

# Introduction to the assessment of medicines in the European Union

09 July 2025

Presented by Prof. Bruno Sepodes

Chair of the Committee for Medicinal Products for  
Human Use (CHMP)



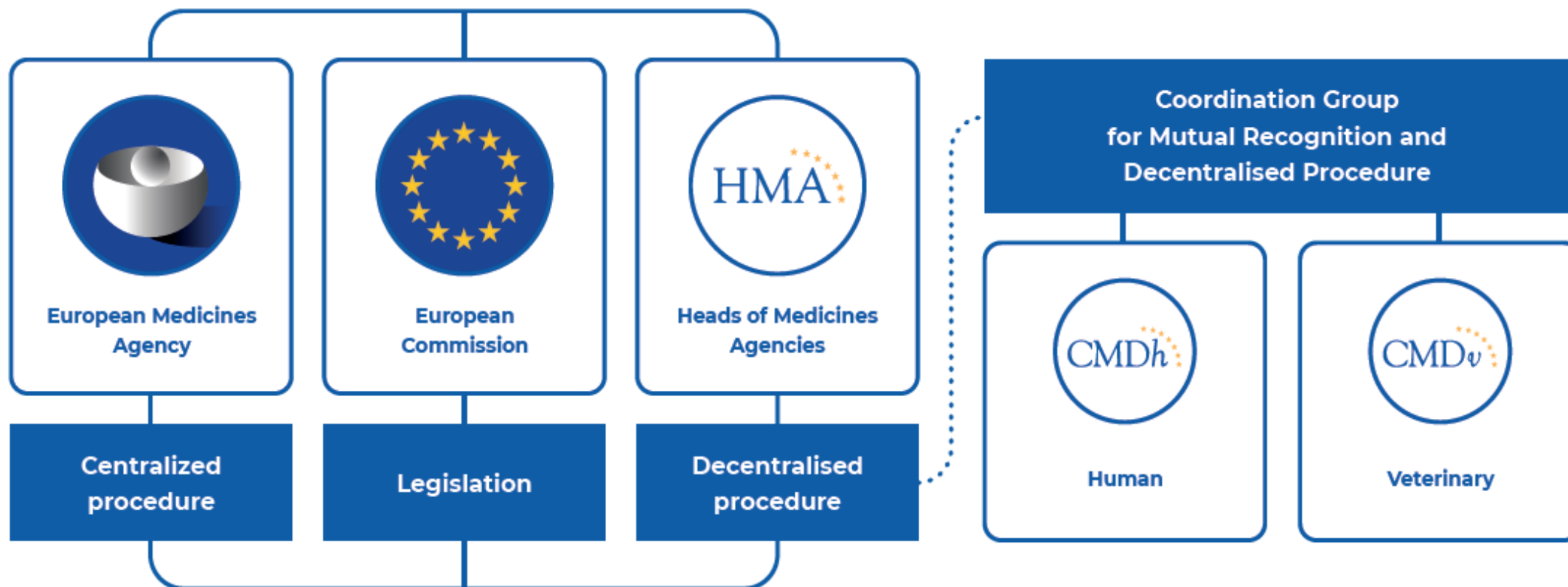
# EMA's mission

Science, Medicines, Health.

To foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the EU.



