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

What we do

Protect human and animal health

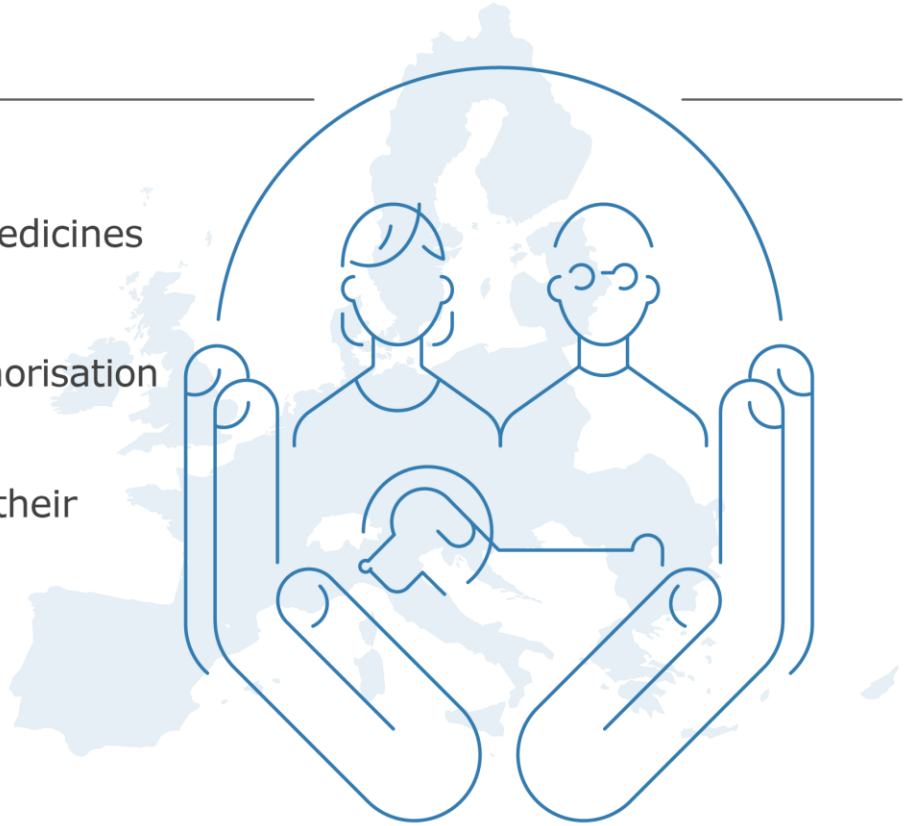
Facilitate development and access to medicines

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



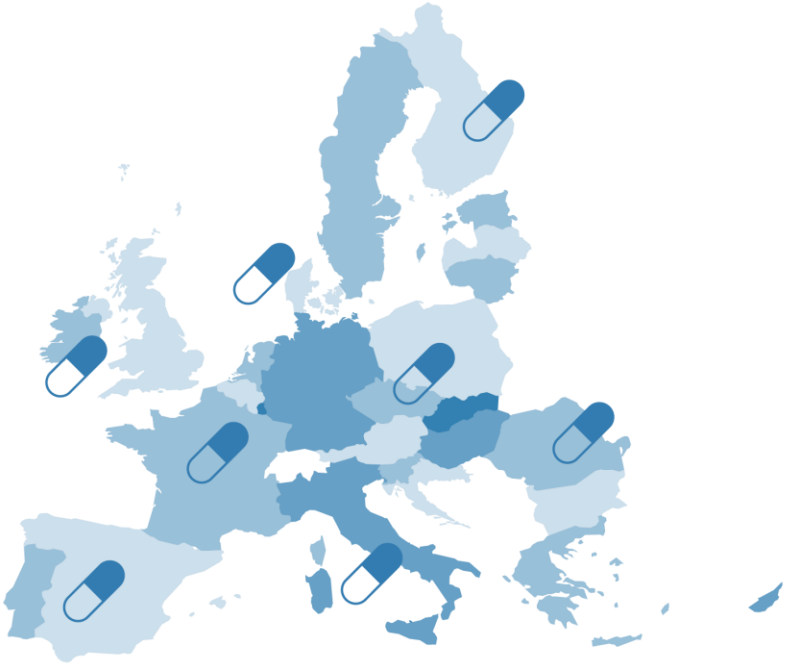
The key roles of the EMA

- 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)



