EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

Introduction to the assessment of medicines in the European Union

Joint meeting of the PCWP and HCPWP

23rd September 2025

Presented by Prof. Bruno Sepodes

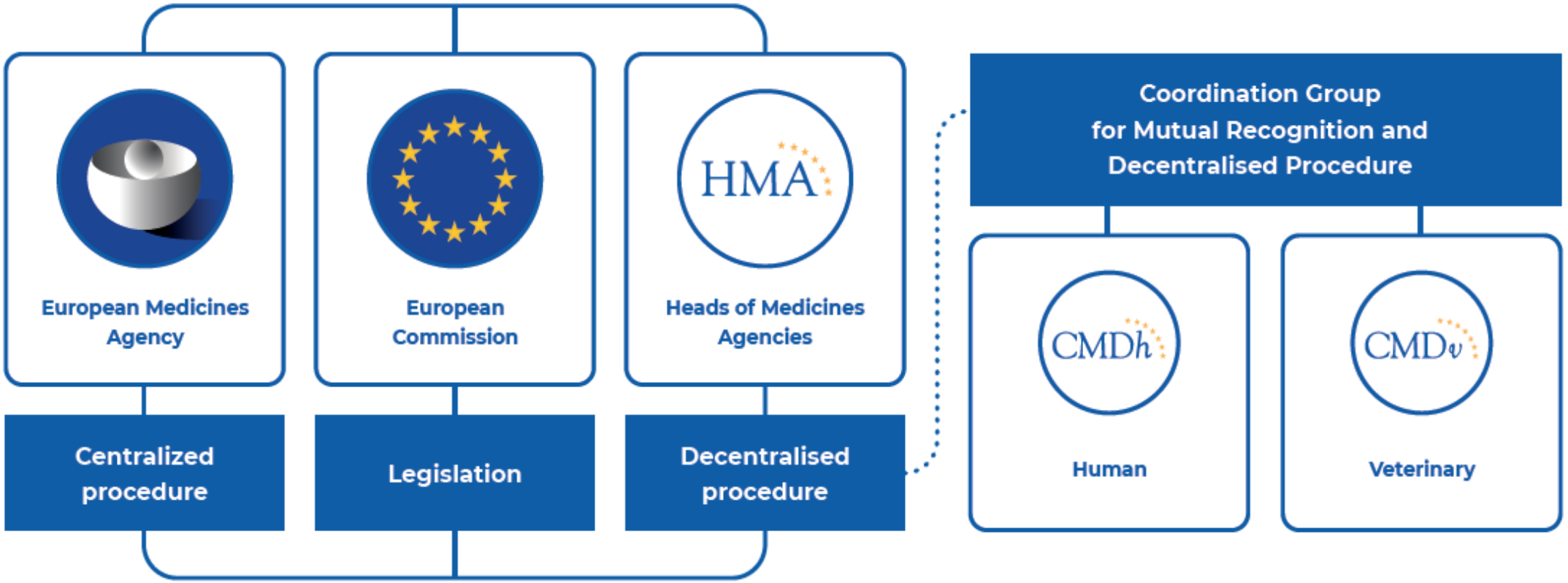
Chair of the Committee for Medicinal Products for Human Use (CHMP)

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.

