EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Medicines Agency (EMA)

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EMA Training Day

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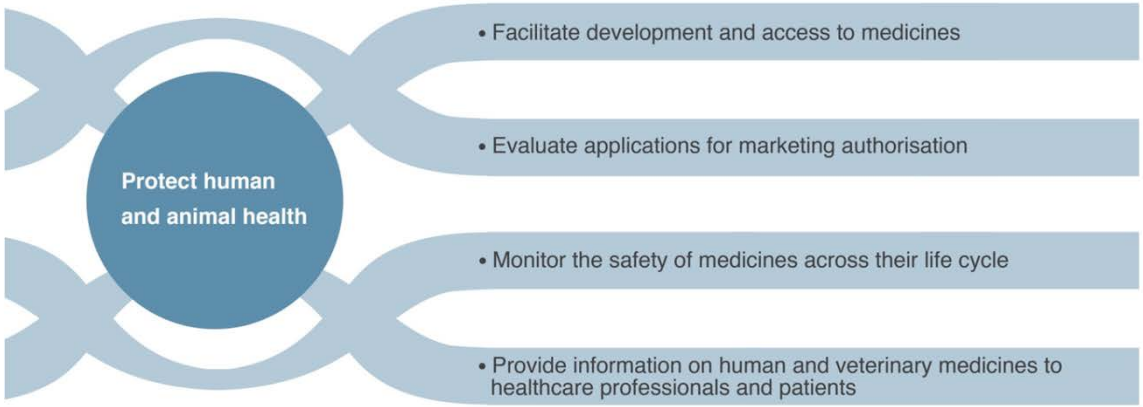
An agency of the European Union

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



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

What the EMA does not control

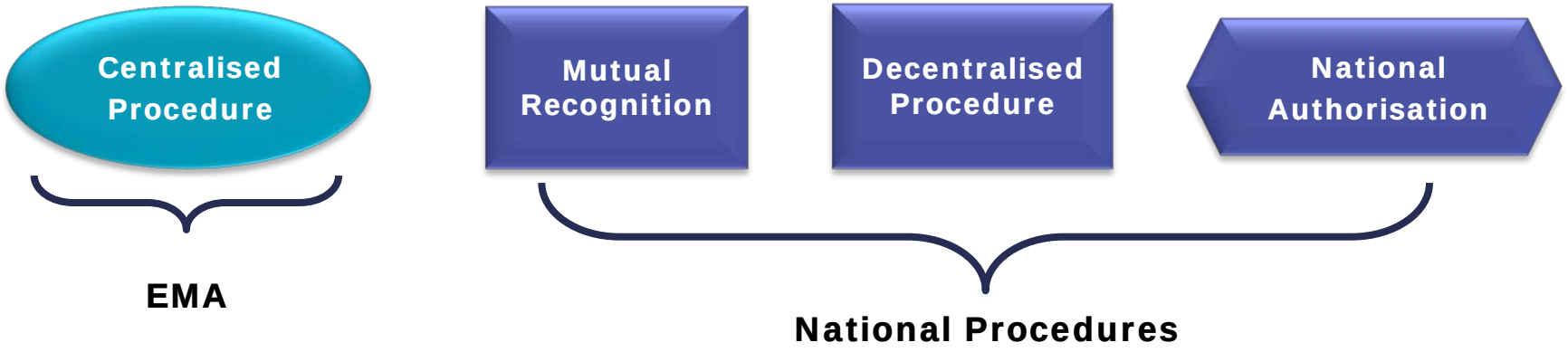
- Pricing of medicines
- Access to medicines
- Advertising of medicines
- Patents on medicines
- Medical devices
- Homoeopathic medicines
- Food supplements
- Cosmetics
- Tobacco

The European System

All medicines must have a marketing authorisation before they can be put on the market

Two ways of obtaining authorisation:

1) The centralised procedure or 2) National marketing authorisation procedures



Benefits of the centralised procedure

- 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

Medicines approved via 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)

Type of Approvals

Standard:
Comprehensive data

Conditional Approval:

- Comprehensive data not available; to be provided after approval
- Must fulfil scope (orphan drugs, emergency threats, serious and life-threatening diseases)
  Approval valid for 1 year, renewable

Exceptional Circumstances:

- Comprehensive data not available and cannot be provided
- Must meet criteria (rarity, medical ethics, state of scientific knowledge)

