



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Medicines Agency (EMA)

Public and Stakeholder Engagement Department

EMA virtual training session

Presented by Nathalie Bere
Public and Stakeholder Engagement Department
Stakeholders and Communication Division

An agency of the European Union





What we do

Protect human and animal health



Facilitate development and access to medicines



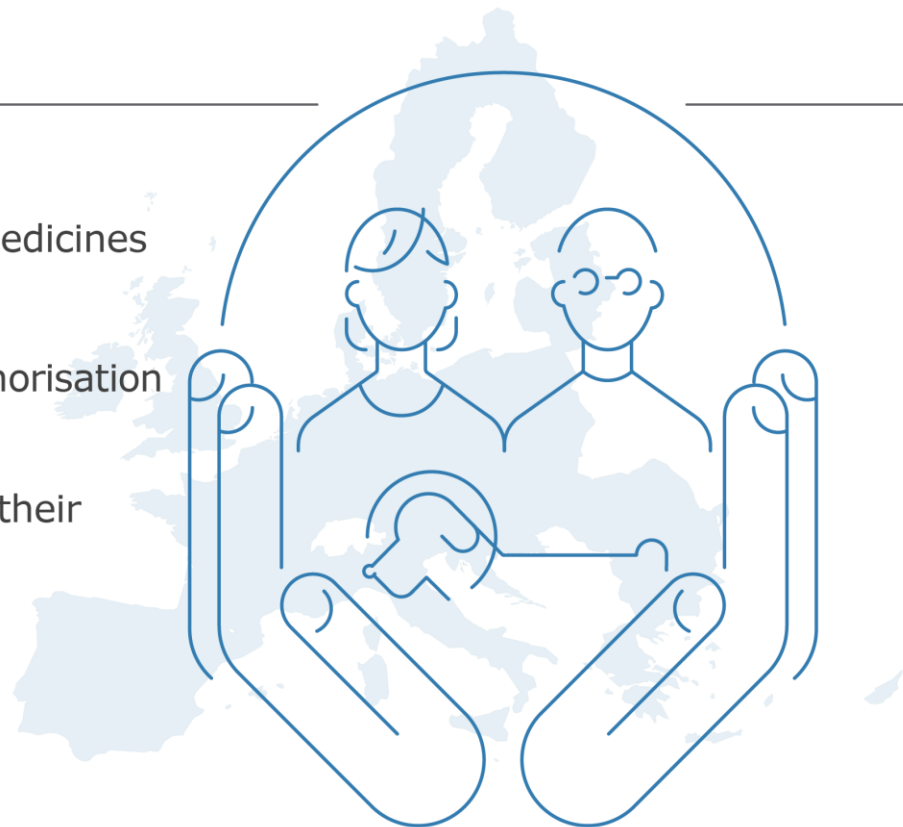
Evaluate applications for marketing authorisation



Monitor the safety of medicines across their life cycle



Provide reliable information on human and veterinary medicines to patients and healthcare professionals



The key roles of the EMA

- Provision of **scientific advice** on the development of medicines
- Evaluation of applications for **orphan designation** in EU
- Evaluation of **paediatric investigation plans** (or waivers)
- **Evaluation** of marketing authorisation applications for human and veterinary medicines
- Coordination of European **pharmacovigilance** (supervision of medicines)
- Provision of **information** on medicines to patients and healthcare professionals
- Evaluation of **arbitration** and **referral** procedures

