EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction to EMA and patient engagement

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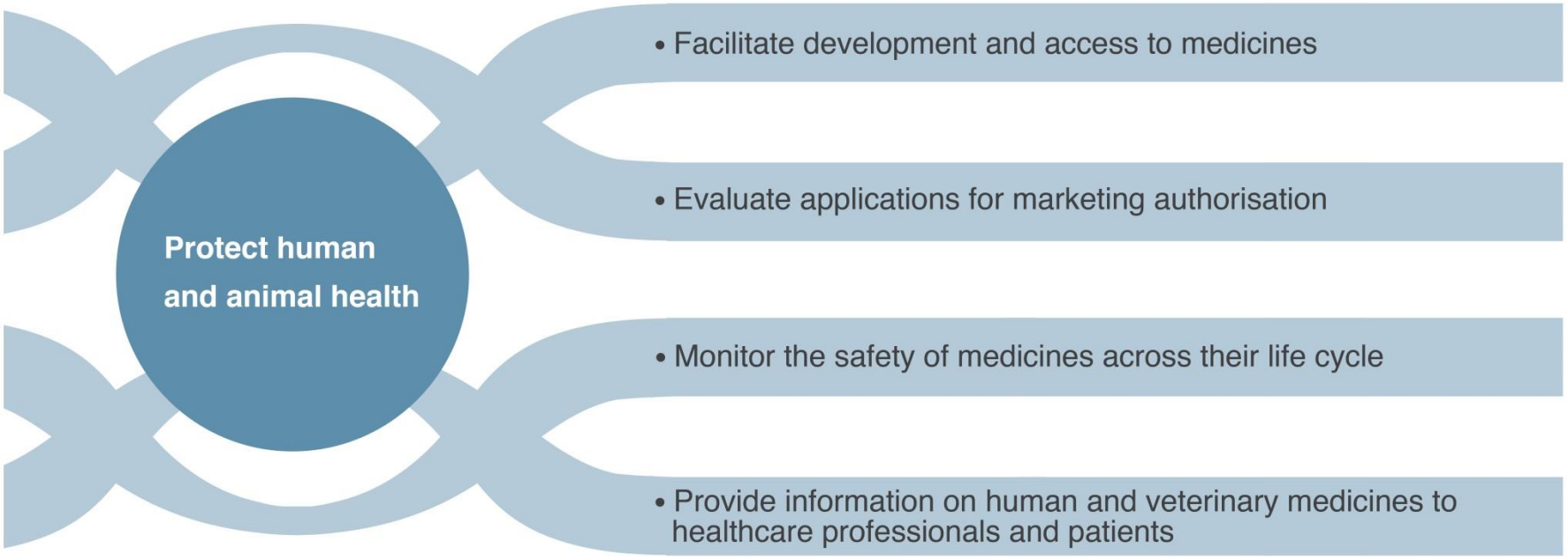
What is the European Medicines Agency (EMA)

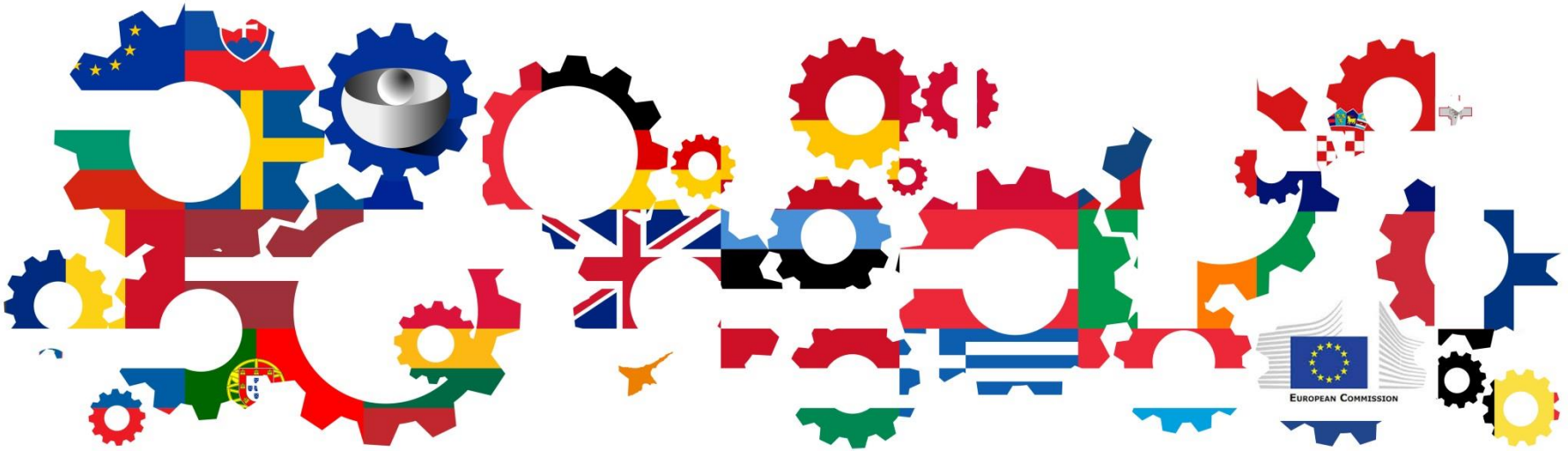
The EMA is the EU regulatory body responsible for the scientific evaluation and supervision of medicines developed by pharmaceutical companies for use in the European Union