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

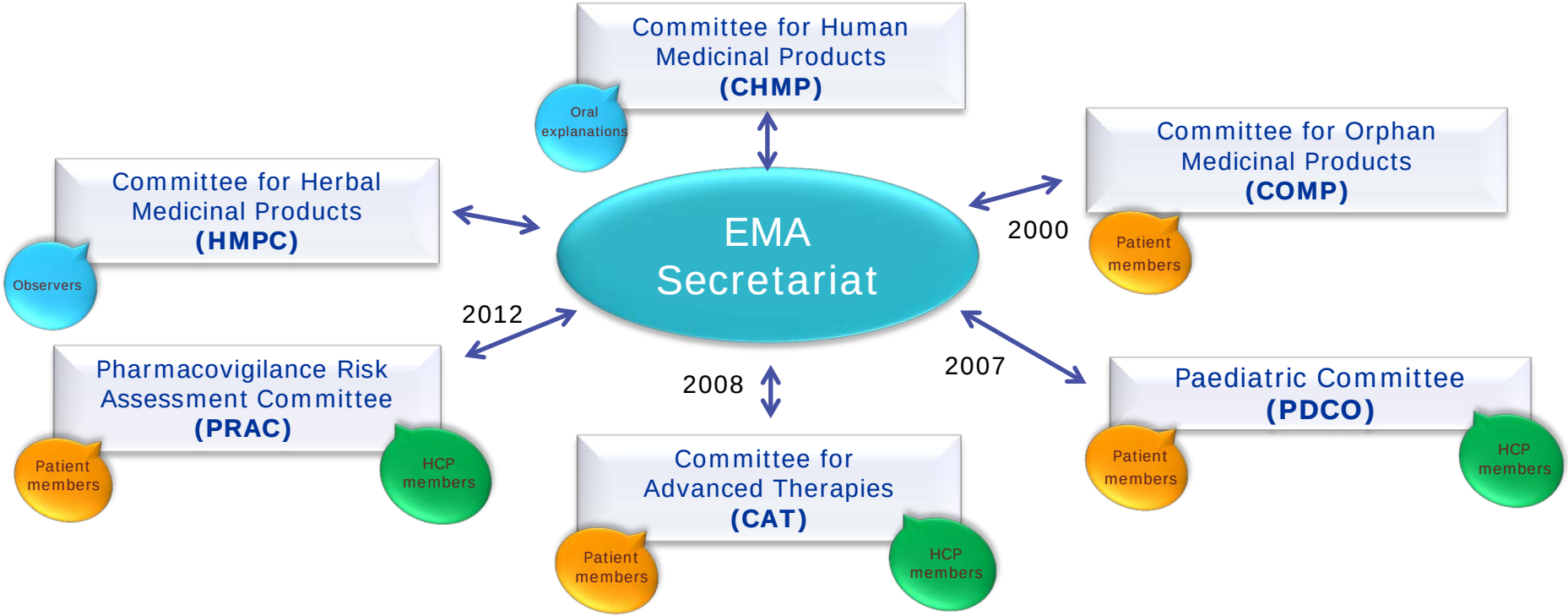
+ working parties and scientific advisory groups

