EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How are medicines evaluated at the EMA – Part I

Nathalie Bere, Patients relations co-ordinator

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).

European Regulatory Network

The European regulatory system for medicines is a unique model in the global regulatory environment.

This system is based on a network that includes all national medicines authorities (human and veterinary) from EU Member States and the European Economic Area, working closely together in an integrated manner.

What does the EMA do

- Evaluation of **marketing authorisation applications** for **human** and **veterinary** medicines submitted by pharmaceutical companies
- Provision of **scientific advice** on the development of medicines
- Evaluation of applications for **orphan designation** in EU
- Evaluation of **paediatric investigation plans** (or waivers)
- Coordination of European **pharmacovigilance** (supervision of the medicines on the market)
- Evaluation of **arbitration** and **referral** procedures
- Provision of good quality and independent **information on the medicines** it evaluates to patients and healthcare professionals
- Coordination of Member States' **inspections**

What the EMA does not do

The European Medicines Agency does not control:

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

Are all medicines approved via the EMA?

No. In the European Union (EU), there are two ways of getting a marketing authorisation for a medicine:

1. Centralised authorisation procedure, via the European Commission after evaluation by EMA, which results in a single marketing authorisation valid throughout the EU;

2. National authorisation procedures, where individual EU Member States authorise medicines for use in their own territory through 3 possible procedures:

- National authorisation
- Mutual-recognition procedure (MRP)
- Decentralised procedure (DCP)

Medicines that are mandatory for evaluation at EMA

- Rare diseases
- HIV, cancer, neurodegenerative disorders, diabetes
- Auto-immune diseases, viral diseases
- All biotech products
- Gene therapy
- Monoclonal antibodies

+ Other innovative products

Medicines outside the mandatory scope can also be evaluated at EMA if they meet certain criteria.

The centralised procedure and the EMA

ONE

Marketing Authorisation application

Evaluation

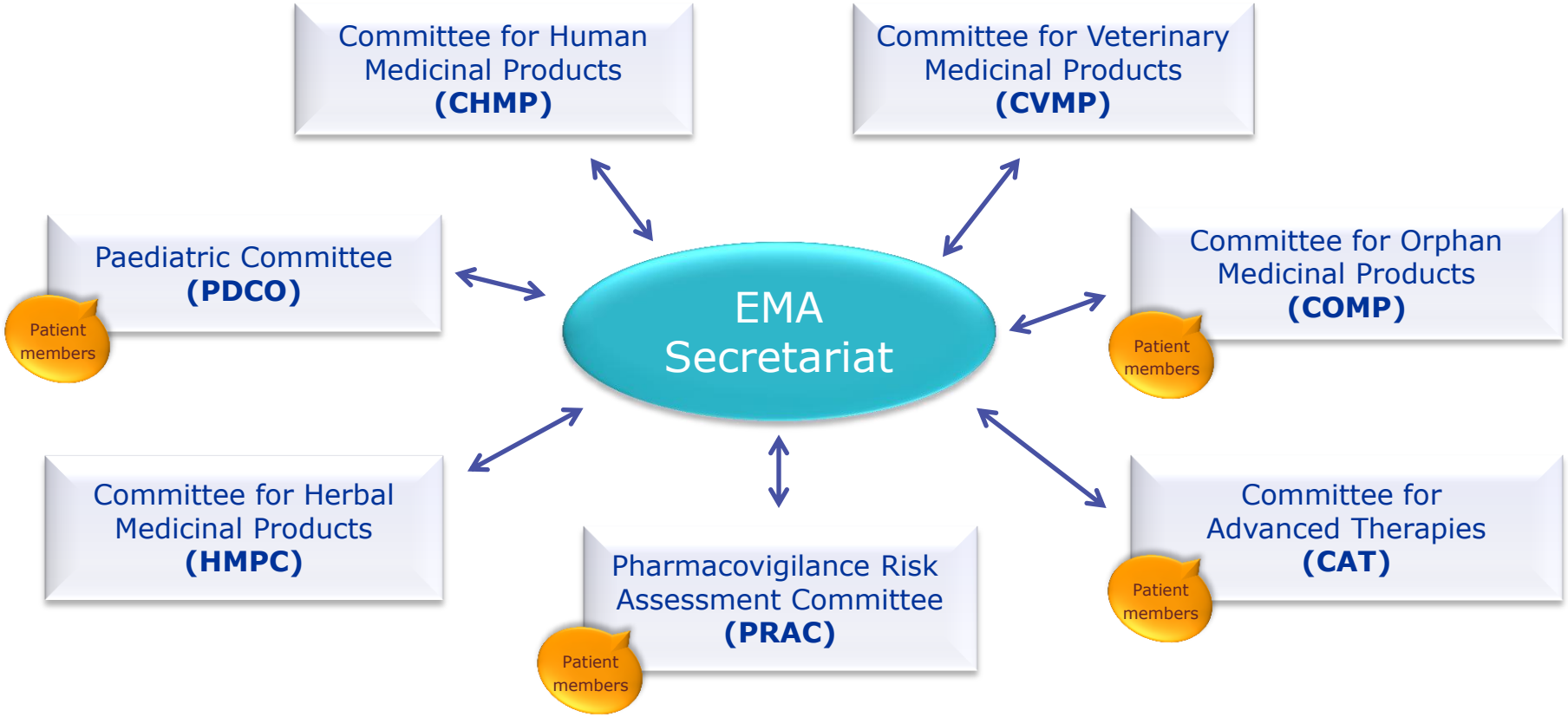
- Authorisation in all EU MS
- Invented name
- Product information
  - Summary of Product Characteristics (SmPC)
  - Labelling
  - Package Leaflet (PL)