(Human and Veterinary)

What do 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 information on human and veterinary medicines to healthcare professionals and patients

The European medicines regulatory network



~ 50 national regulatory authorities European Commission European Medicines Agency

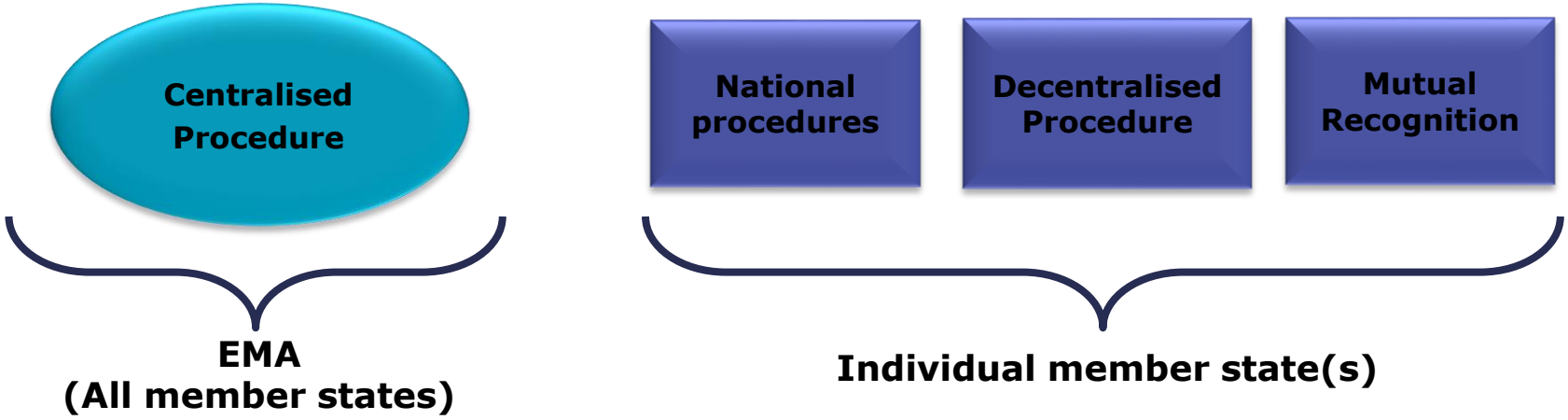
The European System

In Europe all medicines must have a marketing authorisation before they can be put on the market

There are two ways of obtaining an authorisation:

1) Centralised authorisation procedure

2) National marketing authorisation procedures



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

- Medicines are authorised for all EU citizens at the same time
- Centralised safety monitoring
- Product information available in all EU languages at the same time

Which medicines are approved through the centralised procedure?

- Human medicines 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)

Medicines Regulatory Lifecycle – centralised procedure

How is EMA organised?