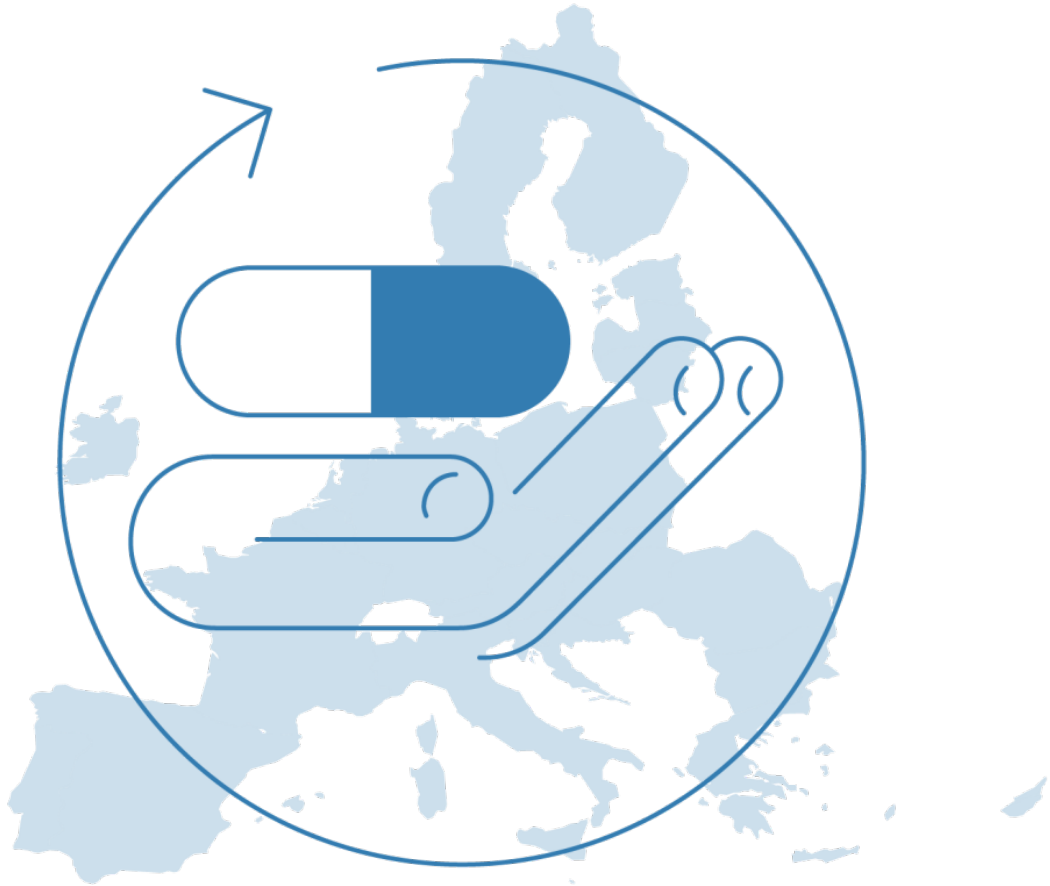
European regulatory network



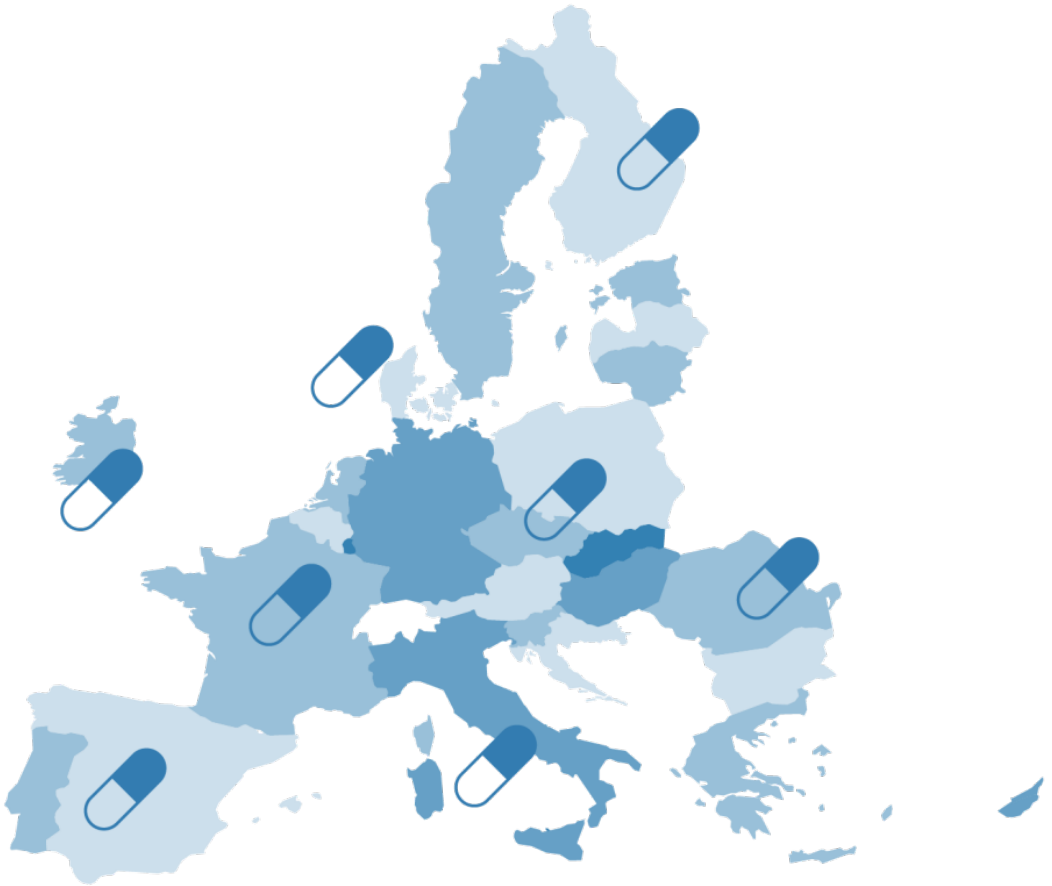
The cooperation between EMA, the National Competent Authorities in the Member States, and the European Commission is key