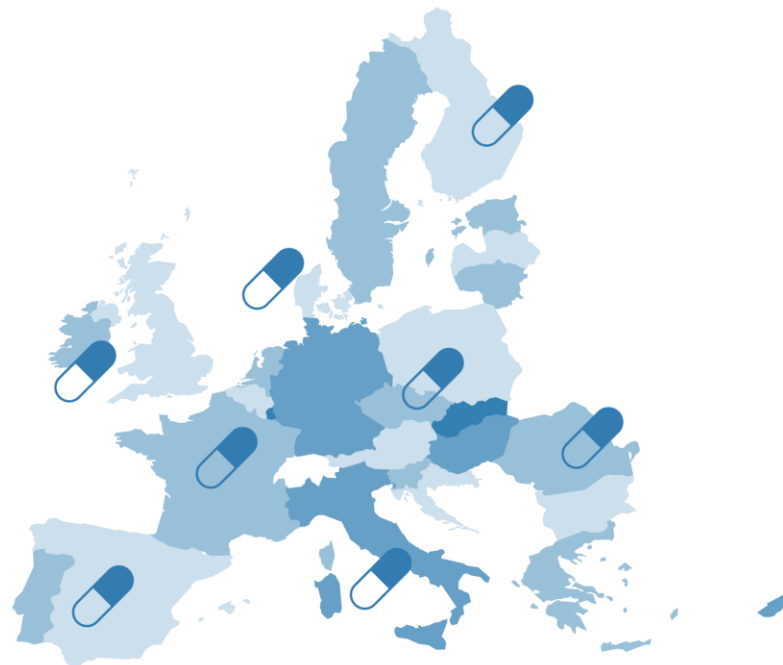


How are medicines approved?

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)
- 💊 Innovative veterinary medicines and products to be used as growth enhancers