Management Board

Executive Director

EMA staff

CHMP Committee for Human Medicines

COMP Committee for Orphan Medicines

HMPC Committee for Herbal Medicines

PDCO Paediatric Committee

CAT Committee for Advanced Therapies

PRAC Pharmacovigilance Risk Assessment Committee

+ working parties and scientific advisory groups

~4000 European experts

- National Agencies
- Healthcare professionals
- Patients
- Academia
- Learned societies

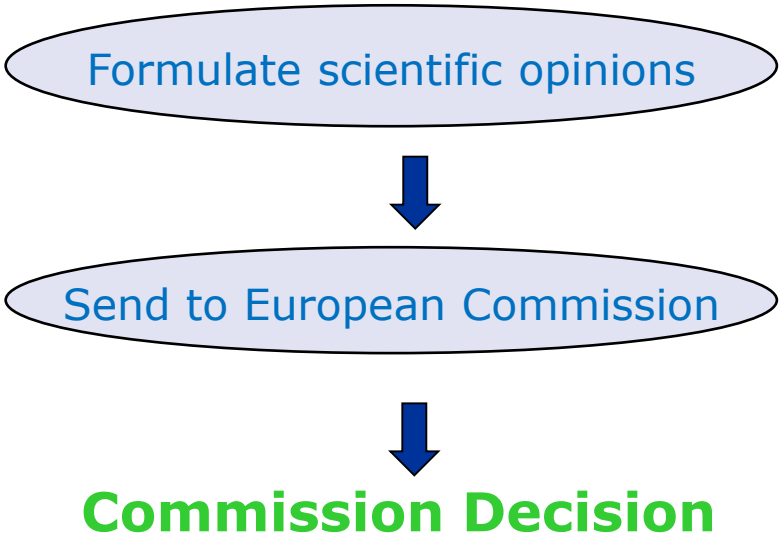
EU institutions

European Commission

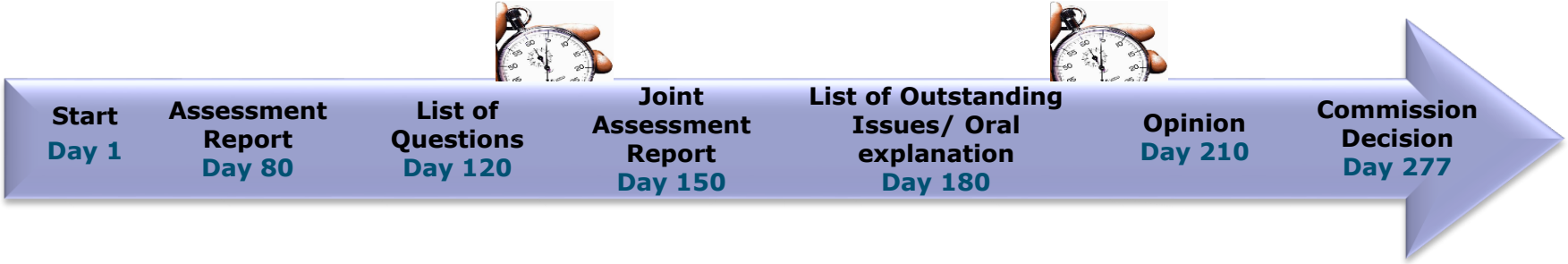
European Parliament

How does the Agency work?

EMA and its committees, working parties & experts:



Evaluation overview - CHMP



What now?

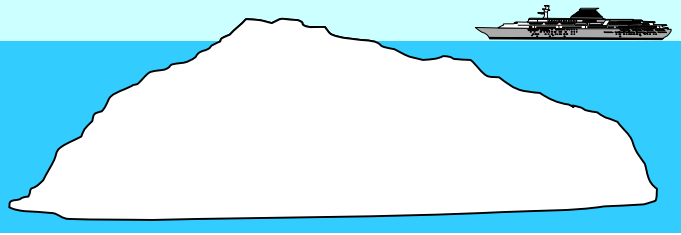
Authorised!