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

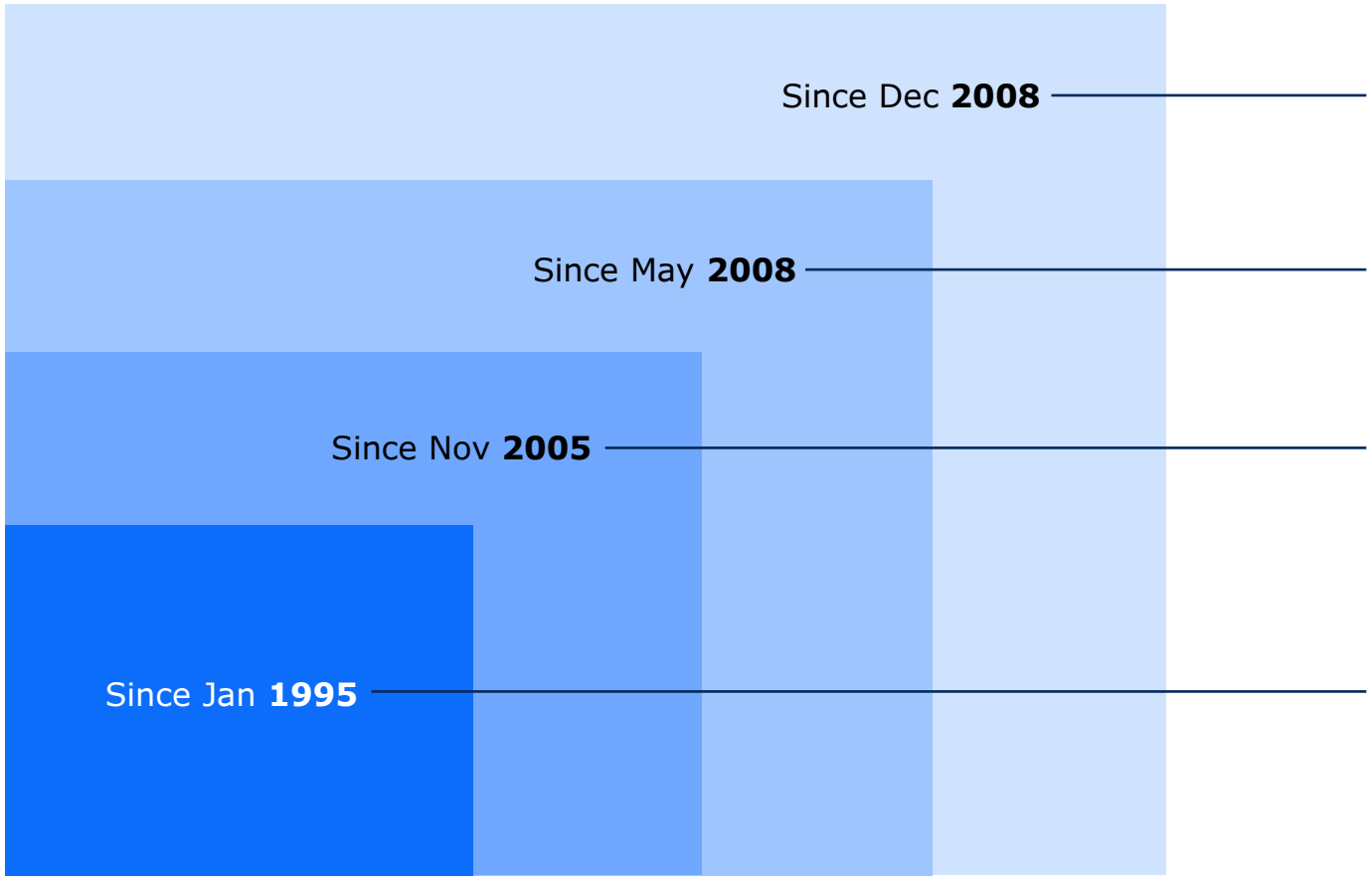
Assessment

27

Member States

Centralised procedure - Eligibility criteria

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



ATMPs (advanced theraphy medicinal products):
- Gene theraphy 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+

NCAs

24

Official languages

How do we do it?