Who we are

~4000 scientific experts
from across Europe



7 Scientific
Committees

CHMP

CVMP

COMP

HMPC

PDCO

CAT

PRAC

1 Management
Board

27 Member States' representatives

4 Civil society representatives

2 European Commission representatives

2 European Parliament representatives

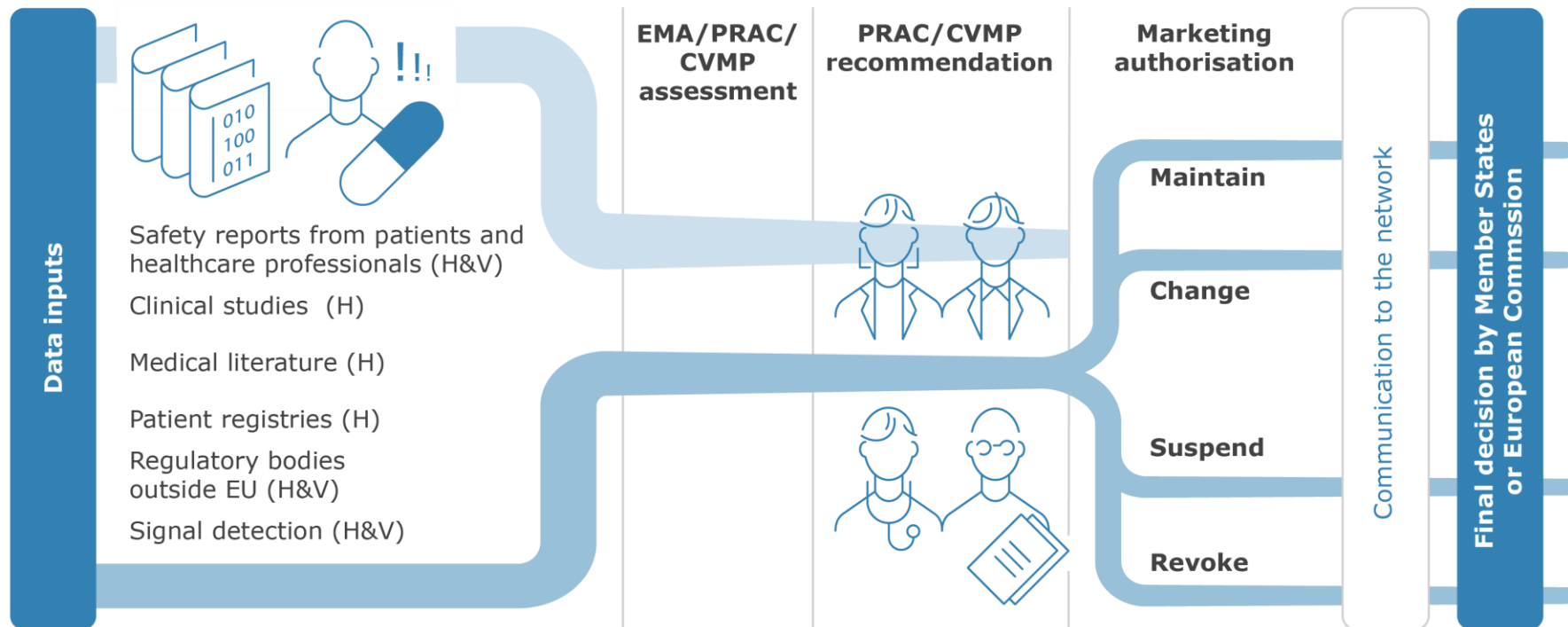


1995 EMA established

~800 staff
members

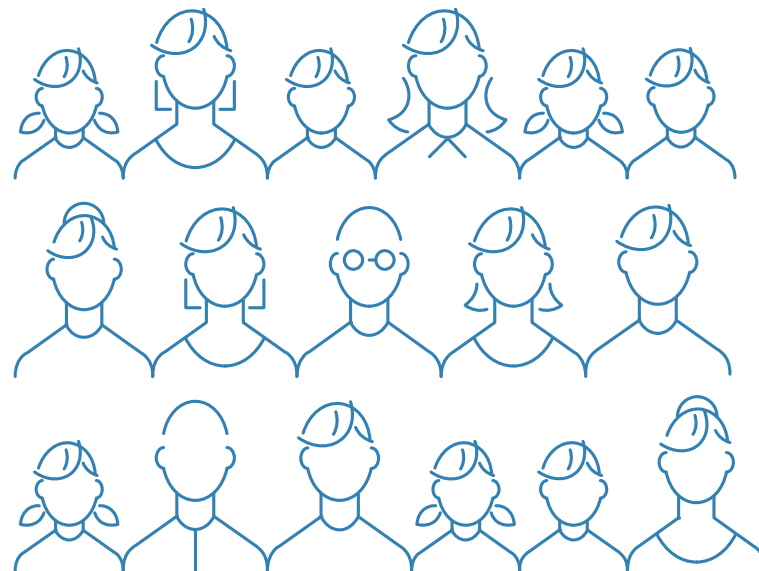


How do we monitor the safety of medicines already on the market?





Patient and healthcare professional engagement: **Integral element of EMA activities**



Patients and healthcare professionals



To gather experience of living with a disease and its treatment
To better understand the reality of clinical practice



European organisations, established representative groups
Individual patients and healthcare professionals
EC nominated members in scientific committees and the Management Board