Pharmacovigilance

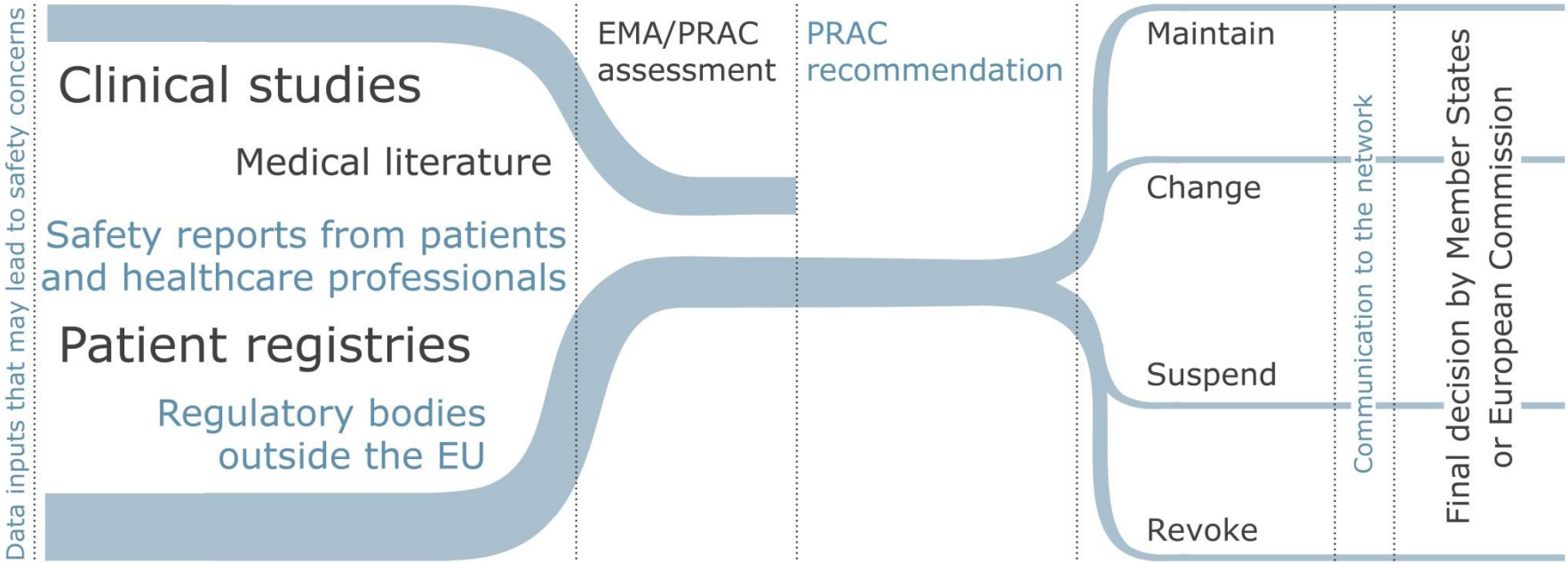
What we know at the end of the clinical trial programme…

What we don't know…

- What happens when the medicine is used in normal practice?
- What is its adverse event profile?



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



Pharmacovigilance & Risk Management

Patient with Adverse Drug Reaction (ADR)

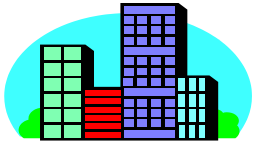
Healthcare professional

ADR report

OR

National Competent Authority (NCA)