EMA

CHMP **CAT** **PRAC** **COMP** **PDCO** **HMPC**

EU institutions

European Parliament

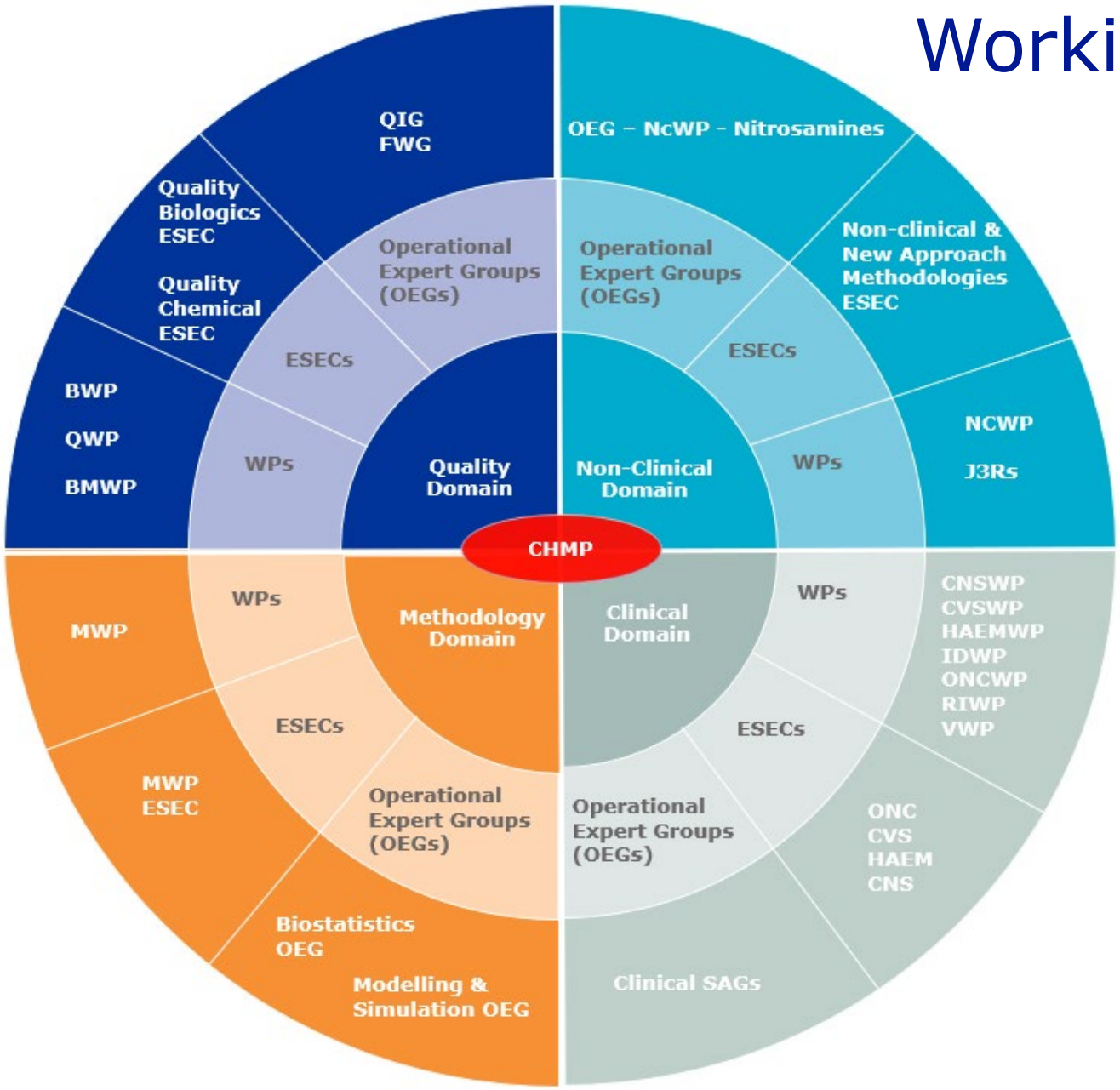
European Commission

EU National Competent Authorities
~ 4000 European experts

~ 50 National regulatory authorities worldwide (ICH)