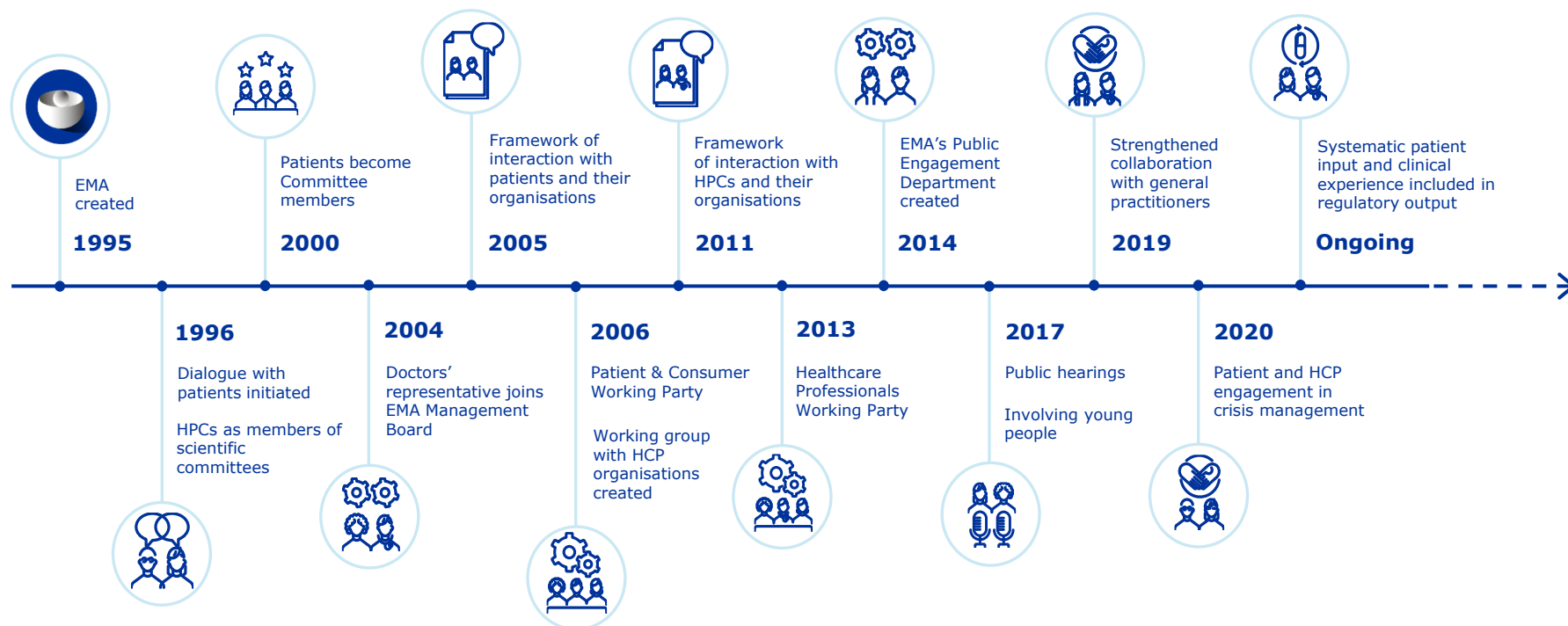


Opportunities all along the regulatory lifecycle (committees, medicines evaluation)
Platforms for dialogue (patient and healthcare professionals working parties)
Workshops and public consultations on policies and guidelines

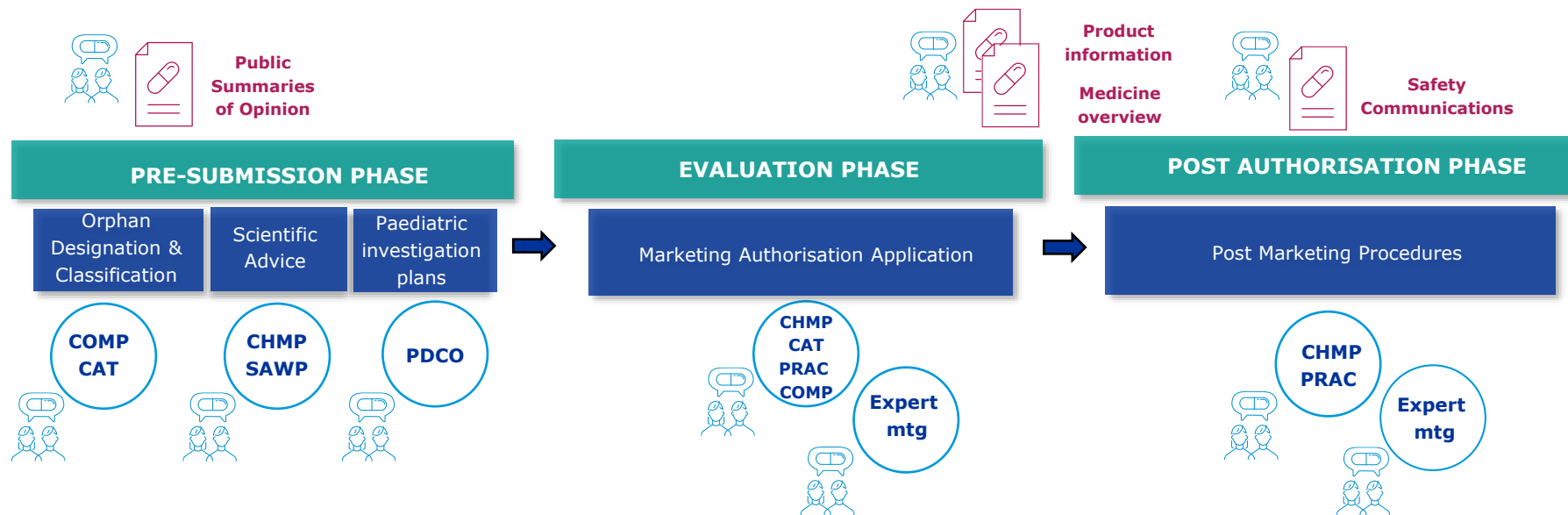


How does EMA engage with patients and healthcare professionals?

Public and Stakeholders Engagement Department



Involvement along the medicine lifecycle at EMA





How are patients and healthcare professionals involved at 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
Scientific Committee consultations
Review of documents

Patient and healthcare professional networks

- **Organisations** representing EU patients / consumers can register on our website [here](#)
- **Individual** patients or carers may register here:



- **Organisations** representing EU healthcare professionals can register [here](#)

Eligible patients and consumers organisations



Eligible healthcare professionals' organisations



How do we ensure reliability/independence of experts?