Marketing Authorisation Holder



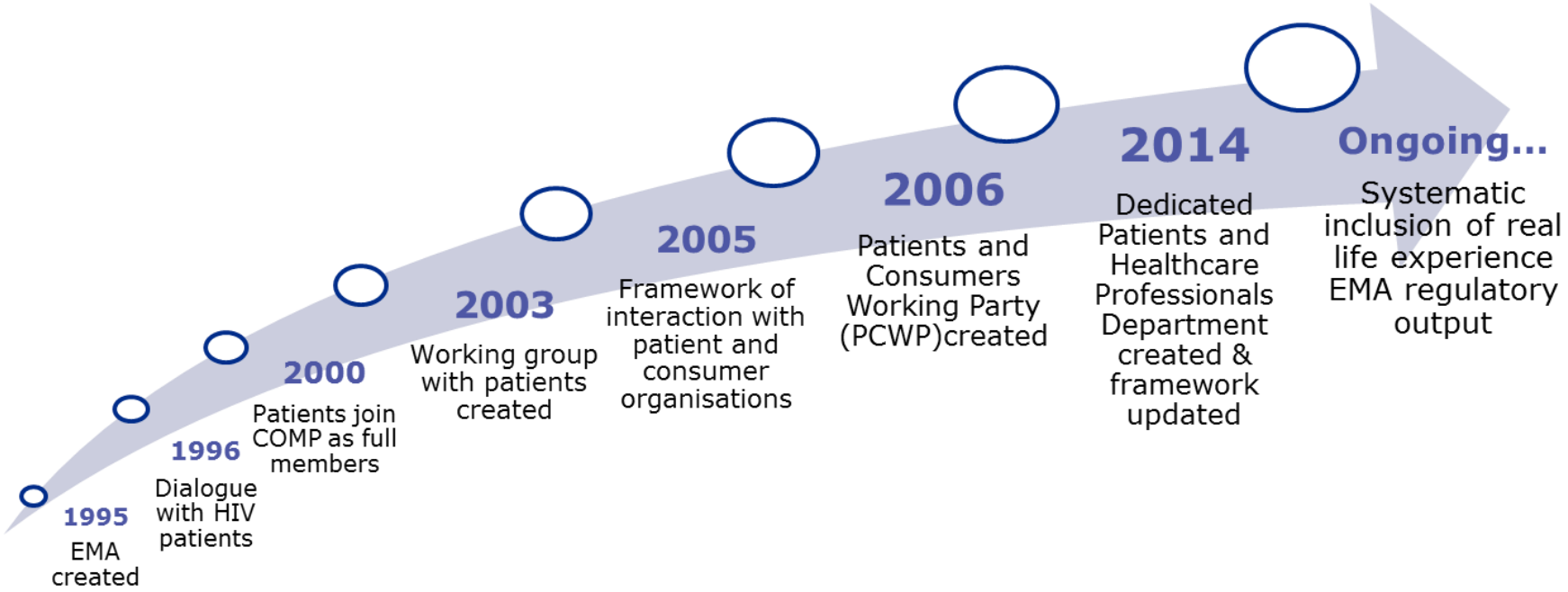
Safety monitoring

EudraVigilance Human

www.adrreports.eu

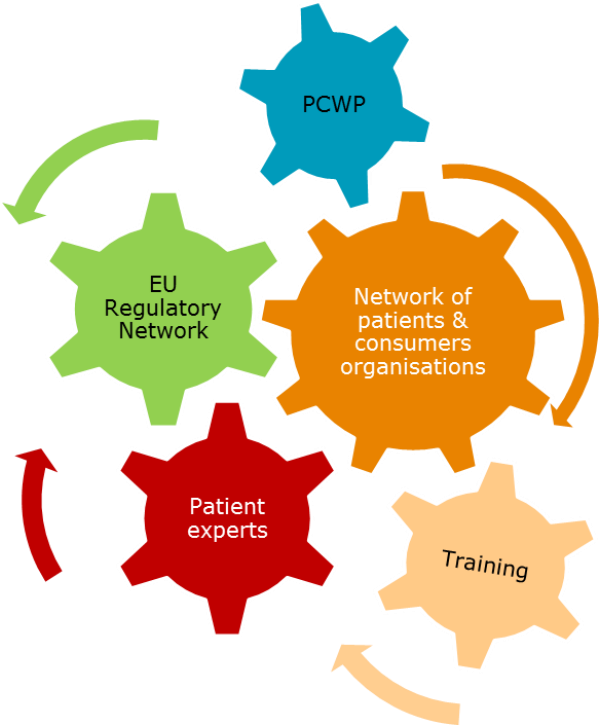
Patient involvement in the EMA

Interaction with patients: the EMA journey… so far

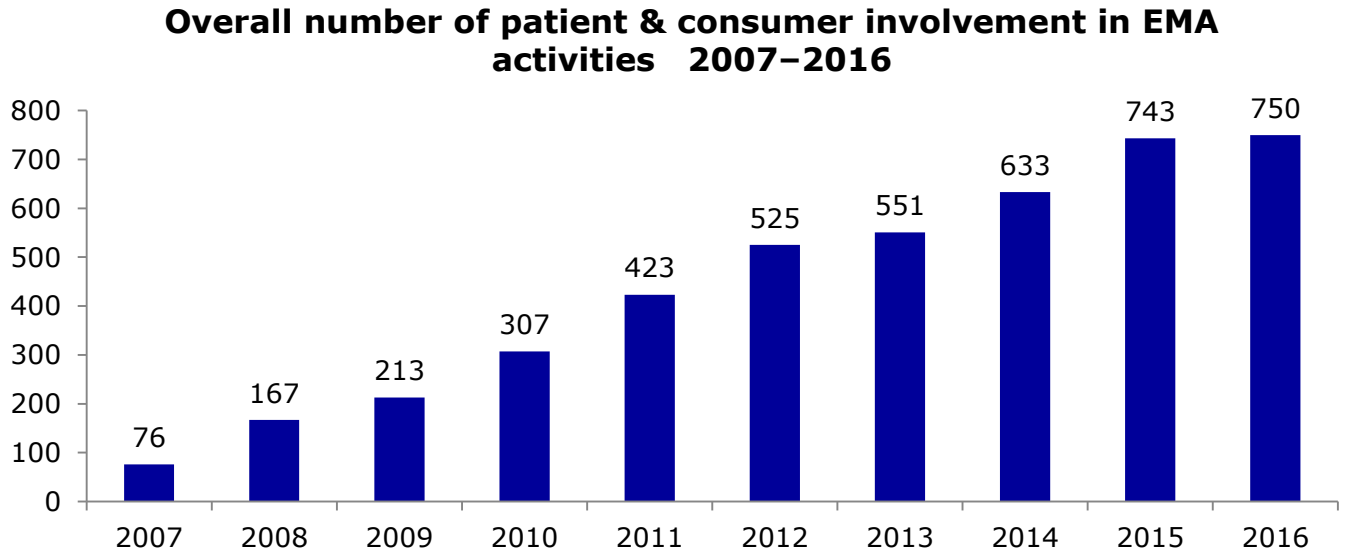


A framework of interaction based on five critical elements

1. A network of European patients and consumers organisations
2. A forum of exchange: EMA Working Party with Patients and Consumers' organisations
3. A pool of patients acting as experts in their disease and its management
4. Interaction with the EU Regulatory Network
5. Capacity-building focusing on training and raising awareness about EU regulatory system



Increasing involvement in EMA activities



Learn by experience

Flexibility

Three categories of patient participation:

1. Patients representing the *patient community*
2. Patients representing *their organisation*
3. Patients as *individual experts*

1. Patients representing the *patient community*