## European regulatory network



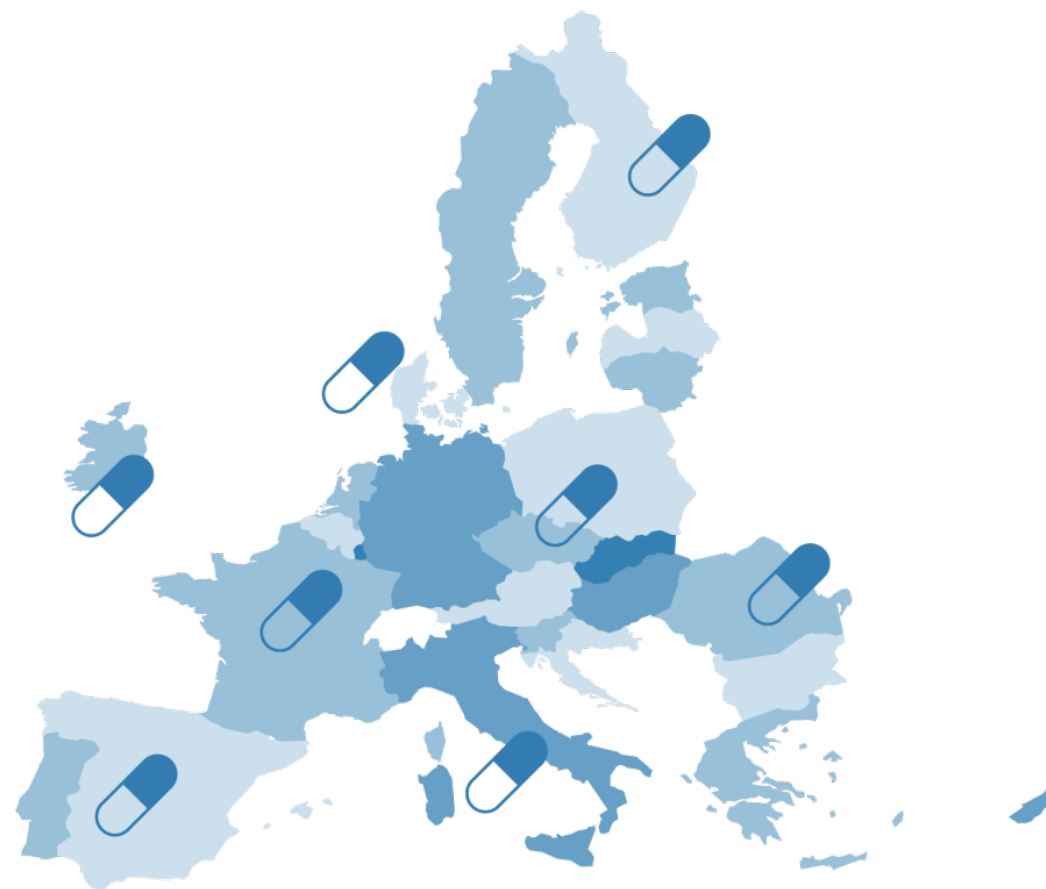
The cooperation between EMA, the National Competent Authorities in the Member States, and the European Commission is key

# How are medicines approved?

Different authorisation routes: one set of common rules



Centralised procedure (via EMA)



National procedures (via Member States)

