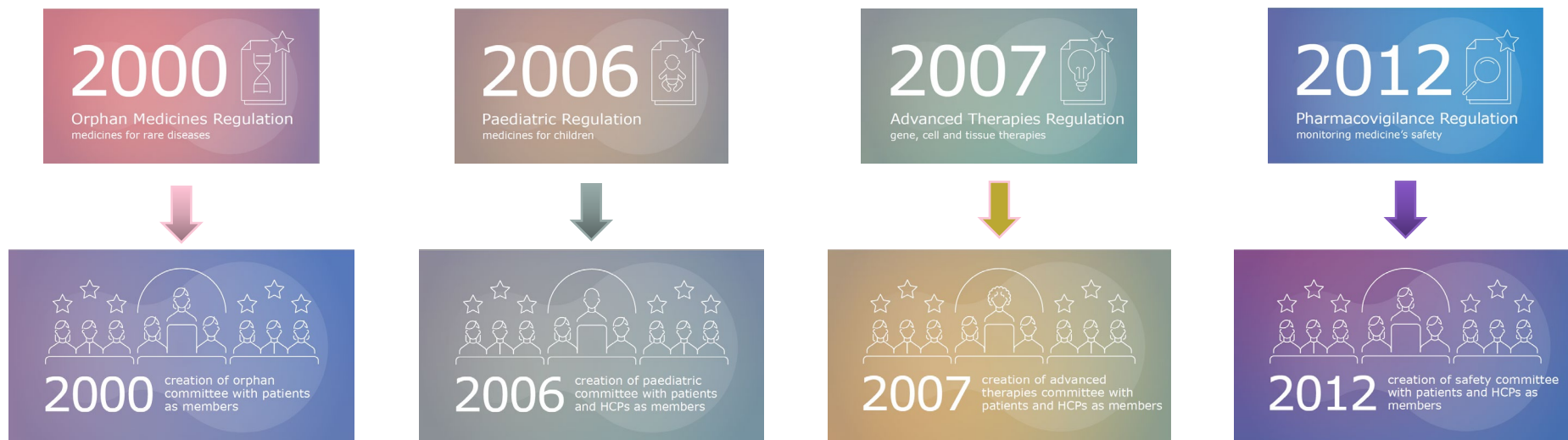
**Patient membership**



**HCP membership**



# Regulations and creation of committees





# Committees and membership

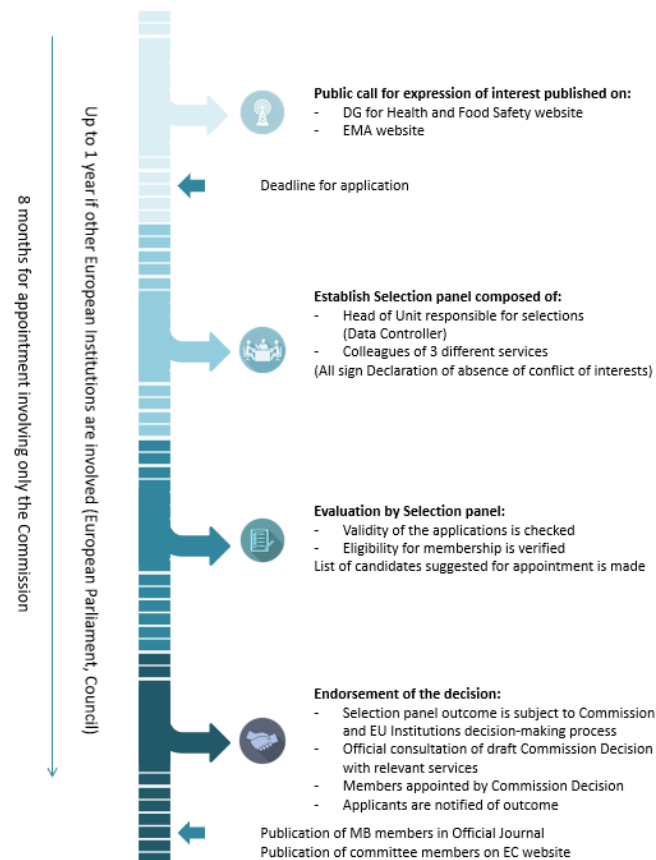
Committee	Members/Alternates
<b>COMP</b>	three members representing patients
	no members representing healthcare professionals
	no alternate for any committee members
<b>PDCO</b>	three members and three alternates representing patients
	three members and three alternates representing healthcare professionals
<b>CAT</b>	two members and two alternates representing patients
	two members and two alternates representing clinicians
<b>PRAC</b>	one member and one alternate representing patients
	one member and one alternate healthcare professionals

\* These members are nominated by the European Commission



# European Commission nomination process: overview

[https://www.ema.europa.eu/en/documents/other/role-members-representing-patients-healthcare-professionals-organisations-ema-scientific-committees\\_en.pdf](https://www.ema.europa.eu/en/documents/other/role-members-representing-patients-healthcare-professionals-organisations-ema-scientific-committees_en.pdf)