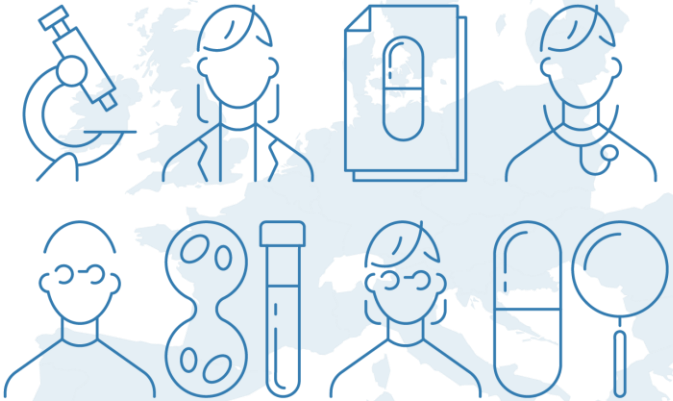
National procedures (via Member States)

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

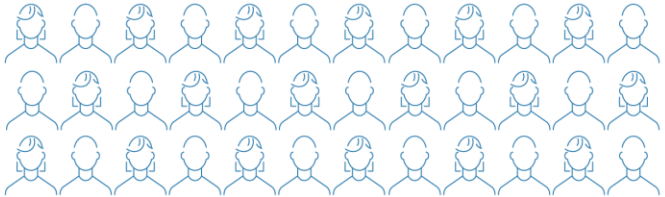


7 Scientific Committees

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

1 Management Board

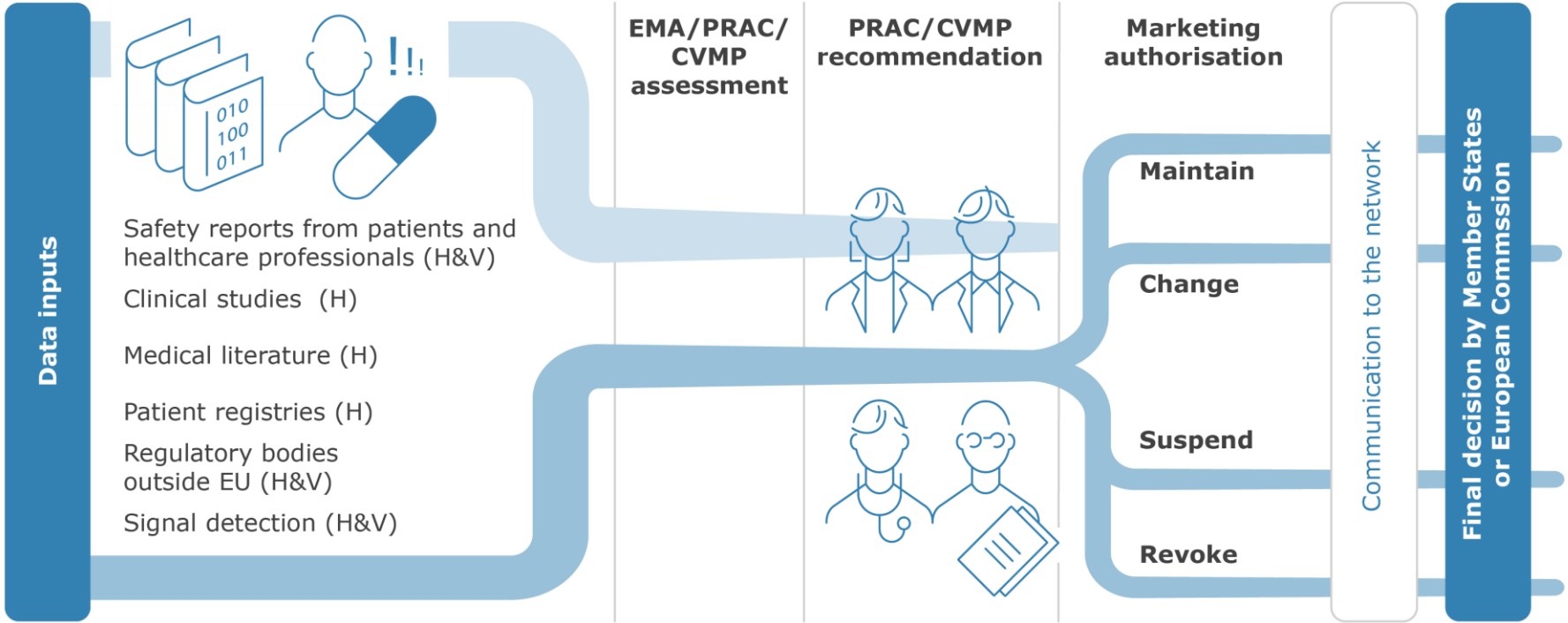
- 27 Member States' representatives
- 4 Civil society representatives
- 2 European Commission representatives
- 2 European Parliament representatives