# One application, everywhere



**1**

Application



**1**

Assessment

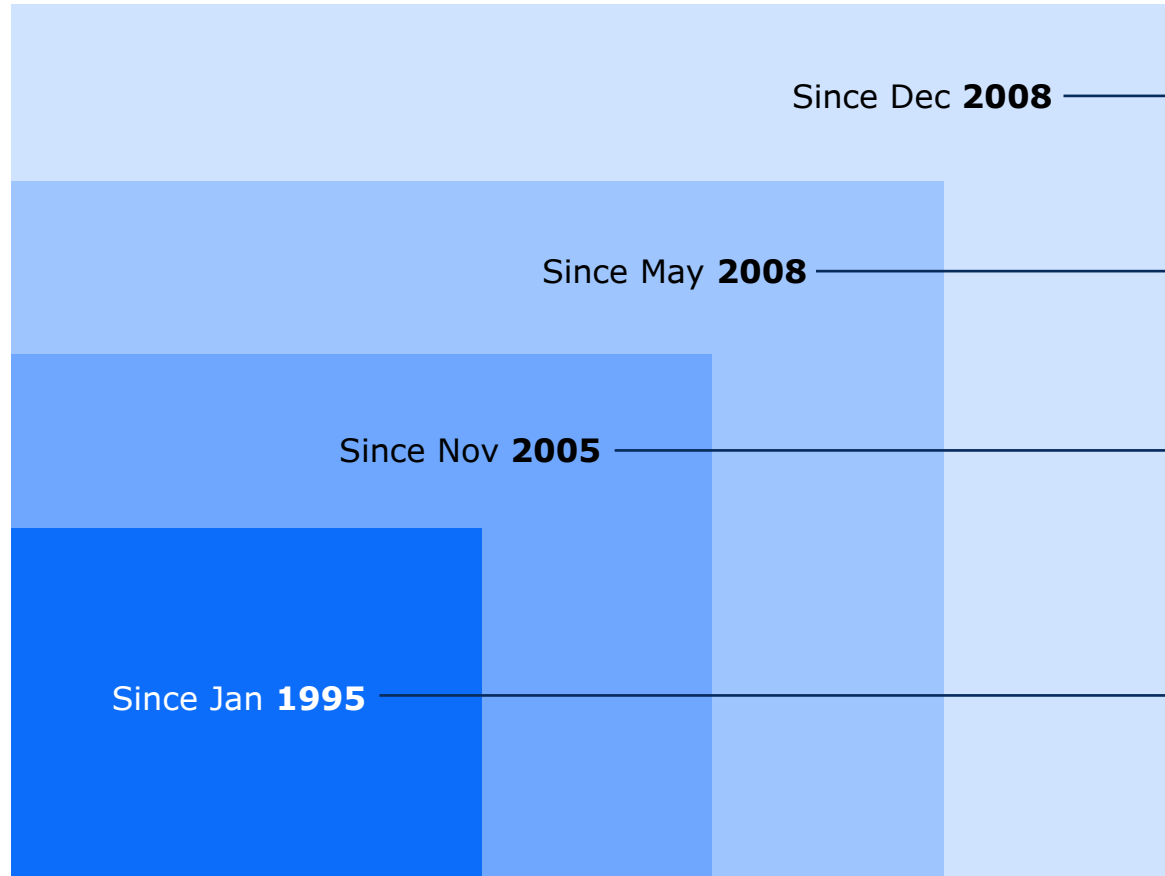


**27**

Member States

# Centralised procedure - Eligibility criteria

**Mandatory scope** - Art. 3(1) Regulation (EC) No 726/2004



ATMPs (advanced therapy medicinal products):

- Gene therapy products
- Somatic cell therapy products
- Tissue engineered products

- Auto-immune diseases and other immune dysfunctions
- Viral diseases

- HIV and/or treatment of AIDS
- Cancer
- Neurodegenerative disorders
- Diabetes
- Orphan medicines