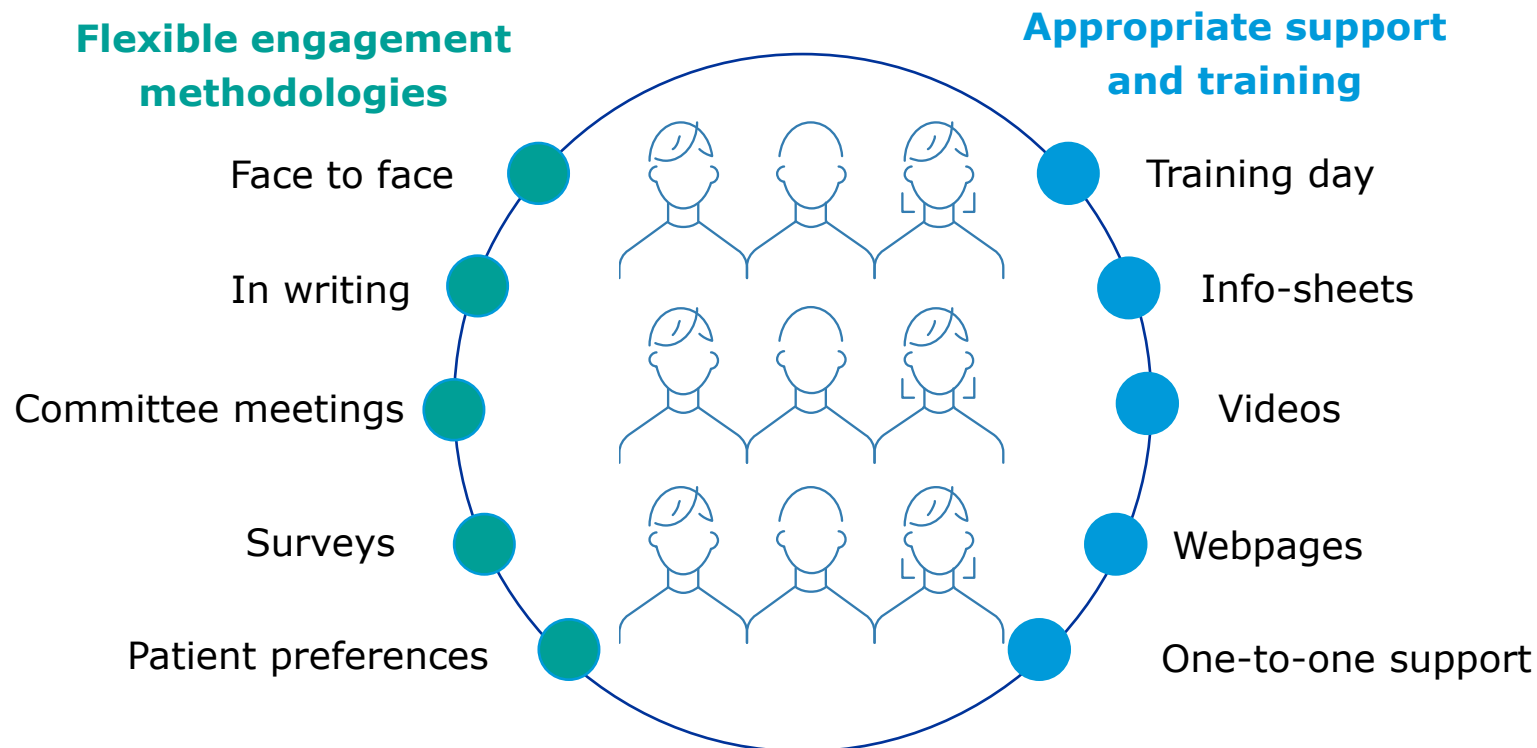
Organisation representatives	Individual Experts
EMA 'eligibility' criteria	Declaration / assessment of Interests
Transparent on the funding of the organisation <ul style="list-style-type: none"> ▶ Legitimacy ▶ Mission/activities ▶ Representation ▶ Structure ▶ Accountability ▶ Transparency 	Confidentiality undertaking <p>Identification through European network of registered organisations and EMA database of individuals</p>



Vital elements



One size does not fit all!