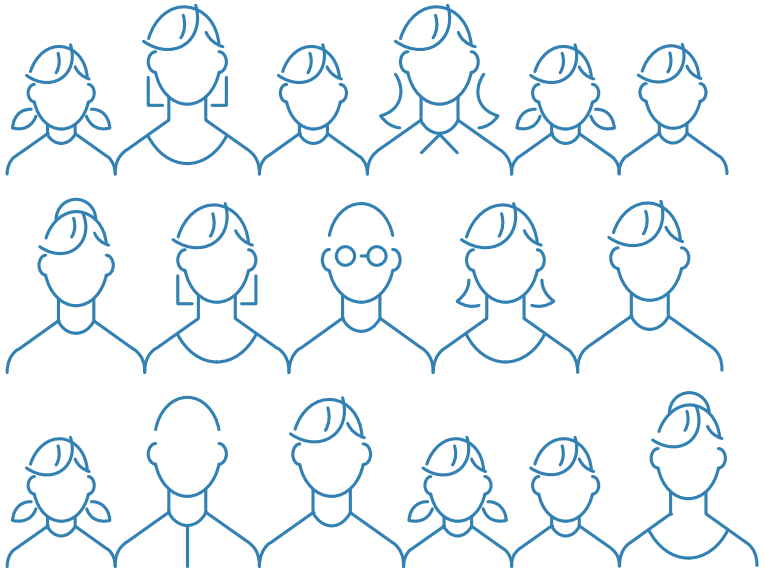
1995 EMA established

~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

1995 — EMA created

1996 — Dialogue with patients initiated; HPCs as members of scientific committees

2000 — Patients become Committee members

2004 — Doctors' representative joins EMA Management Board

2005 — Framework of interaction with patients and their organisations

2006 — Patient & Consumer Working Party; Working group with HCP organisations created