- Recombinant DNA technology
- Controlled gene expression
- Monoclonal AB

# Our regulatory network



**4000**

Experts



**50+**

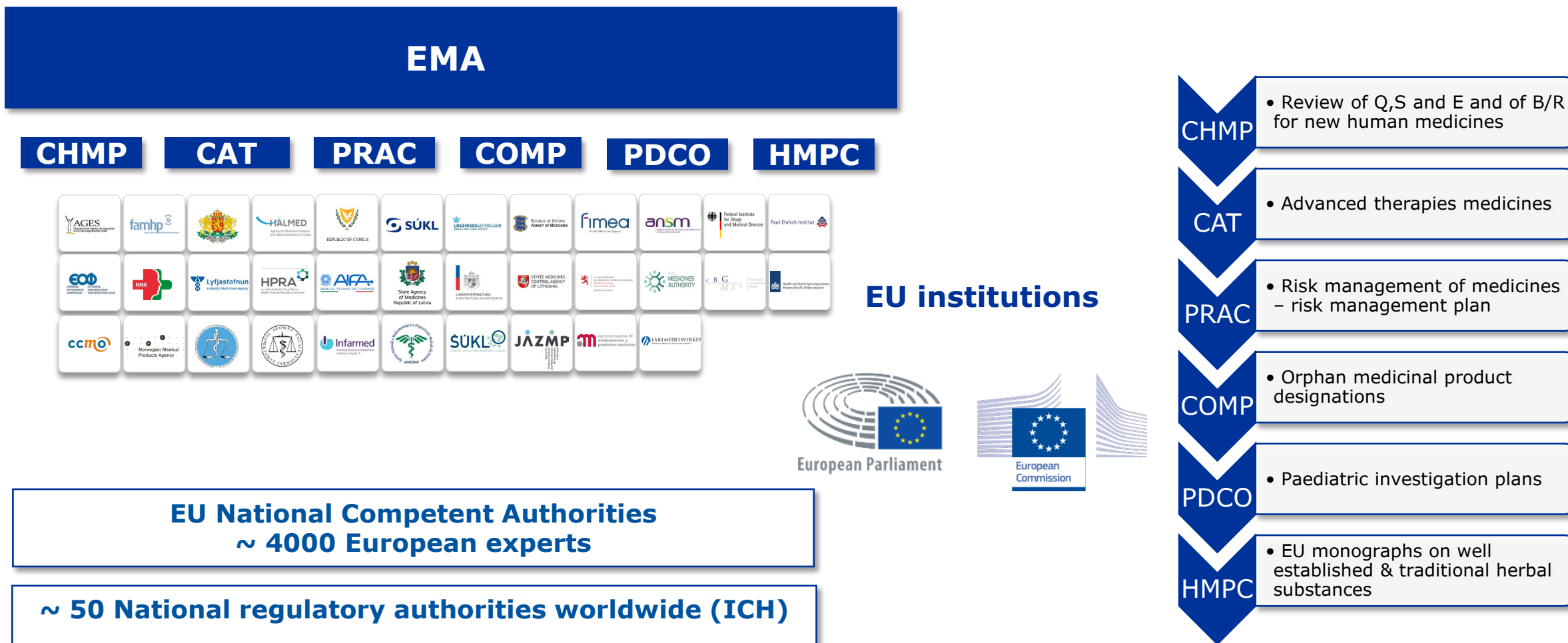
NCA's



**24**

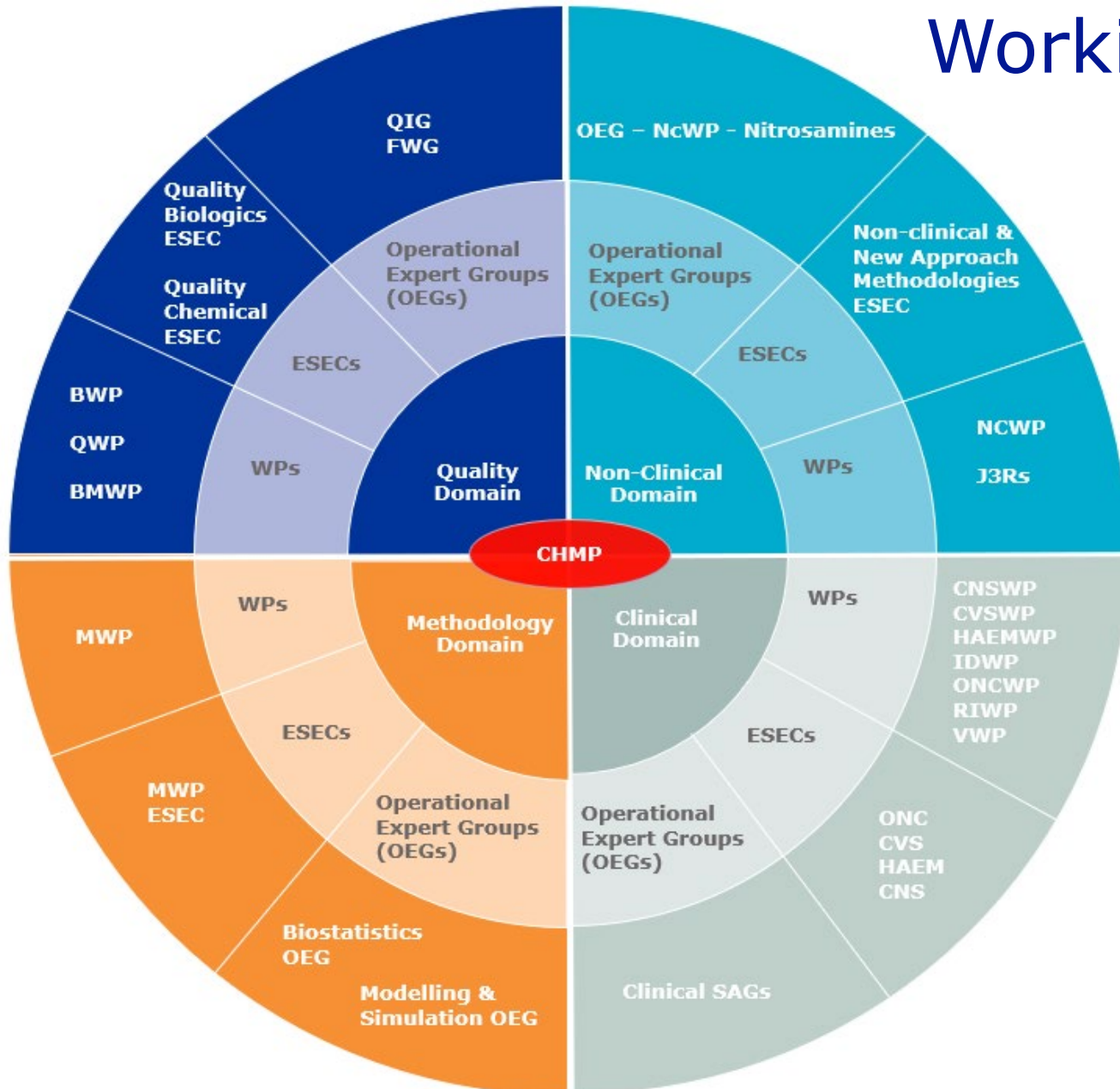
Official languages

# How do we do it?



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# Working parties, Advisory bodies



## Working parties (WPs)

- Provide **advice on regulatory procedures**
- Support the drafting of **scientific guidelines**
- Reinforced advice provided to the Committees on **specific requests** across different scientific areas

## Scientific Advisory Groups (SAGs) and Ad-Hoc Expert Groups (AHEGs)

- Therapeutic Areas covered by **SAGs: Vaccines, Oncology, Neurology, Cardiovascular, Infectious diseases, Immune and Inflammatory Diseases**; rest of areas are covered by AHEGs.