Members of :

- EMA Management Board (MB)

- Committee for Orphan medicines (COMP)
- Committee for paediatric medicines (PDCO)
- Committee for advanced therapies (CAT)
- Pharmacovigilance Risk Assessment Committee (PRAC)

2. Patients representing their organisations

- Platform for dialogue and exchange between the EMA and patient organisations
- Representation from 20 organisations, EMA committees & Management Board
- Four plenary meetings per year, and consulted as and when needed

2016:

10th Anniversary!

Continued…

- Participate in EMA conferences and workshops
- Respond to EMA consultations
- Comment on draft guidelines

Contribute to EU-wide initiatives where EMA is involved such as:

- Enpr-EMA - European Network of Paediatric Research at the European Medicines Agency
- ENCePP - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
- WEB-RADR - Recognising Adverse Drug Reactions

3. Patients as individual experts

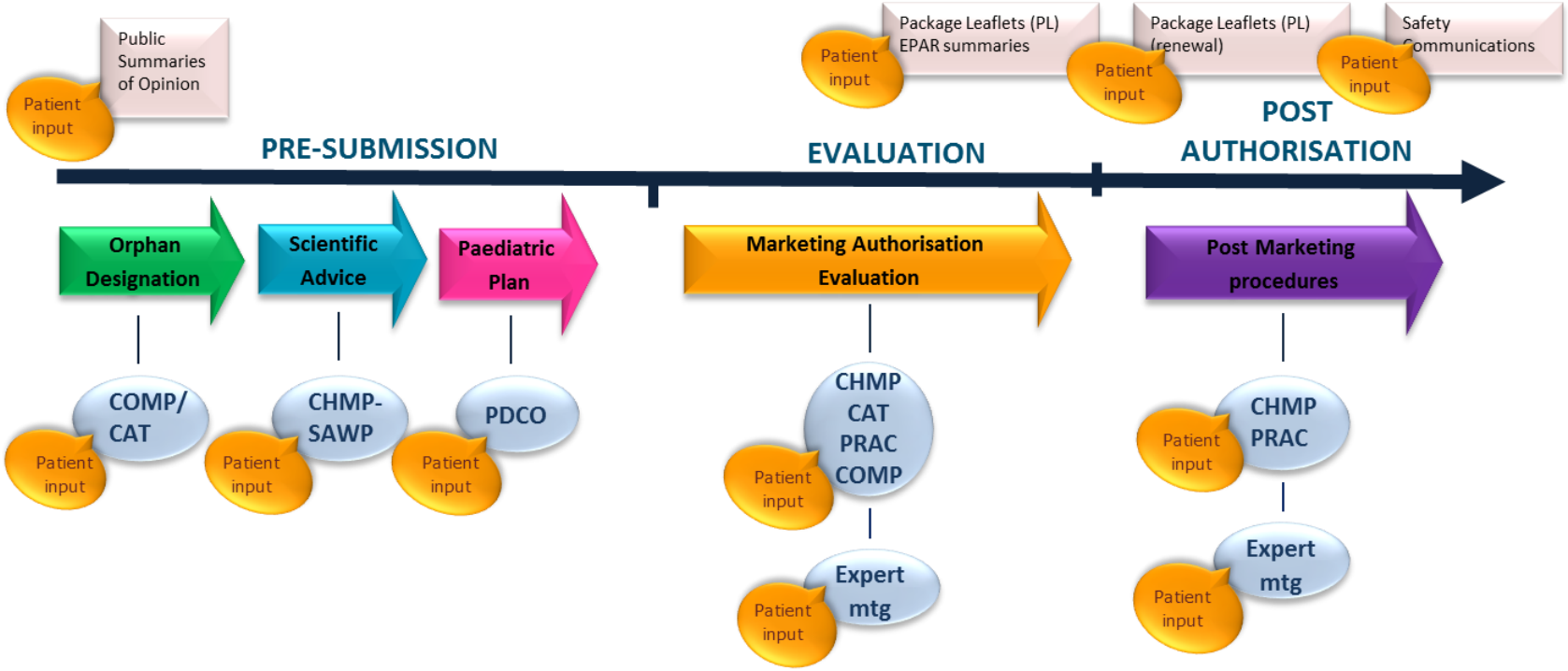
Medicines' development:

