

IMAGE 1

EUROPEAN MEDICINES AGENCY

Training session for patients and healthcare professionals

- 2020 is first virtual training session
- EMA training began in 2007
- Adapted progressively to changing regulatory environment and needs
- Interactive sessions with real examples
- Pilot session for healthcare professionals

- 25 participants from eligible **patient** organisations
- 11 participants from eligible **healthcare professional** organisations
- 13 participants from the **individual patient** database
- 2 participants representing **youth groups**

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IMAGE 2

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Lily Cannon Me Nora Lazaro Host Maria Cohost Antonella Roma... Angela Bradshaw

garcia

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Objectives

- Understand the role of the European Medicines Agency
 - the process of medicines evaluation in Europe;
 - how medicines are evaluated and continually monitored for safety
- Using a hands-on approach, you will see where you may be consulted in these processes
- Learn more about how you can be involved

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Patient and healthcare professional involvement

Public Summaries of Opinion

Medicine overview

Product information

Safety Communications

Pre-submission

- Designation & Classification (COMP, CAT)
- Scientific Advice (CHMP, SAWP)
- Paediatric Investigation Plan (PDCCO)

Evaluation for marketing authorisation

- Marketing Authorisation Evaluation (CHMP, CAT, PRAC, COMP, SAG)

Safety of medicines

- Post Marketing procedures (CHMP, PRAC, CAT, SAG)

Patient input

HCP input

* COMP: Committee for Orphan Medicinal Products; CHMP: Committee for Human Medicinal Products; CAT: Committee for Advanced Therapies; PDCCO: Paediatric Committee; SAWP: Scientific Advice Working Party; SAG: Scientific Advisory Group; PRAC: Pharmacovigilance and Risk Assessment Committee; Classified as Internal/staff & contractors by the European Medicines Agency

IMAGE 4

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What the EMA does not control

- Pricing of medicines
- Access to medicines
- Advertising of medicines
- Patents on medicines
- Homoeopathic medicines
- Food supplements
- Cosmetics
- Tobacco

11

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The European medicines regulatory network

~50 national regulatory authorities

European Medicines Agency

European Commission

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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

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How are medicines approved?

Different authorisation routes: one set of common rules



EMA 25 years 13 Centralised procedure (via EMA)

National procedures (via Member States)

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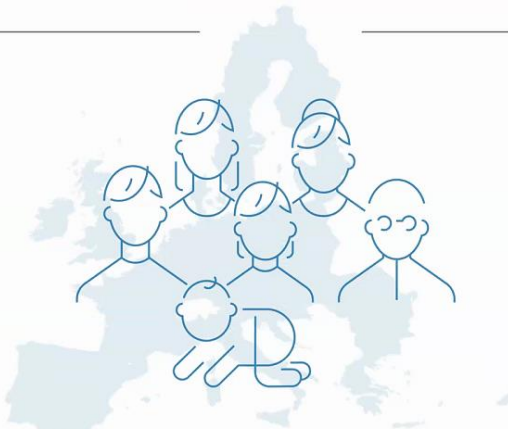
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What is the benefit of the centralised procedure for EU citizens?



- 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

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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

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Who we are

~4000 scientific experts from across Europe

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

1995 EMA established

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

Data inputs

- Safety reports from patients and healthcare professionals (H&V)
- Clinical studies (H)
- Medical literature (H)
- Patient registries (H)
- Regulatory bodies outside EU (H&V)
- Signal detection (H&V)

EMA/PRAC/ CVMP assessment

PRAC/ CVMP recommendation

Marketing authorisation

- Maintain
- Change
- Suspend
- Revoke

Communication to the network

Final decision by Member States or European Commission

18

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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

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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 Identification through European network of registered organisations and EMA database of individuals

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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

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Patient involvement in Scientific Advice procedures at EMA

Patient involvement in scientific advice procedures (2008- 2019)

Year	Number of procedures
2008	8
2009	13
2010	18
2011	16
2012	19
2013	32
2014	37
2015	76
2016	82
2017	131
2018	107
2019	143