- Deliver **answers to specific questions** asked by the Committees; these bodies are not responsible for establishing or concluding on the B/R of a medicine.
- The members/participants are clinical experts and patient representatives
- Public call for interest to become a SAG member

# Supporting research and innovation of medicines

## Pre-authorisation

Innovation task force (H&V)

Paediatric investigation plan (PIP) (H)

Scientific advice (H&V)

Qualification of novel methodologies (H) / NTWP (V)

Advanced therapy medicinal product classification (H)

Regulatory and administrative assistance for SMEs (H&V)

Orphan designation (H) / Minor Use Minor Species (MUMS) (V)

PRiority MEDicines (H)

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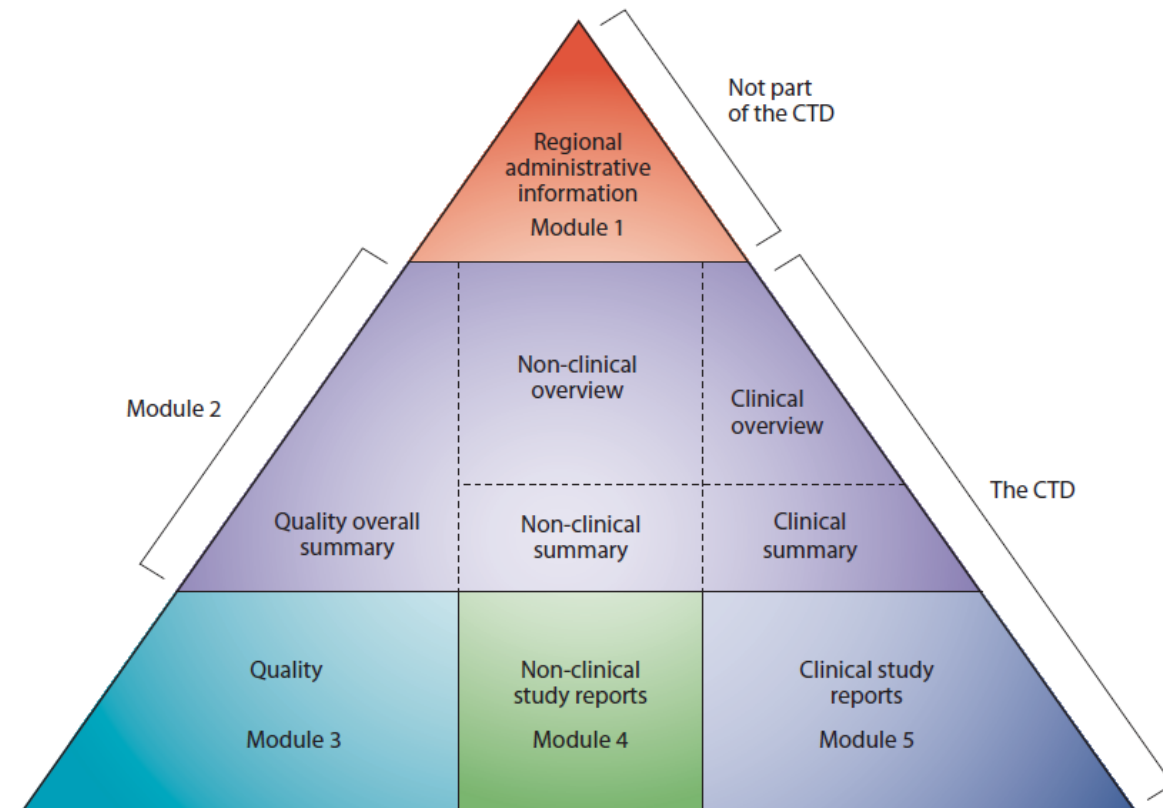
## Post-authorisation