- Participation in scientific advice/protocol assistance procedures

Medicines' evaluation:

- Participation in expert meetings convened by the Committees
- Respond to ad-hoc consultations on assessment of medicines from all Committees
- Review information on medicines: Package leaflets, EPAR summaries, safety communications (Q&As) and soon herbal summaries

Opportunities for involvement along the medicine lifecycle at EMA



Engagement methodologies

One size does not fit all!

Support and training

Tool kit

- **Webpages**
- **Annual training day**
- **One-to-one personalised support**
- **Videos; EMA basics**
- **Info-sheets**

Monitoring and measuring

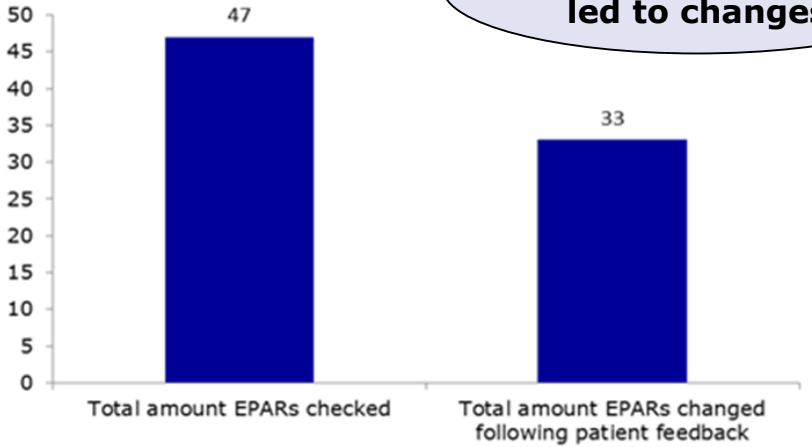
- Questionnaires sent to patients who participate
- Proposals for improvements included in the next work-plan
- Annual report to EMA Management Board

Feedback

- Meeting minutes
- Thank you acknowledgement
- Comments taken into account

Review of documents

70% of comments led to changes



Which patients and organisations?

- Any **organisation** representing EU patients or consumers may express an interest to work with the Agency, however they must meet the defined eligibility criteria (application form on the EMA website)
- List of eligible patients & consumers organisations published on the EMA website
- Any patient, consumer or carer can also register to be included in pool of **individuals** interested to work with EMA (application form on the EMA website)

Now have large network of EU patient organisations and individuals representing many different areas.

Eligible organisations: patients/consumers

Wider Engagement; share practices

- EMA cross-agency departments
- Healthcare professionals
- Patient initiatives
- EMA/FDA exchange
- EU projects
- National Competent Authorities

Challenges

- 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

Value of involving patients in EMA

- Patients are a recognised and integral part of the Agency's work
- Involvement has brought the everyday aspects of living with a disease into the scientific discussions
- Participation has increased and diversified but also been refined to ensure involvement is mutually beneficial

Different perspectives are crucial and result in more meaningful decisions for everyone.

Any questions?

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