2011 — Framework of interaction with HPCs and their organisations

2013 — Healthcare Professionals Working Party

2014 — EMA's Public Engagement Department created

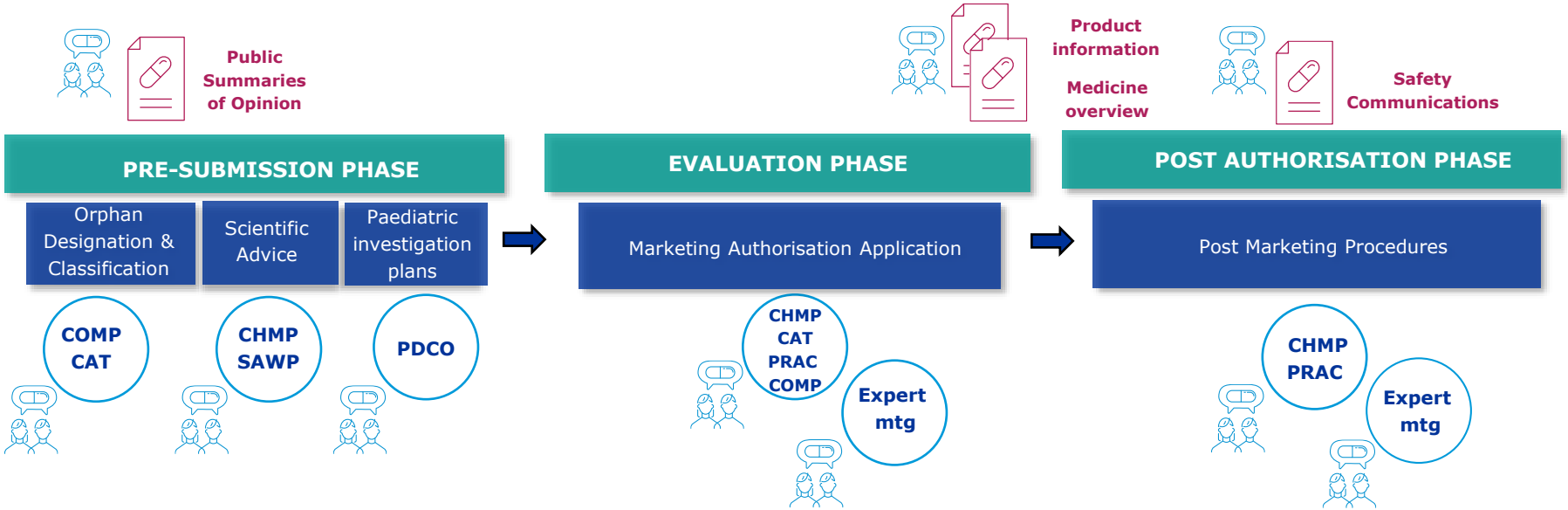
2017 — Public hearings; Involving young people

2019 — Strengthened collaboration with general practitioners

2020 — Patient and HCP engagement in crisis management

Ongoing — Systematic patient input and clinical experience included in regulatory output

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?

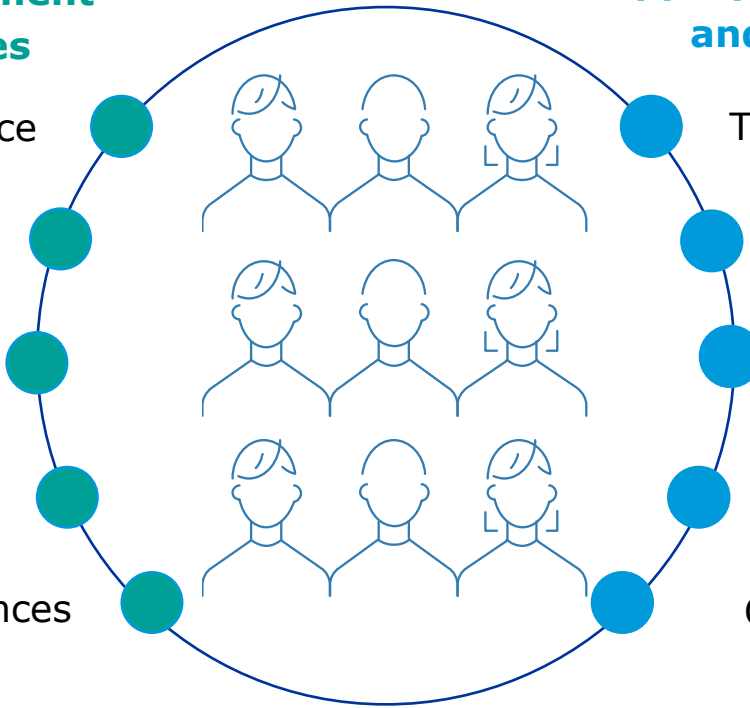
Organisation representatives	Individual Experts
EMA 'eligibility' criteria	**Declaration / assessment of Interests**
Transparent on the funding of the organisation ▶ Legitimacy ▶ Mission/activities ▶ Representation ▶ Structure ▶ Accountability ▶ Transparency	**Confidentiality undertaking** Identification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