Where patients gave input on medicine development plan

Category	Percentage
Population	49%
Study feasibility	27%
Endpoints	54%
Comparator choice	23%
Quality of life	40%
Standard of care	28%
Other	26%

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Patient involvement in Benefit-Risk at EMA

Committee for Human Medicinal Products (CHMP)

- ❖ Scientific Advisory Groups
- ❖ Oral explanations at plenary meetings
- ❖ Written consultations
- ❖ Patient preference studies
- ❖ Pilot: Early interactions with patient community

Pharmacovigilance and Risk Assessment Committee (PRAC)

- Members representing patients on committee
- Written consultations
- Ad hoc expert groups
- Multi-stakeholder meetings
- Public hearings

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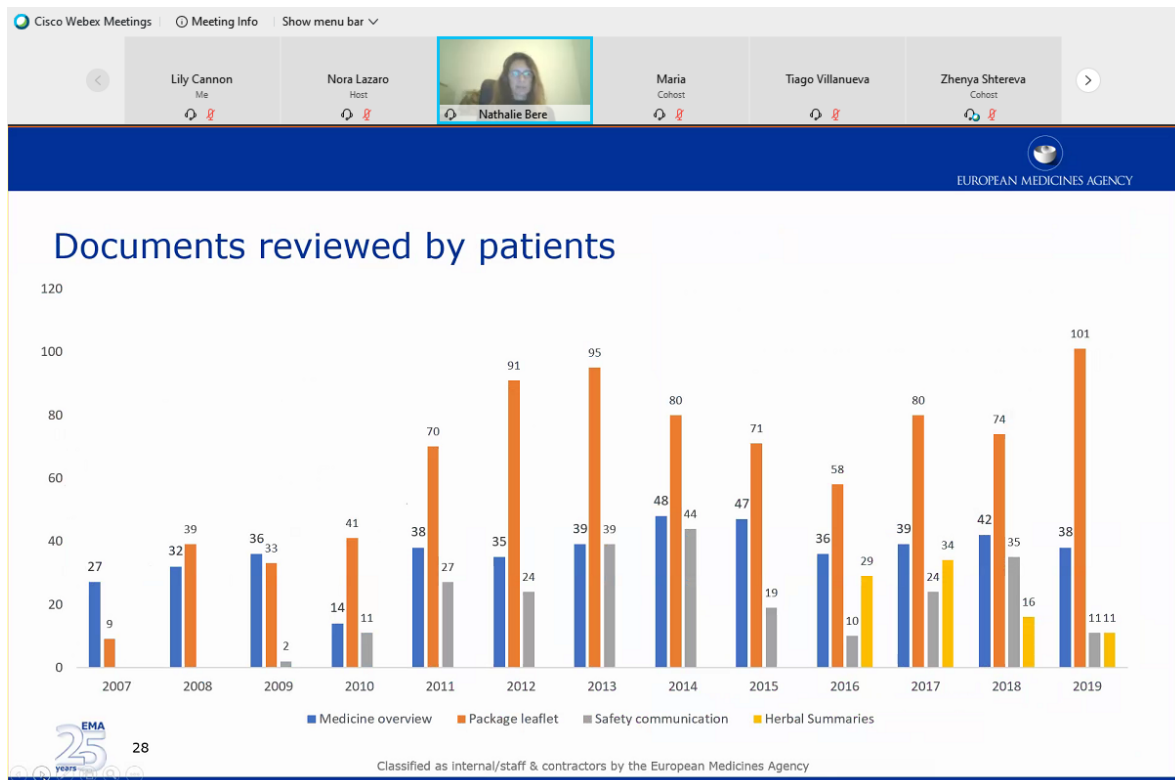


IMAGE 19

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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



The graphic features the text 'Patient Voice' in a bold, teal font, centered within a large, stylized heart shape. The heart is composed of many small, colorful icons representing people and speech bubbles, arranged in a circular pattern around the text.

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