EU institutions

European Commission

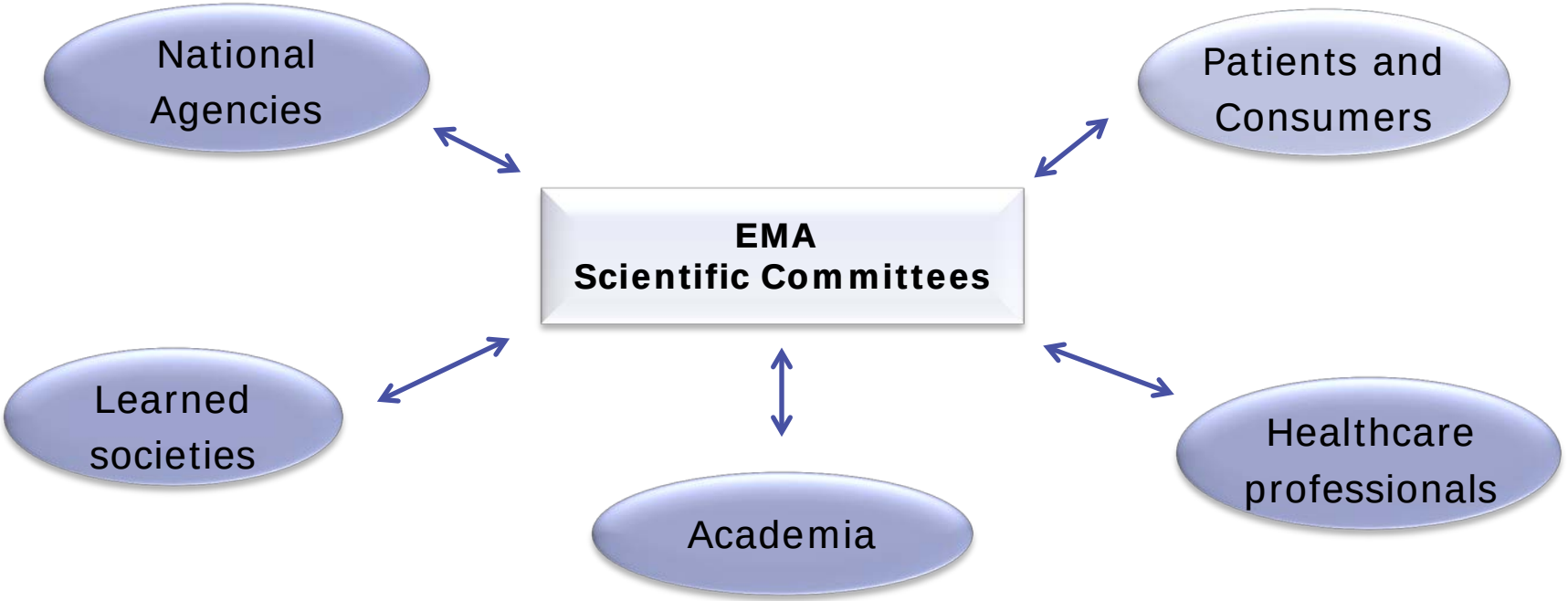
European Parliament

EMA's human scientific committees



The EMA committees contain members nominated by the medicines regulatory authorities of the EU Member States (the 'national competent authorities')

Experts working with the scientific committees



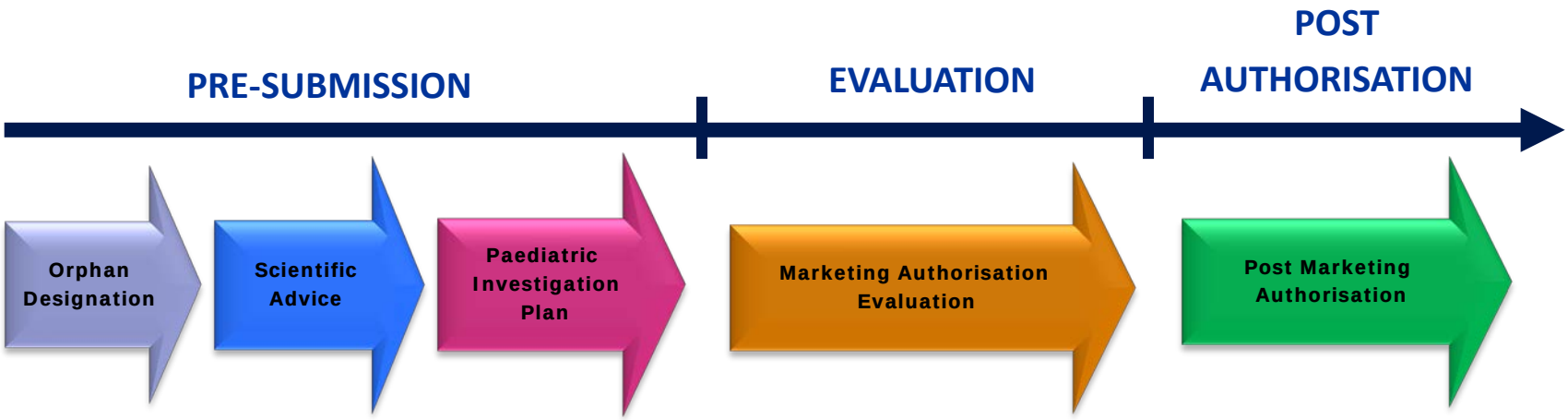
EMA and its committees, working parties & experts:

Formulate scientific opinions

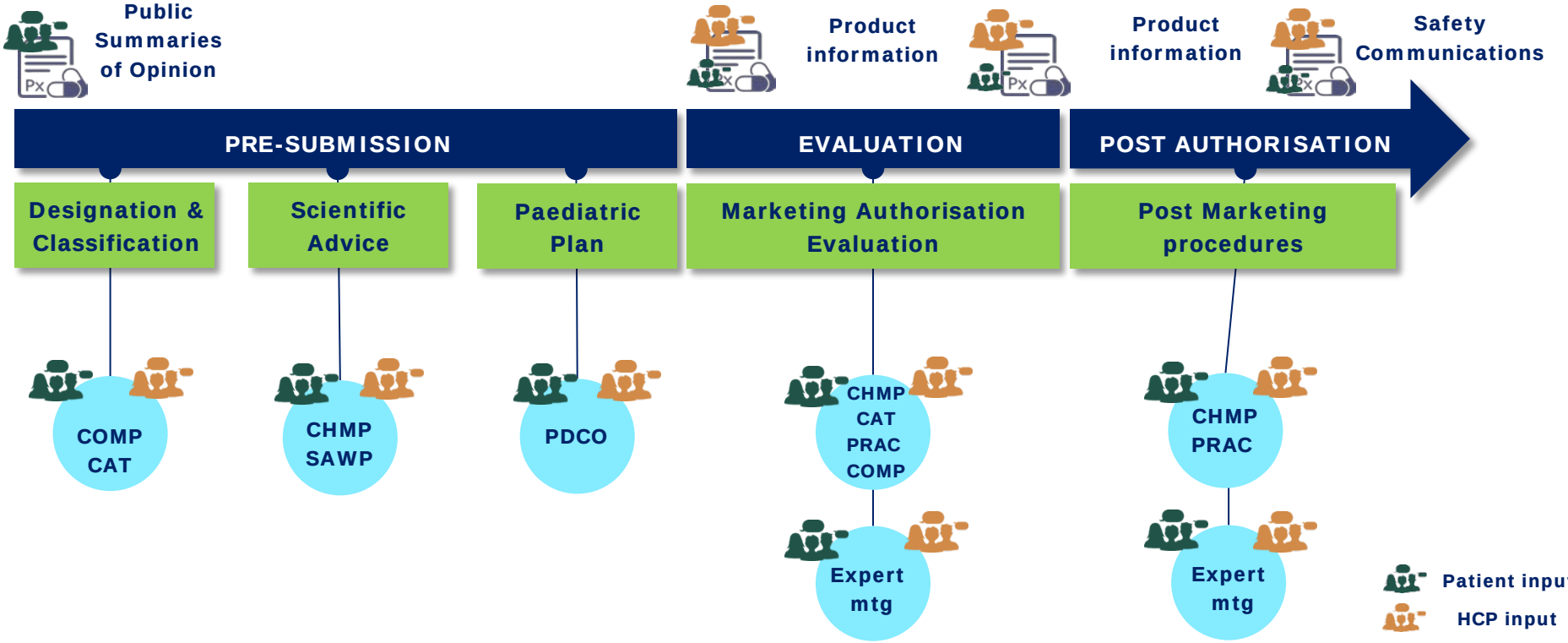
Send to the European Commission

Commission Decision

Medicines Regulatory Lifecycle



Involvement along the medicine lifecycle at EMA

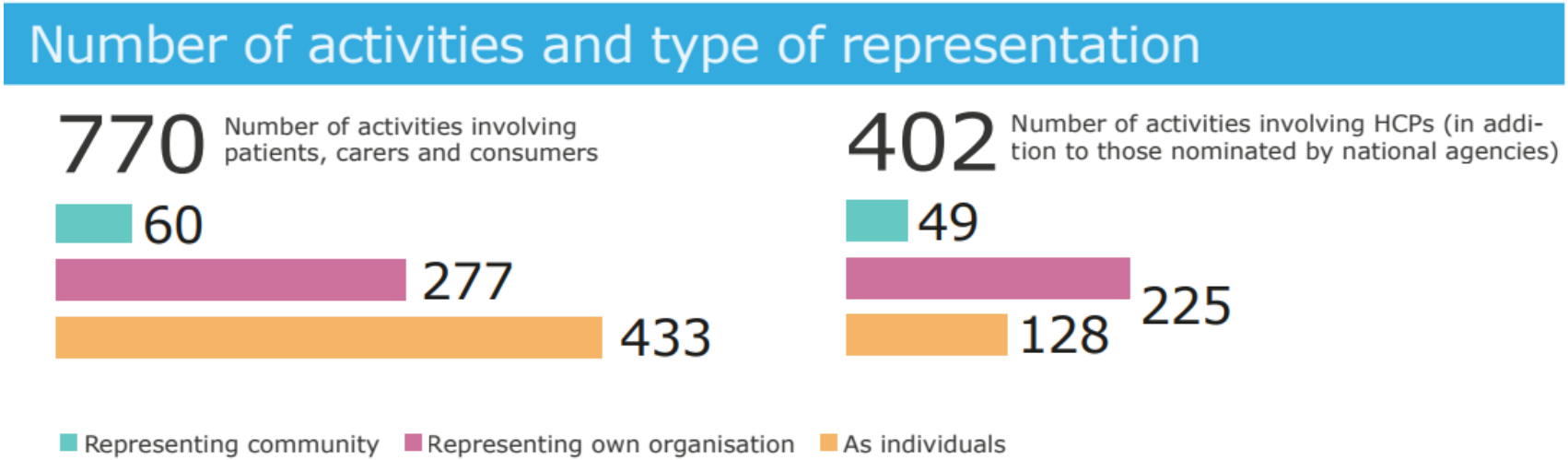


Patients, Healthcare Professionals and Academia at EMA

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 involvement at EMA



Involvement as individual experts in EMA activities

Pre-submission:

- Participation in scientific advice/protocol assistance procedures

Evaluation and Post-authorisation

- Participation in expert meetings (SAG and ad hoc)
- Respond to consultations on assessment of medicines from scientific committees and working parties
- Review information on medicines: Package leaflets, EPAR summaries, safety communications and other Agency documents for the public

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Scientific Advice at EMA


PRE-SUBMISSION
EVALUATION
POST AUTHORISATION
Designation & Classification
Scientific Advice
Paediatric Plan
Marketing Authorisation Evaluation
Post Marketing procedures

Scientific Advice / protocol assistance

- Pharmaceutical companies can request scientific advice from the EMA regarding the development of a medicine.
- Aimed at ensuring the most appropriate studies are conducted, avoiding major objections related to the study design during evaluation
- The Scientific Advice Working Party (SAWP) and the CHMP provide scientific advice by giving feedback on specific questions laid out by the companies.

The role of patients and healthcare professionals

Experts are invited to participate in EMA scientific advice procedures:

- Either face to face meeting or via written comments