Vital elements

One size does not fit all!

Flexible engagement methodologies

- Face to face
- In writing
- Committee meetings
- Surveys
- Patient preferences



Appropriate support and training

- Training day
- Info-sheets
- Videos
- Webpages
- One-to-one support

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

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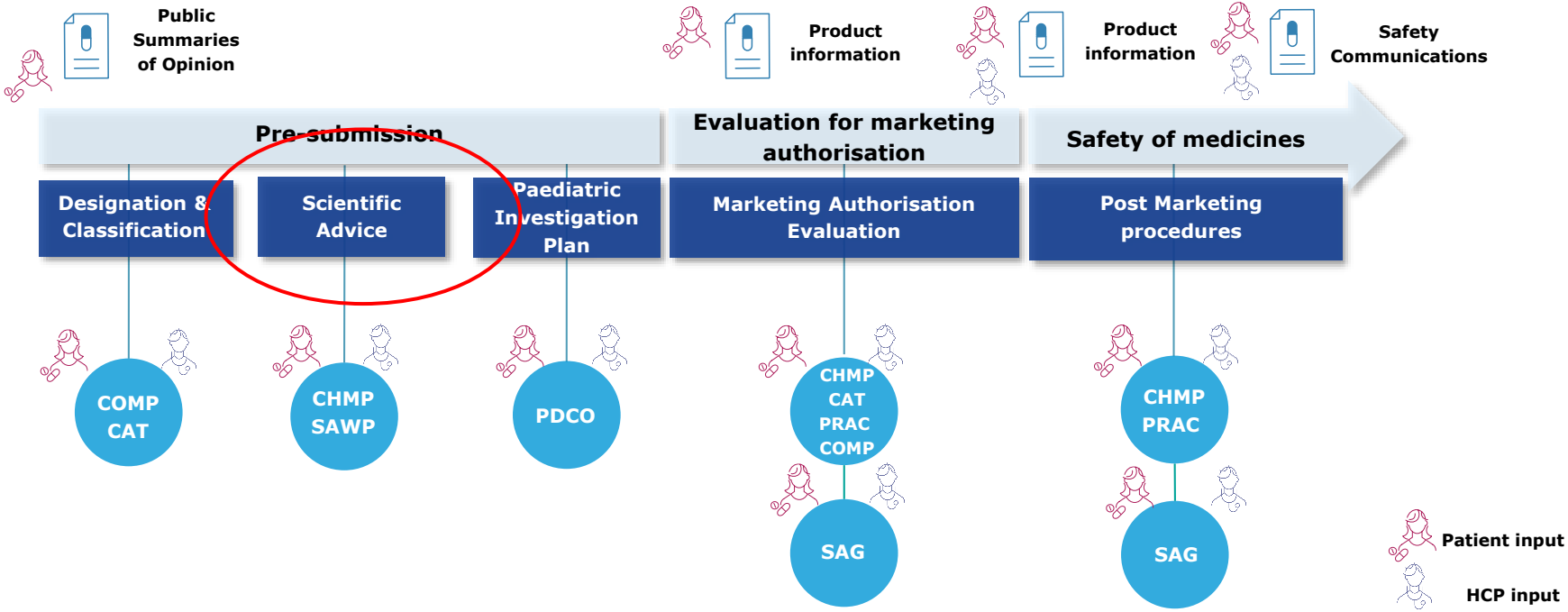
Take home messages