Evaluation of application

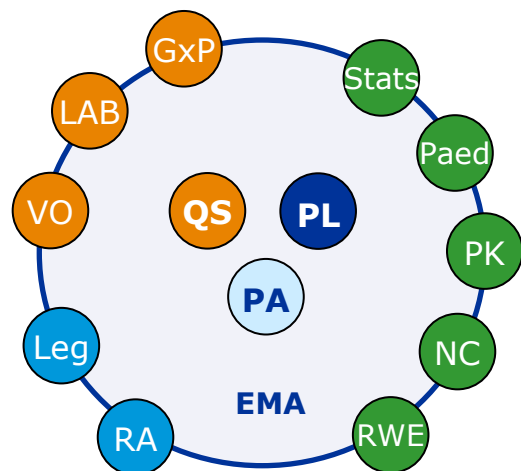
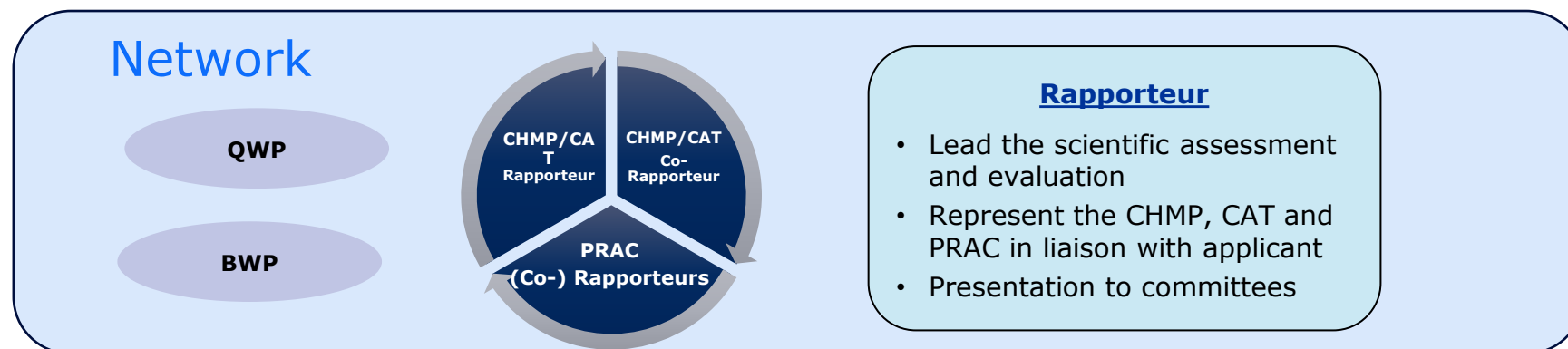