- Share their perspective and experience with the condition or treatment with the scientific advice working party and the pharmaceutical company, in relation to a particular medicine in their disease area.
- Provide comments on the development proposals from the company (e.g. endpoints, population, feasibility etc)

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Scientific Advisory Group (SAG) / ad hoc expert meetings


PRE-SUBMISSION
EVALUATION
POST AUTHORISATION
Designation & Classification
Scientific Advice
Paediatric Plan
Marketing Authorisation Evaluation
Post Marketing procedures

Scientific Advisory/Ad hoc expert Groups

- Any Committee can convene a SAG during the evaluation of a medicine when they encounter specific questions that are best answered by experts in the field, including patients and healthcare professionals
- SAGs exist for specific therapeutic areas and when an issue arises for which there is no SAG, an ad hoc expert group is organised
- Experts (patients and healthcare professionals), with experience of the disease/condition/treatment, are invited to participate in all SAG / ad hoc expert group meeting
- Experts contribute by providing input to the discussions on the benefits and risks, from their perspective in relation to the questions that the CHMP is asking

Part II

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Pharmacovigilance at EMA

Pharmacovigilance

Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines.


PRE-SUBMISSION
EVALUATION
POST AUTHORISATION
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Scientific Advice
Paediatric Plan
Marketing Authorisation Evaluation
Post Marketing procedures

EUROPEAN COMMISSION

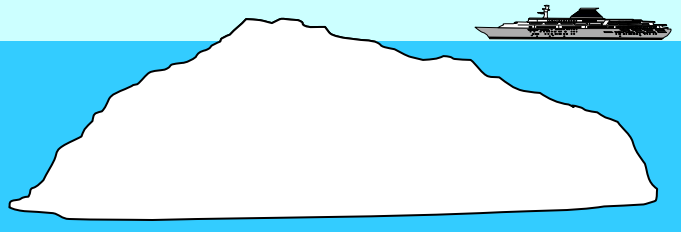
What now?