EMA virtual training session

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

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;

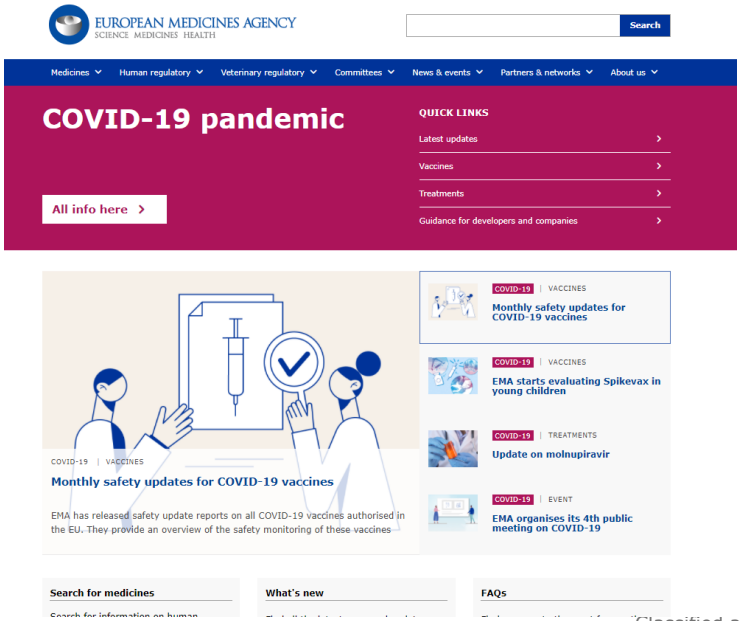
When will I be contacted?

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

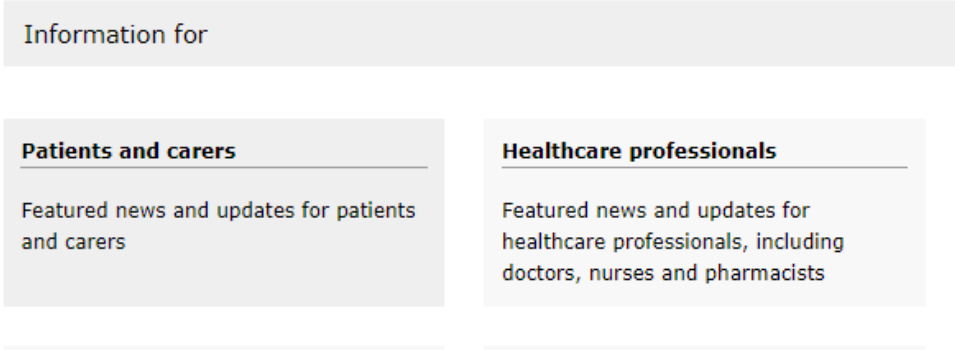
however, your name is in our database and you can keep up to date using various means…