ALL

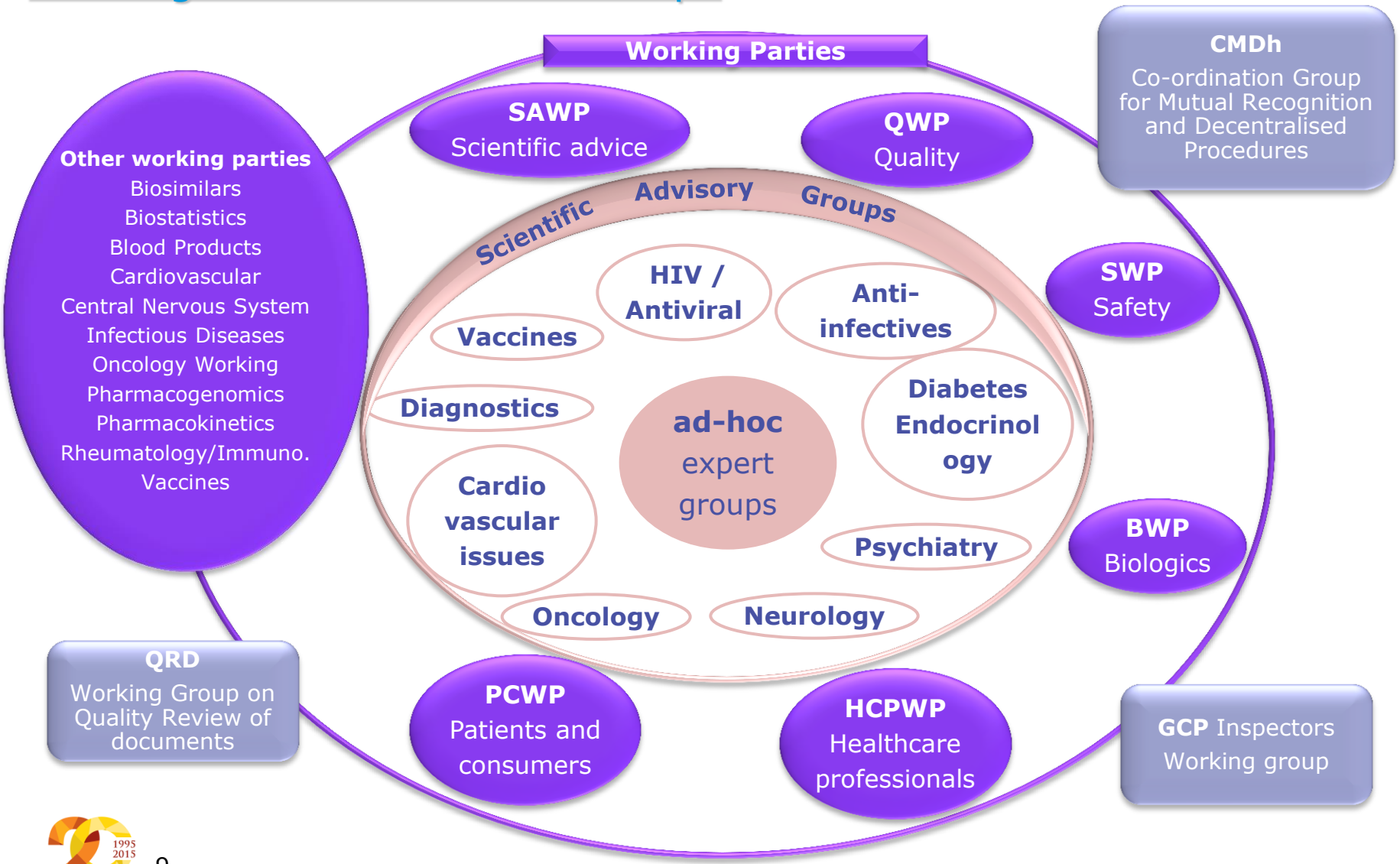
EU languages

EMA and its scientific committees

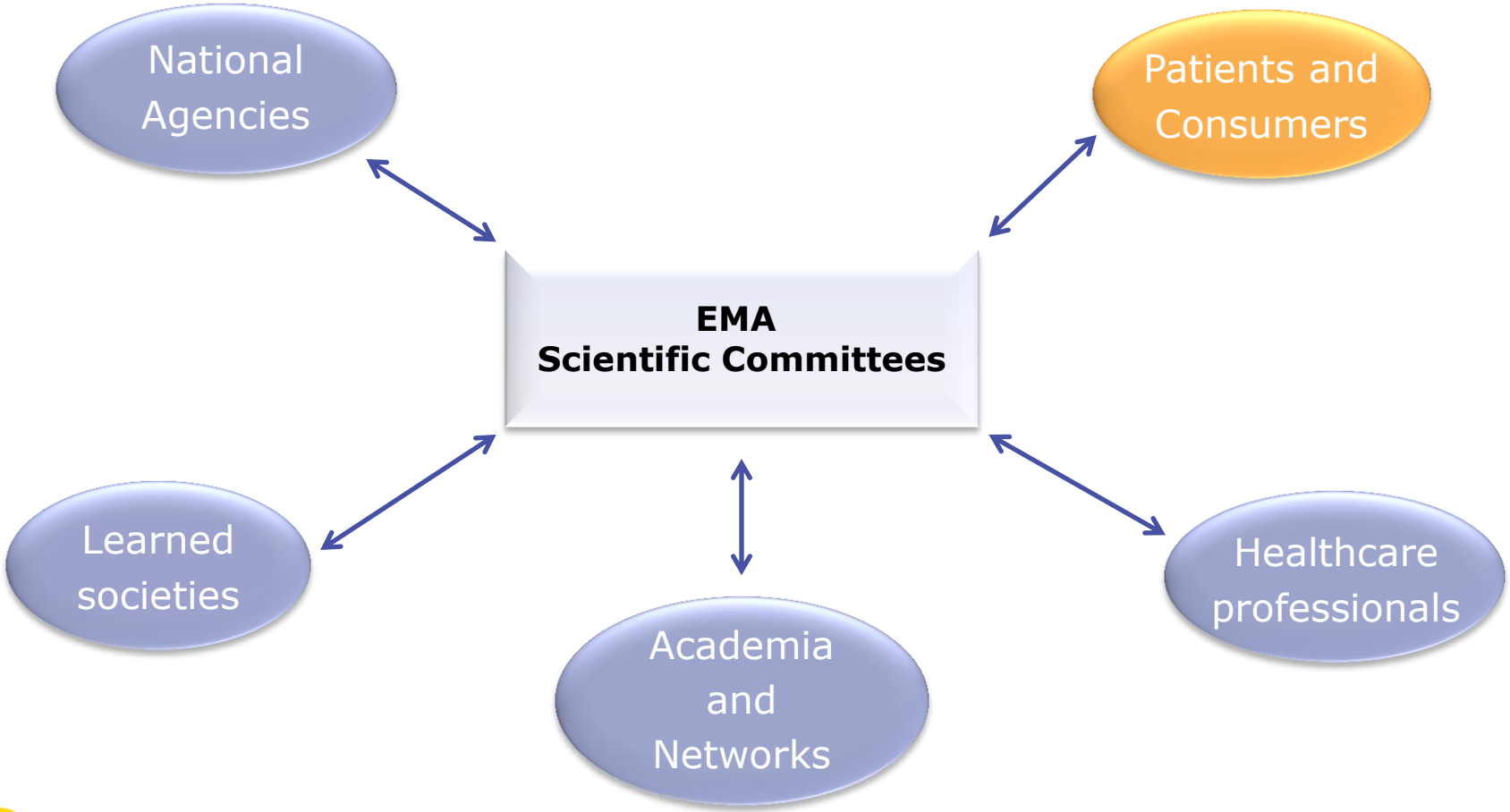
The EMA committees contain members nominated by the medicines regulatory authorities of the EU Member States (the 'national competent authorities')