# Dossier submission and content

- **Only in eCTD** (electronic Common Technical Dossier) **format (e-submission)**
  - module 1 region specific,
  - modules 2, 3, 4 and 5 intended to be common for all regions
- National competent authorities have access through **common repository**
- All applications to be submitted in **English**
- **Timeslots** – Timetables published on the EMA website
- Administrative **validation** conducted by the EMA



# EMA support and product team



**Product Lead**

- Leads the product team output
- Provides input on procedural, regulatory & scientific matters to the Rapporteurs, Committee and applicant

**Specialist Functions:** Responsible for delivery of specific components of the opinions

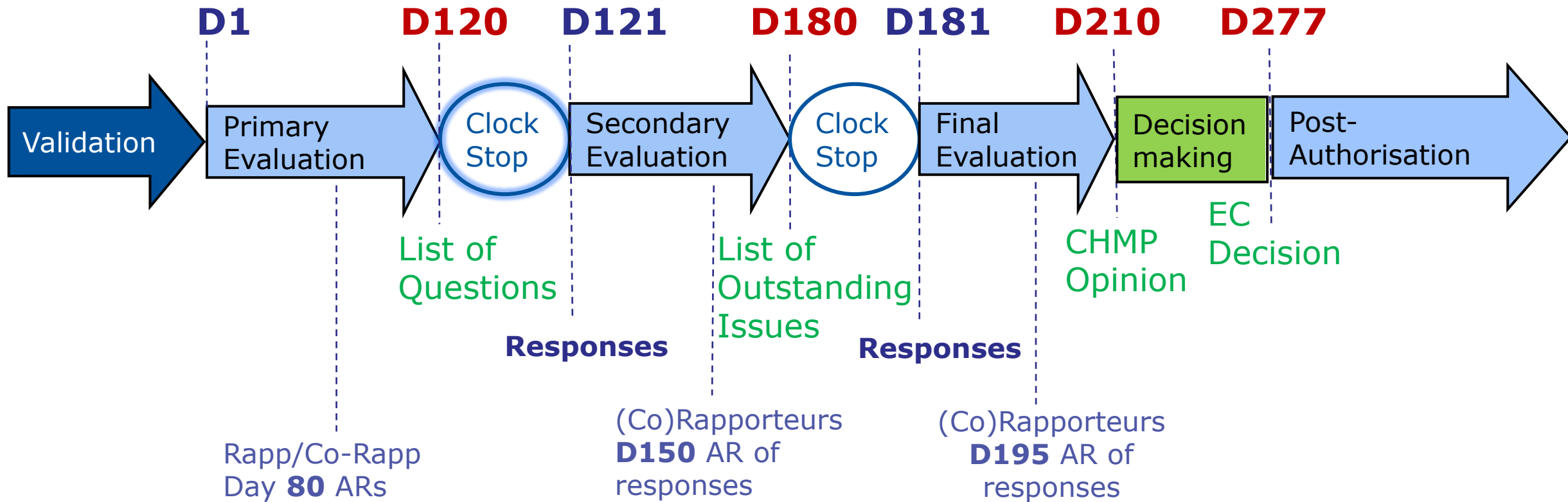
**Advisory Functions:** Provide Legal/RA advice, support when needed

**Consultation Functions:** Consulted on specific technical aspects if required

- \*QWP – quality working party
- \*BWP – biological working party
- \*QS – quality specialist
- \*GMP – good manufacturing practices
- \*GCP – good clinical practices
- \*GLP – good laboratory practices
- \*RA- regulatory affairs
- \*PK – pharmacokinetics
- \*RWE – real world evidence
- \*LAB – labelling
- \*VO – validation officer
- \*leg – legals
- \*NC – non-clinical
- \*Paed – paediatrics
- \*Stats - statistics

# Overview of the assessment process for initial MAA

## EMA – CHMP - CAT – PRAC










### Potential additional steps:

- GMP, GLP, GCP Inspections
- Consultation of Scientific Advisory Group (SAG) or *ad hoc* expert group, other committees or WP
- Oral explanation