Summary messages – patients

Engaging with patients;

- brings **everyday aspects** of living with a condition into **scientific discussions**
- helps **bridge the gap** between clinical trial data and real world data
- increases **transparency, awareness** and **understanding**

Looking ahead:

- Adapt to new ways of data collection, including digital and RWD
- Broaden patient data collection (focus groups, patient preferences)
- Enrich training and support with new tools and content





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Take home messages

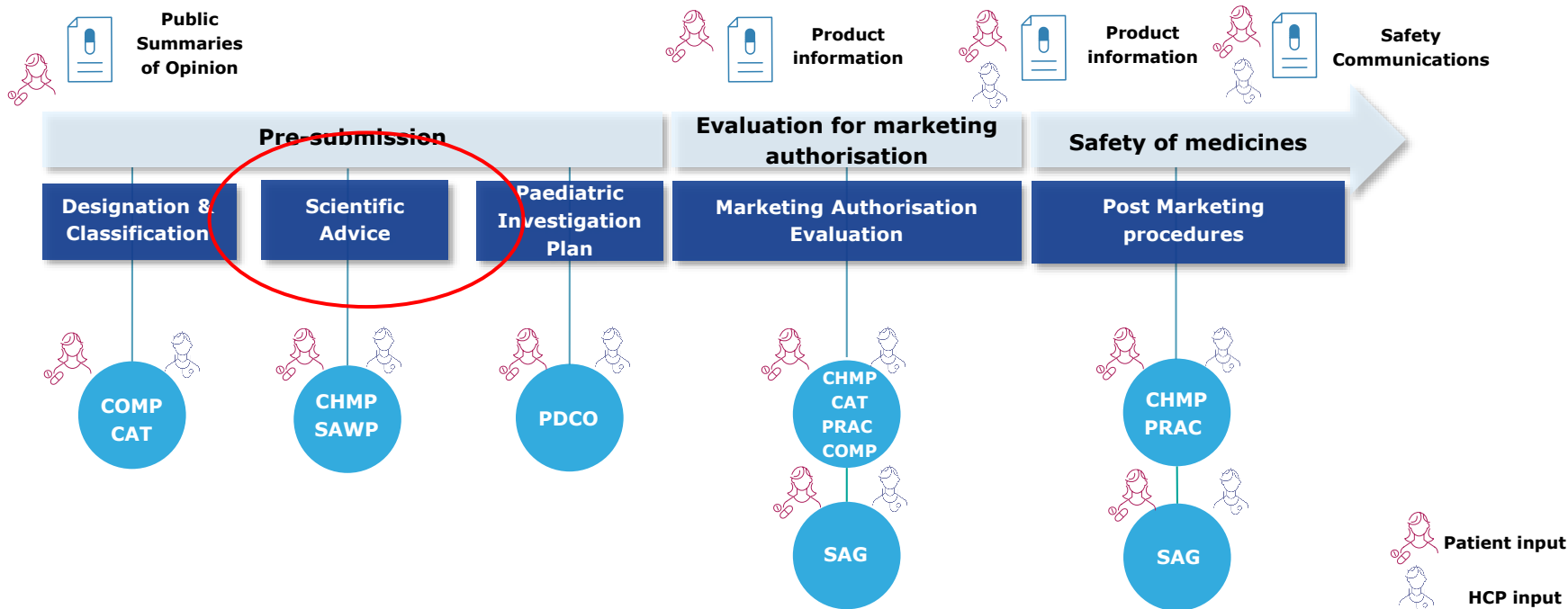
EMA virtual training session

Presented by Juan Garcia Burgos on 24 November 2021
Head of Public and Stakeholder Engagement Department

An agency of the European Union



Patient and healthcare professional involvement



* **COMP:** Committee for Orphan Medicinal Products; **CHMP:** Committee for Human Medicinal Products; **CAT:** Committee for Advanced Therapies; **PDCO:** Paediatric Committee; **SAWP:** Scientific Advice Working Party; **SAG:** Scientific Advisory Group; **PRAC:** Pharmacovigilance and Risk Assessment Committee;



When will I be contacted?

It is not always possible to predict when a medicine will be developed for your disease area of interest,

however, your name is in our database and you can keep up to date using various means...