Working Parties and other Groups

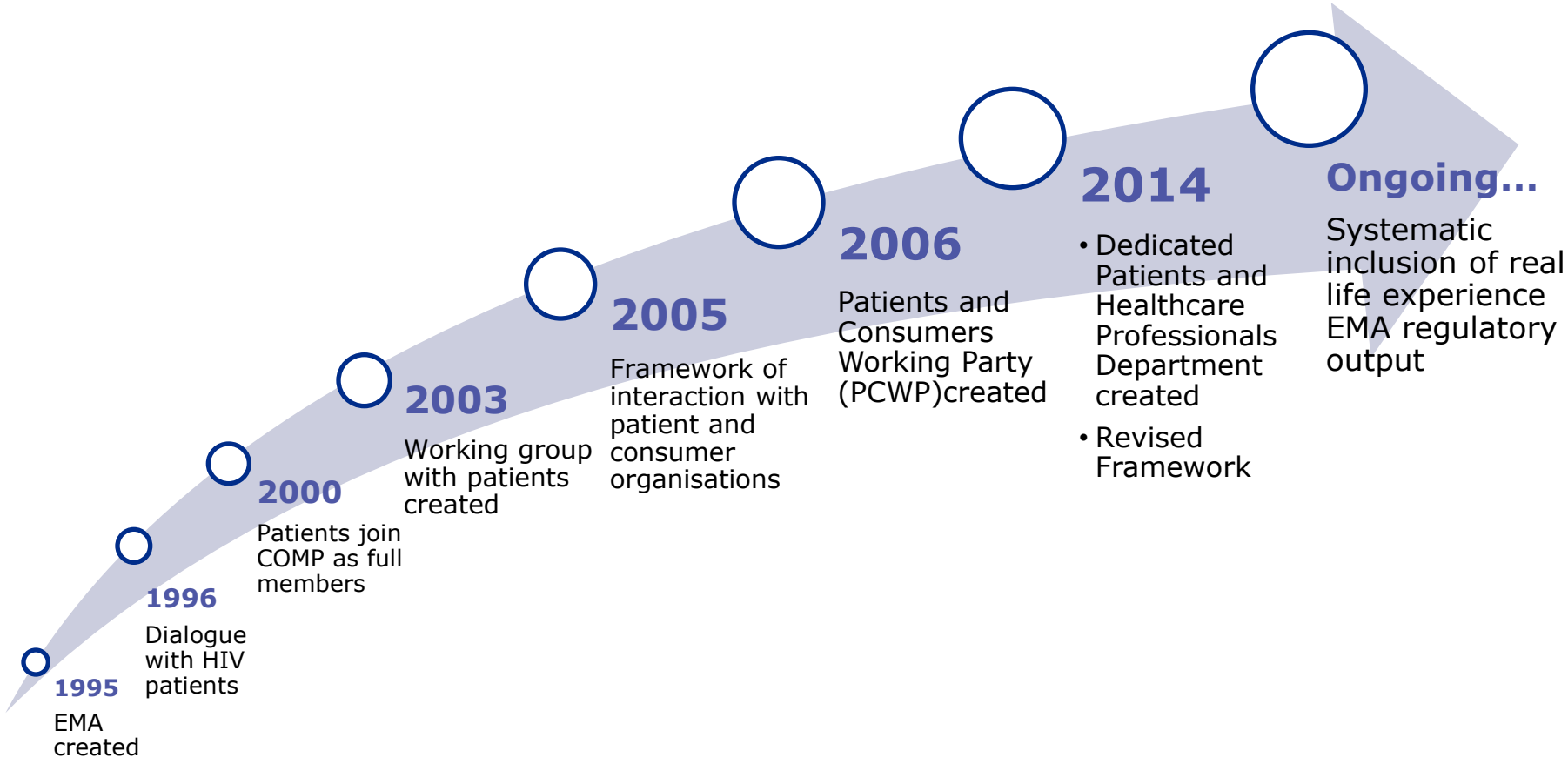


Experts who work with the scientific committees



Patient/consumer involvement in the EMA

Interaction with patients: the EMA journey… so far



How are patients involved at EMA?