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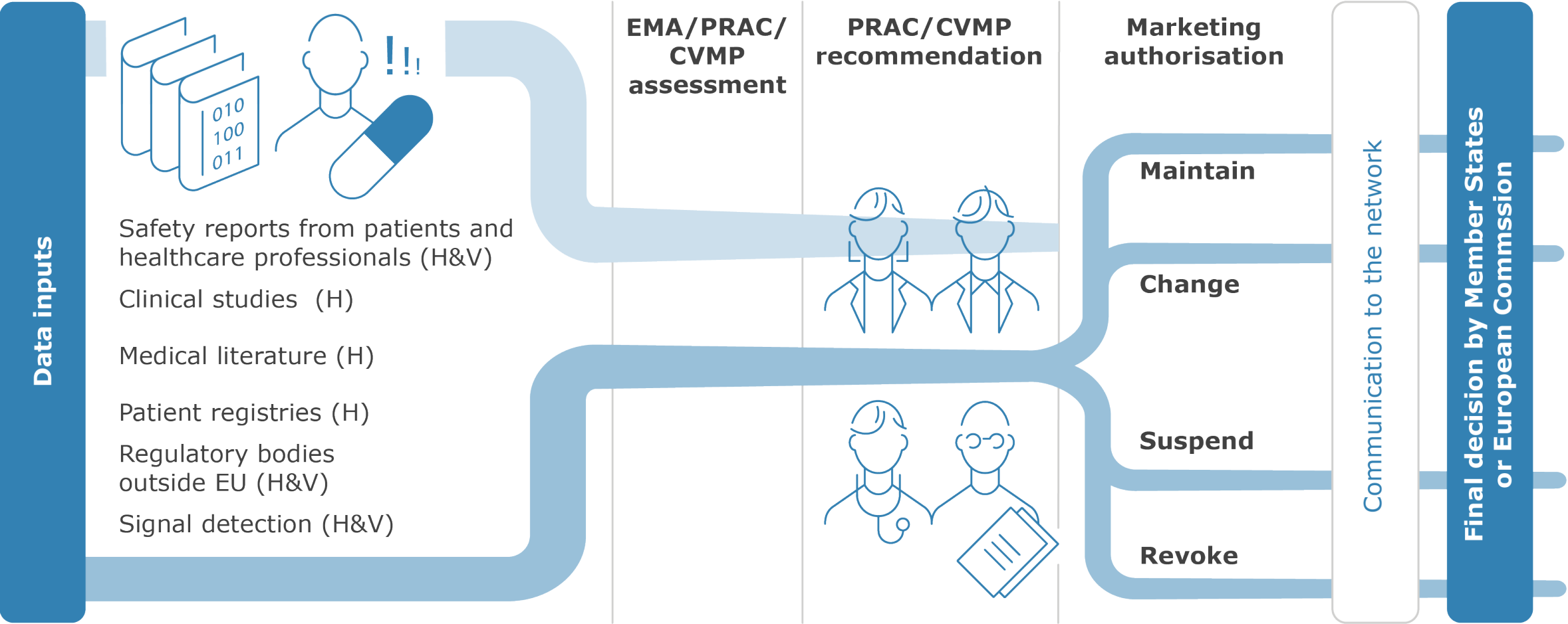
# Final CHMP Opinion

-  **CHMP opinion + Annex A (listing all authorised presentations)**
-  **Annex I: Summary of the Product characteristics (basis for healthcare professionals on how to use the medicine)**
-  **Annex II: information on manufacturers, legal status (on prescription or not, etc.)**
-  **Annex III: Labelling and Package Leaflet**
-  *Annex IV MA Specificities\*: similarity, derogation for orphans, eMA, cMA, additional data exclusivity*
-  *Annex 127a\*: Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states*
-  **CHMP Assessment report (EN only)**

## Post-opinion phase

- **Linguistic review** (27 days) – translations in all EU official languages
- European Commission (EC) prepares **draft decision**
- **Standing Committee** on Medicinal Products for Human Use (representatives from Member States) gives Opinion on the draft decision
- **EC adopts the decision** on granting (or refusing) MA, which takes effect from the date of notification

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



# The bigger picture



**Promoting good,  
evidence-based  
information for patients**



**Aligning with global  
regulators to address  
common challenges**



**Building trust in science  
and public health in the EU**

# Thank you