Keep up with EMA Activity

EMA Corporate Website

The screenshot shows the EMA Corporate Website homepage. At the top is the EMA logo and a search bar. Below the logo is a navigation menu with links to Medicines, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, and About us. The main content area features a large red banner for the 'COVID-19 pandemic' with a link 'All info here'. To the right of the banner is a 'QUICK LINKS' section with links to Latest updates, Vaccines, Treatments, and Guidance for developers and companies. Below the banner is a large illustration of two people looking at a document with a syringe and a checkmark. To the right of the illustration is a list of featured news items, including 'Monthly safety updates for COVID-19 vaccines', 'EMA starts evaluating Spikevax in young children', 'Update on molnupiravir', and 'EMA organises its 4th public meeting on COVID-19'. At the bottom of the page are three sections: 'Search for medicines', 'What's new', and 'FAQs'.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicines Human regulatory Veterinary regulatory Committees News & events Partners & networks About us

COVID-19 pandemic

All info here

QUICK LINKS

- Latest updates
- Vaccines
- Treatments
- Guidance for developers and companies

COVID-19 | VACCINES
Monthly safety updates for COVID-19 vaccines

COVID-19 | VACCINES
EMA starts evaluating Spikevax in young children

COVID-19 | TREATMENTS
Update on molnupiravir

COVID-19 | EVENT
EMA organises its 4th public meeting on COVID-19

Search for medicines
What's new
FAQs

Landing Pages

Information for


Patients and carers

Featured news and updates for patients and carers

Healthcare professionals

Featured news and updates for healthcare professionals, including doctors, nurses and pharmacists

Patient webpages



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

Medicines ▾ Human regulatory ▾ Veterinary regulatory ▾ Committees ▾ News & events ▾ Partners & networks ▾ About us ▾

Partners & networks

EU partners	International activities	Patients and consumers
Healthcare professionals	Academia	Pharmaceutical industry
Networks	Health technology assessment bodies	

- Getting involved
- Eligible organisations
- Patients' and Consumers' Working Party
- Training & resources
- Key documents

Patients and consumers [◀ Share](#)

Table of contents


- Framework for interaction
- Activities of patients and consumers
- Input towards revision of global clinical practice guidance
- More information

The European Medicines Agency (EMA) and patients have been actively interacting since the creation of the Agency in 1995. This cooperation was extended to include consumer groups with an interest in medicines. Both of these stakeholder groups bring a 'real-life' experience as well as specific knowledge and expertise to scientific discussions on medicines and on the impact of regulatory decisions. Collaborating with these groups supports transparency and improves regulatory processes.

Key milestones of EMA interaction with patients and consumers



Healthcare professional webpages



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

Medicines ▾ Human regulatory ▾ Veterinary regulatory ▾ Committees ▾ News & events ▾ Partners & networks ▾ About us ▾

Partners & networks

EU partners	International activities	Patients and consumers
Healthcare professionals	Academia	Pharmaceutical industry
Networks	Health technology assessment bodies	

- Getting involved
- Eligible organisations
- Healthcare Professionals' Working Party
- Resources
- Key documents

Healthcare professionals [◀ Share](#)

Table of contents

- Framework for interaction
- Collaboration with general practitioners
- Activities of healthcare professionals
- Stakeholder engagement report 2017
- Input towards revision of global clinical practice guidance

The European Medicines Agency (EMA) has been interacting with European healthcare professionals in various areas of its work since it was founded in 1995. As prescribers and handlers of the medicines that the Agency evaluates, healthcare professionals are key stakeholders in the Agency's work and have specific knowledge and expertise to offer. The Agency is committed to maintaining a strong working relationship with this group.

Key milestones of EMA interaction with healthcare professionals (HCPs)



Keep up with EMA Activity

What's new

Find all the latest news and updates published on this website in one place.



FAQs

Find answers to the most frequently asked questions we receive.



Send a question to the European Medicines Agency

 RSS feed  Twitter  YouTube  LinkedIn

@EMA_News



LinkedIn

YouTube

Register as a Patient Expert

Getting involved as an individual expert

Patient experts contribute their real-life experience of living with their condition directly into scientific regulatory discussions.

Primarily, EMA contacts experts via its network of [eligible organisations](#). Individuals interested in working with EMA can also be included in the individual **experts' stakeholder database**, by completing the online registration form at:

- [Involvement in EMA activities: registration for interested individuals](#)

For more information on the database, see:

- [Questions and answers - EMA individual experts' stakeholder database: patients and consumers](#)





Any questions?

Further information

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Send us a question Go to www.ema.europa.eu/contact

Telephone +31 (0)88 781 6000

Follow us on  **@EMA_News**