Non-product related

Patients representing *patients'* organisations	• Management Board • EMA Scientific Committee(s)
Patients representing *their* organisations	• Patients' and Consumers' Working Party (PCWP) • EMA consultations • Workshops

Product related

Patients as *individual* experts	• Scientific Advice / Protocol Assistance Procedures • Scientific Advisory / *ad hoc* expert Groups • Scientific committee consultations • Review of documents

Patient involvement as individual experts in EMA activities

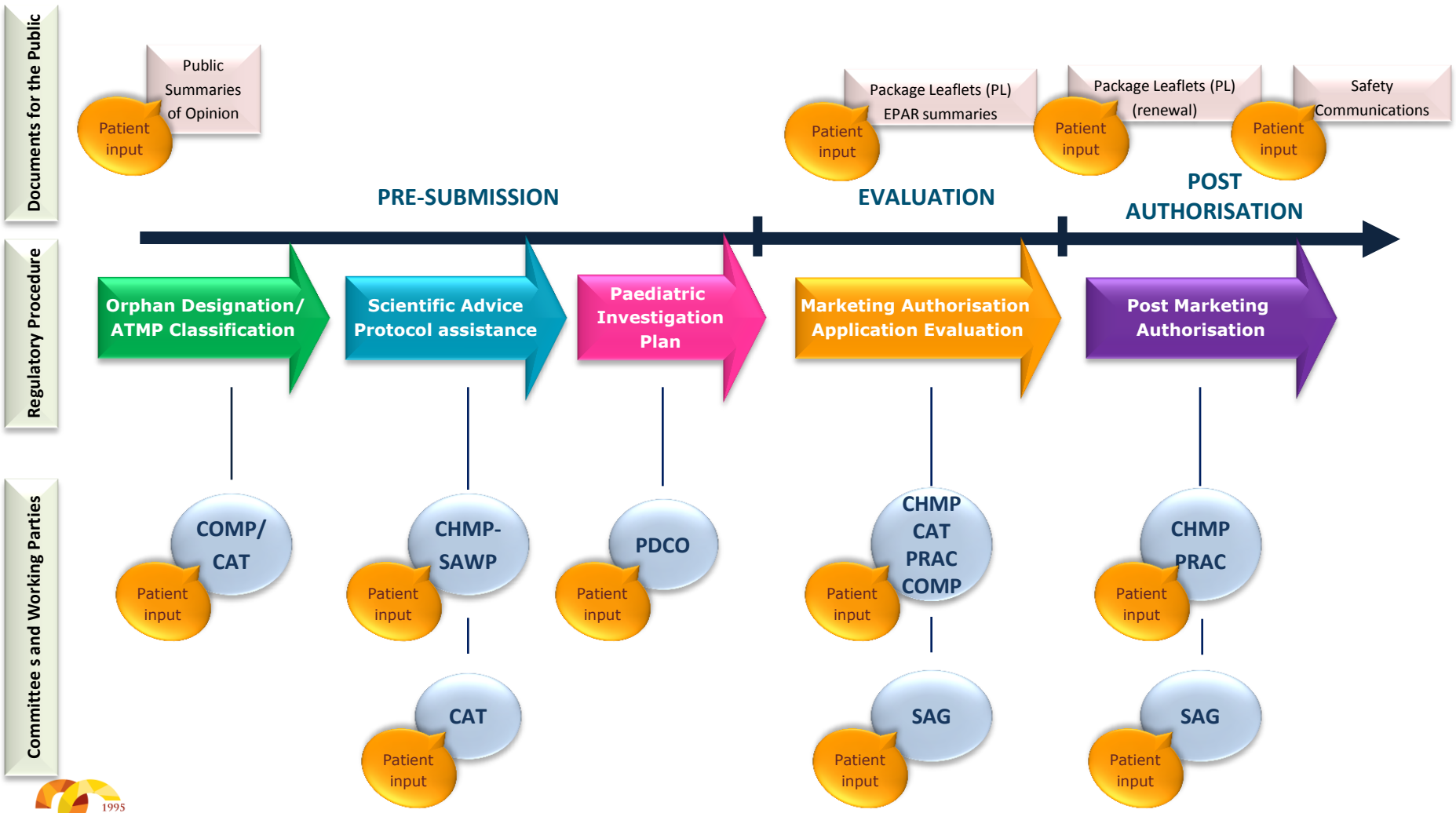
Pre-submission:

- 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

Patient involvement along the medicine lifecycle at EMA



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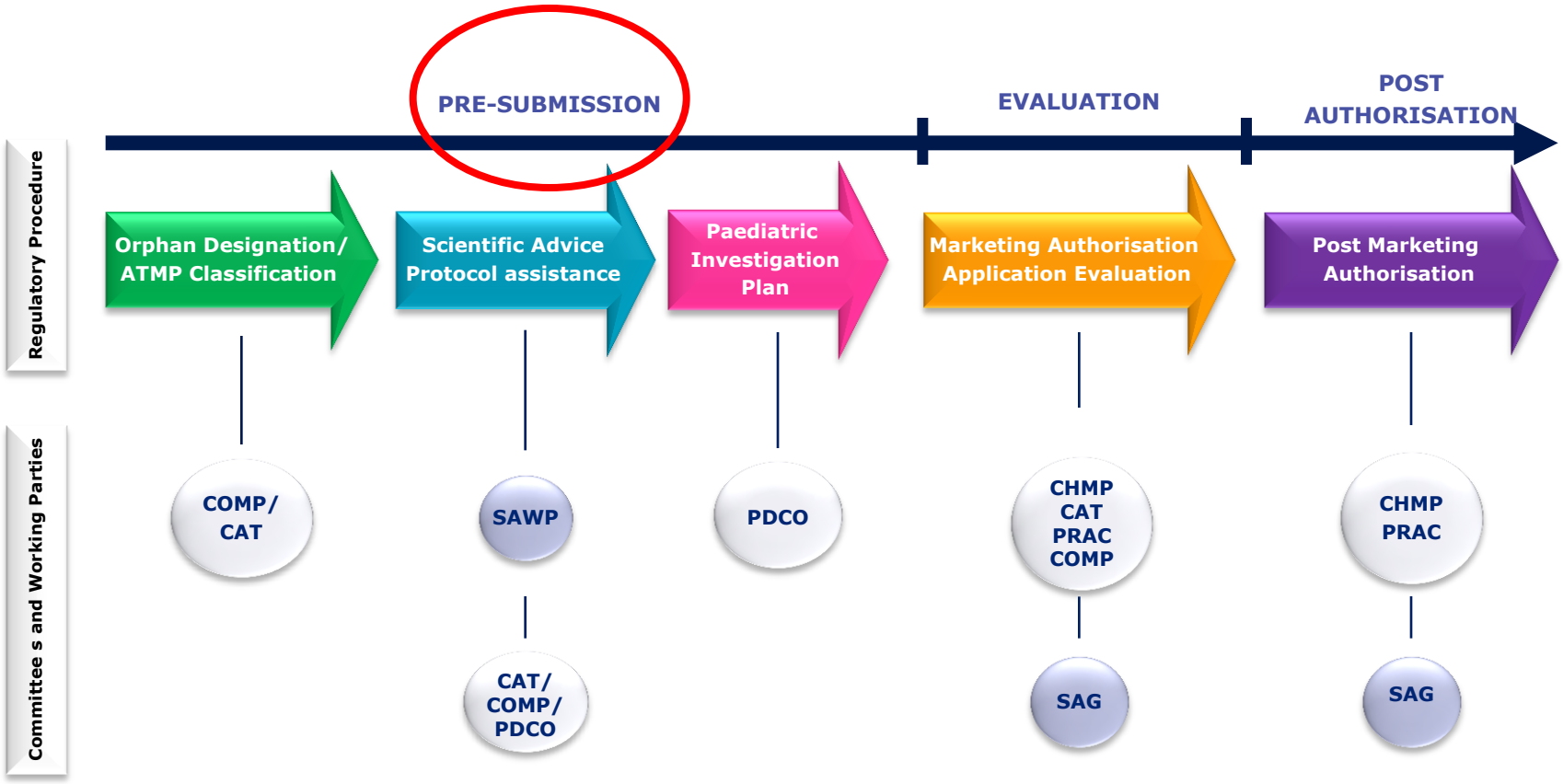
Scientific Advice at the EMA

Committees in human Medicines Regulatory process



Scientific Advice

- 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 Committee for Medicinal Products for Human Use (CHMP) provide scientific advice by answering specific questions posed by the companies.