Pharmacovigilance

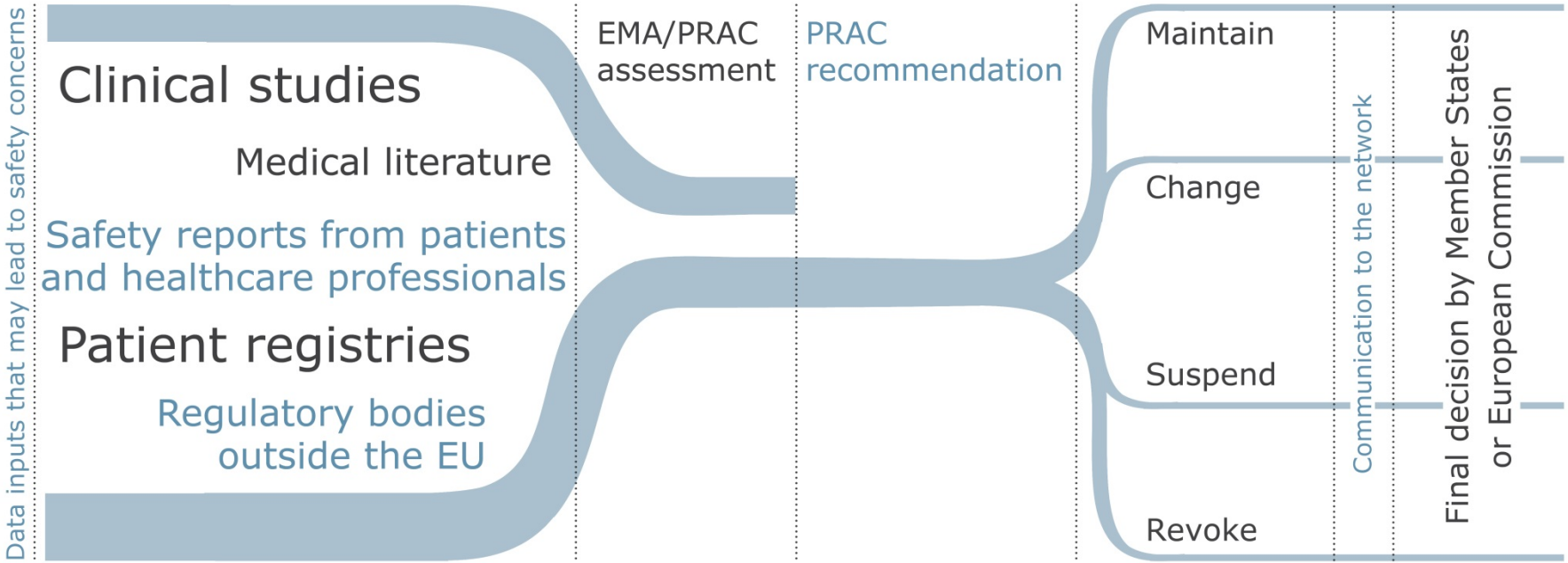
What we know at the end of the clinical trial programme…

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

EudraVigilance Human

Safety monitoring

Pharmacovigilance overview

- Collect information on the potential side effects
- Decide if new or changing side effects are observed
- Decide if action is needed to optimise the safe and effective use of the medicine
- Take action and communicate to users
- Has action been effective?

What safety actions can be taken

When new information arises that warrants action, regulators have several tools available:

- Update patient information/Summary of Product Characteristics (SmPC)
- Inform patients and/or healthcare professionals (Safety Communications, Direct healthcare professional communication (DHPC), educational material)
- Review of benefit-risk profile of medicine (referral)
- Restrict access to medicine

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Review of Documents

Involvement along the medicine lifecycle at EMA

Patients, Healthcare Professionals and Academia at EMA

Why the review?

To ensure message is clear and all relevant information is there. We want reviewers to tell us about:

- Complicated/oversimplified language
- Unexplained scientific terms
- Inappropriate explanations
- Unnecessary/missing information
- Confusing numbers

Which documents are reviewed by patients?

- Medicines overview (formerly EPAR summaries)
- Safety communications
- Herbal summaries
- Package leaflets (PL)

Which documents are reviewed by healthcare professionals?

- Safety communications
- Direct healthcare professional communications (DHPC)

Thank you for your attention

Further information

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