Keep up with EMA Activity

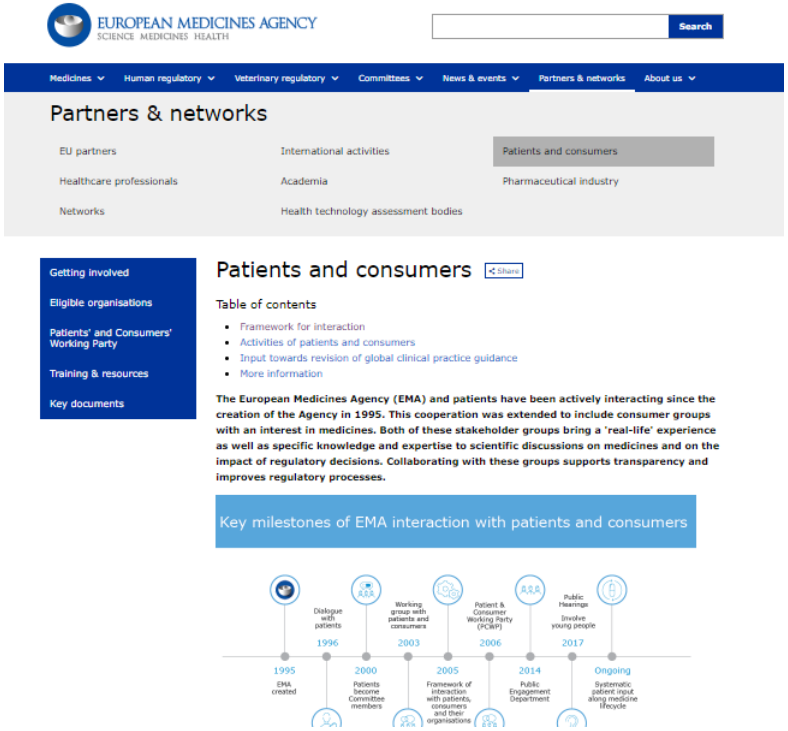
EMA Corporate Website



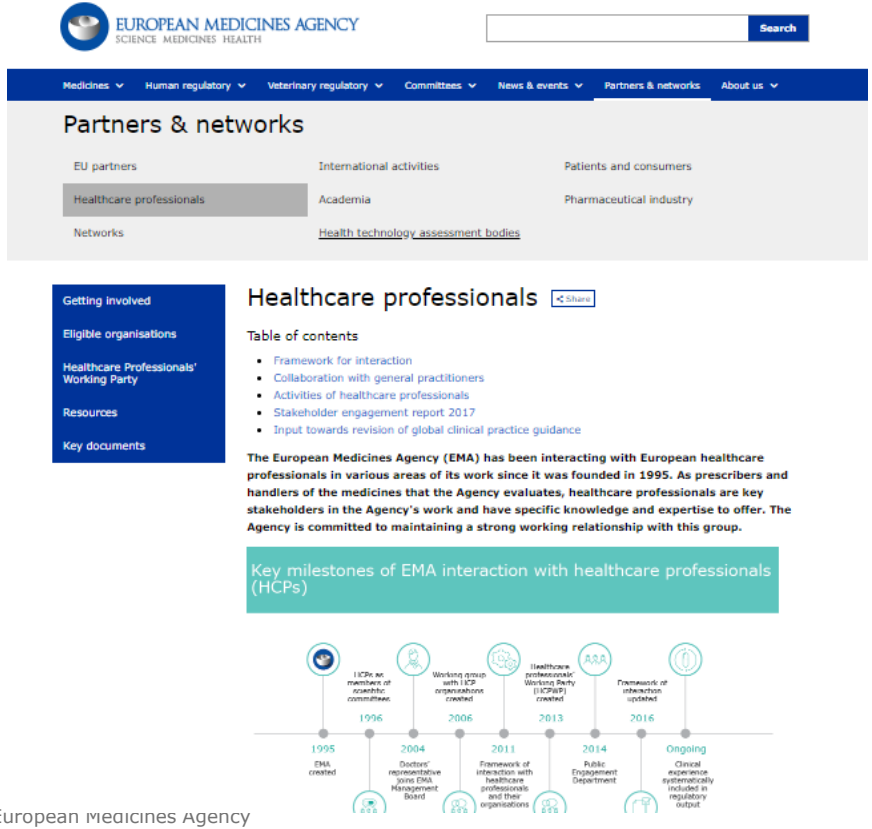
Landing Pages



Patient webpages



Healthcare professional webpages



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.

RSS feed Twitter YouTube LinkedIn

@EMA_News

Send a question to the European Medicines Agency

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

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