Types of questions

Scientific Advice can be provided on questions ranging from:

- Quality – manufacture of medicines
- Non-clinical – animal studies – interpretation and extrapolation of results
- **Clinical** – discussion of study population, endpoints, feasibility of trial
- Regulatory – including statistics
- **Significant benefit** – for orphan medicines (where applicable)

The role of patients and patient representatives

Patient representatives are invited to participate in EMA scientific advice procedures:

- Either face to face meeting or via written comments
- Share their 'real-life' perspective and experience with the SAWP 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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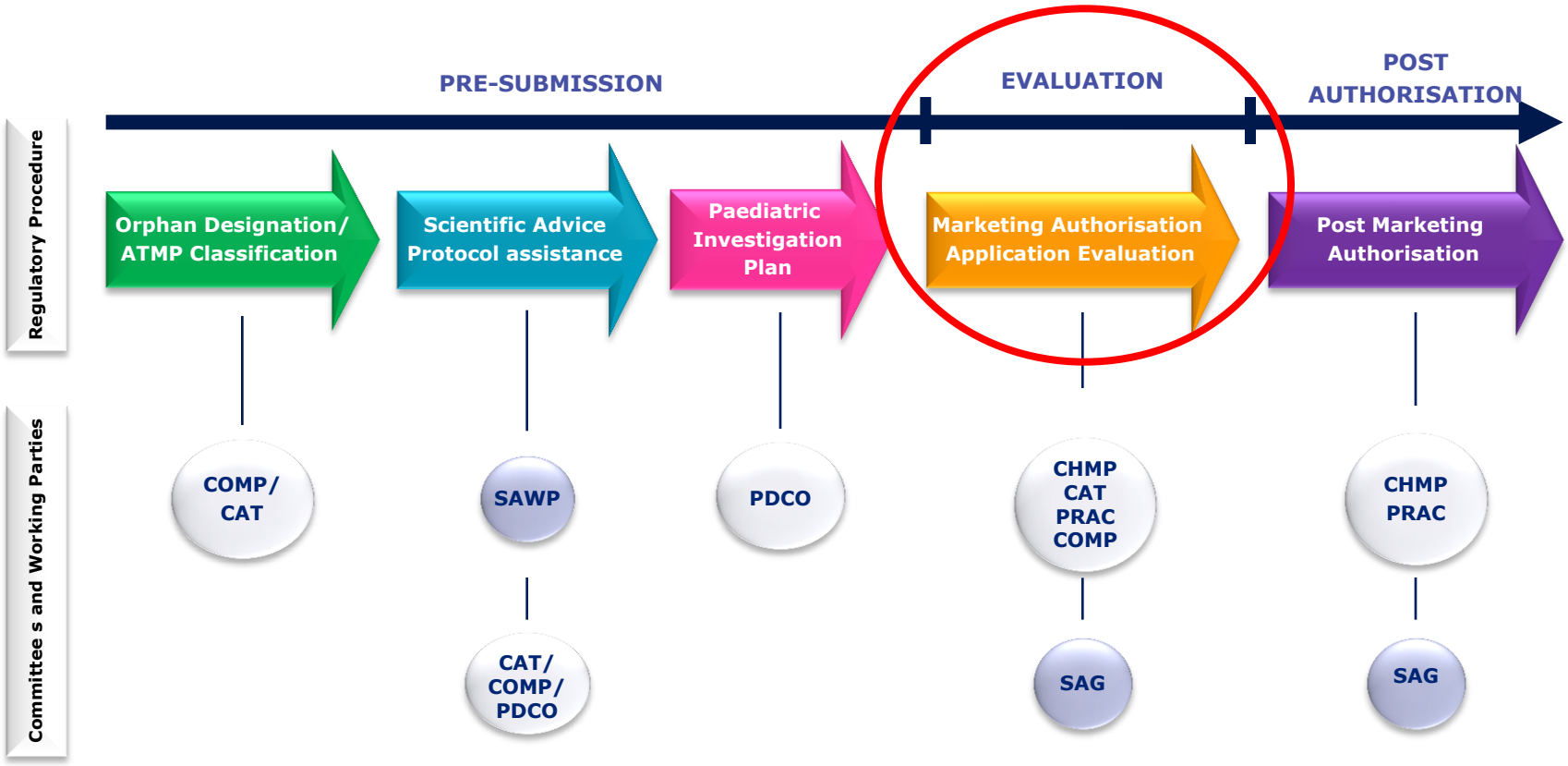
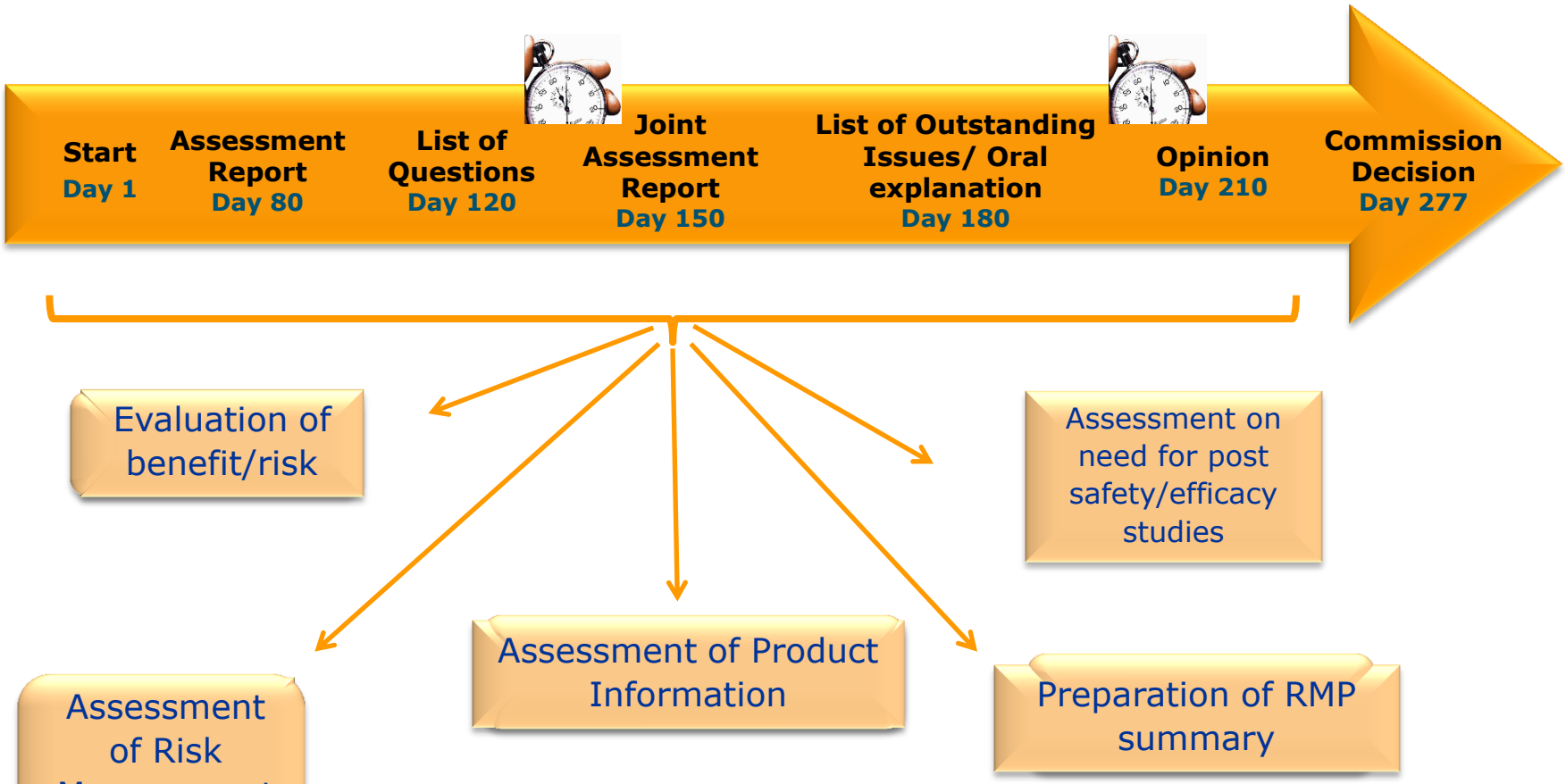
Scientific Advisory/ad hoc expert Group meetings

Committees in human Medicines Regulatory process



Evaluation overview - CHMP



Additional information:

- Brochure – Applying for marketing authorisation
- CHMP overview

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)

For these hyperlinks – please refer to question 56

Scientific Advisory/Ad hoc expert Groups

- The CHMP or the Pharmacovigilance and Risk Assessment Committee (PRAC) can convene a SAG during the evaluation of a specific medicine when they encounter specific questions that are best answered by experts in the field, including patients

- SAGs exist for specific therapeutic areas and when an issue arises for which there is no SAG, an *ad hoc* expert group is organised

- Two patients, with experience of the disease/condition, are invited to participate in every SAG / ad hoc expert group meeting

- Patients 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

Contact

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