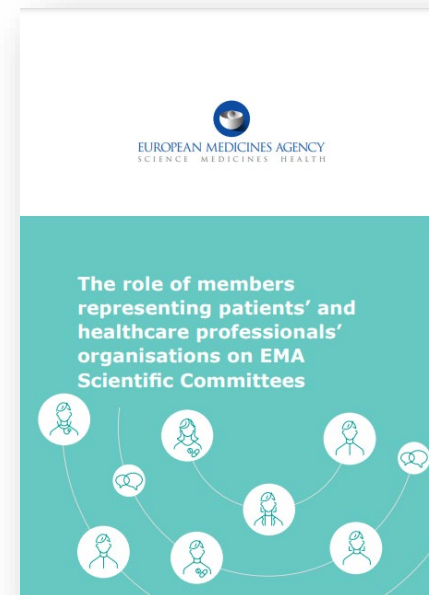




# Role of civil society members in committees

Analysis of experience acquired demonstrated

- participation of patients and healthcare professional representatives **improves** the **quality of the opinion** of the committees.
- their contribution **increases transparency** and **trust** in regulatory processes
- develops **mutual respect** between regulators and the community.





## The role of the members representing patients' organisation:

- bring a **unique and critical input** based on **living with a condition** and its **current therapeutic environment**;
- **complements the scientific information** and fills a gap;
- **not expected** to be of a scientific nature;
- although patients can frequently contribute scientifically to the discussion;

**Added value** is to bring their unique real-life perspective as **end-users of medicines** and to ensure that this is delivered throughout the committee's activities and outcome.



## The role of members representing healthcare professionals' organisations:

- bring expertise and views of wider community of **practicing specialists, general practitioners, nurses and pharmacists**.
- **support and reinforce existing knowledge** within the European Regulatory Network with **additional input from day-to-day** clinical practice;
  - includes prescribing, dispensing and/or administering medicines and provide valuable insight on the potential **impact of regulatory decisions**.
- **not expected** to bring regulatory expertise to the committees,

**Added value** is to ensure the implications of regulatory decisions are taken into account.





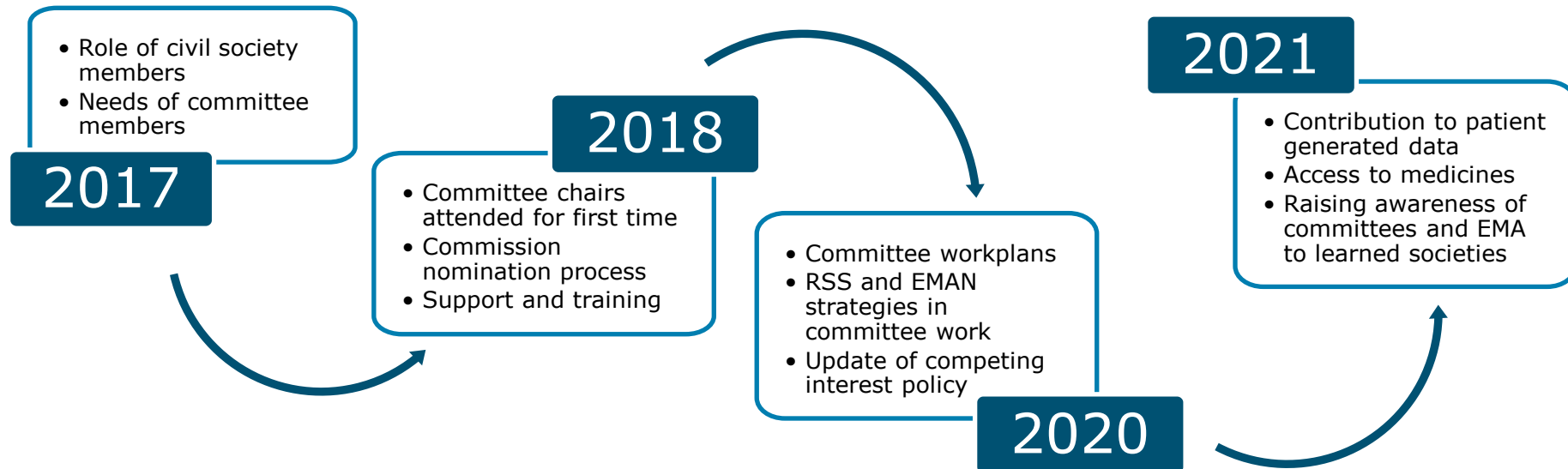
# Support

- Regular meetings with civil society members of each committee (2 x year)
- Annual meetings with all civil society members since 2017
- Committee chairs may attend regular meetings and annual meetings
- Public engagement contact point in addition to individual committee secretariats





# Discussions



Engagement of patients and HCP in committee activities



# Conclusions

Opportunity for :

- exchange between all civil society members on rare disease, paediatric, advanced therapy and safety committees;
- Committee chairs to discuss with civil society members and further explore needs of patients and healthcare professionals in the EU;
- EMA to hear the views of the different committees outside of the committee work in the plenary meetings
- Identification and exploration of overlapping issues identified by different committees



# Any questions?

## Further information

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