- **CHMP**
  - Review of Q,S and E and of B/R for new human medicines
- **CAT**
  - Advanced therapies medicines
- **PRAC**
  - Risk management of medicines – risk management plan
- **COMP**
  - Orphan medicinal product designations
- **PDCO**
  - Paediatric investigation plans
- **HMPC**
  - EU monographs on well established & traditional herbal substances

Working parties, Advisory bodies



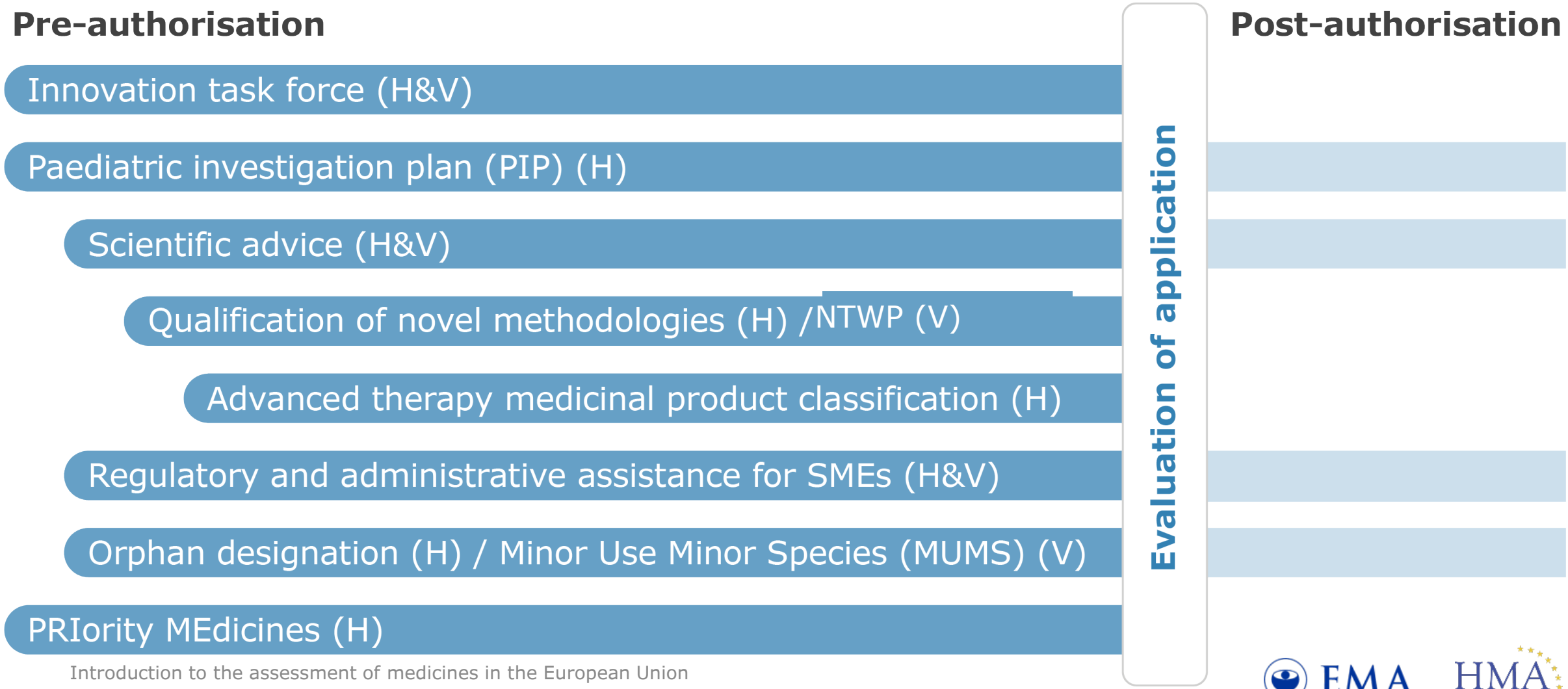
Working parties (WPs)

- 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)

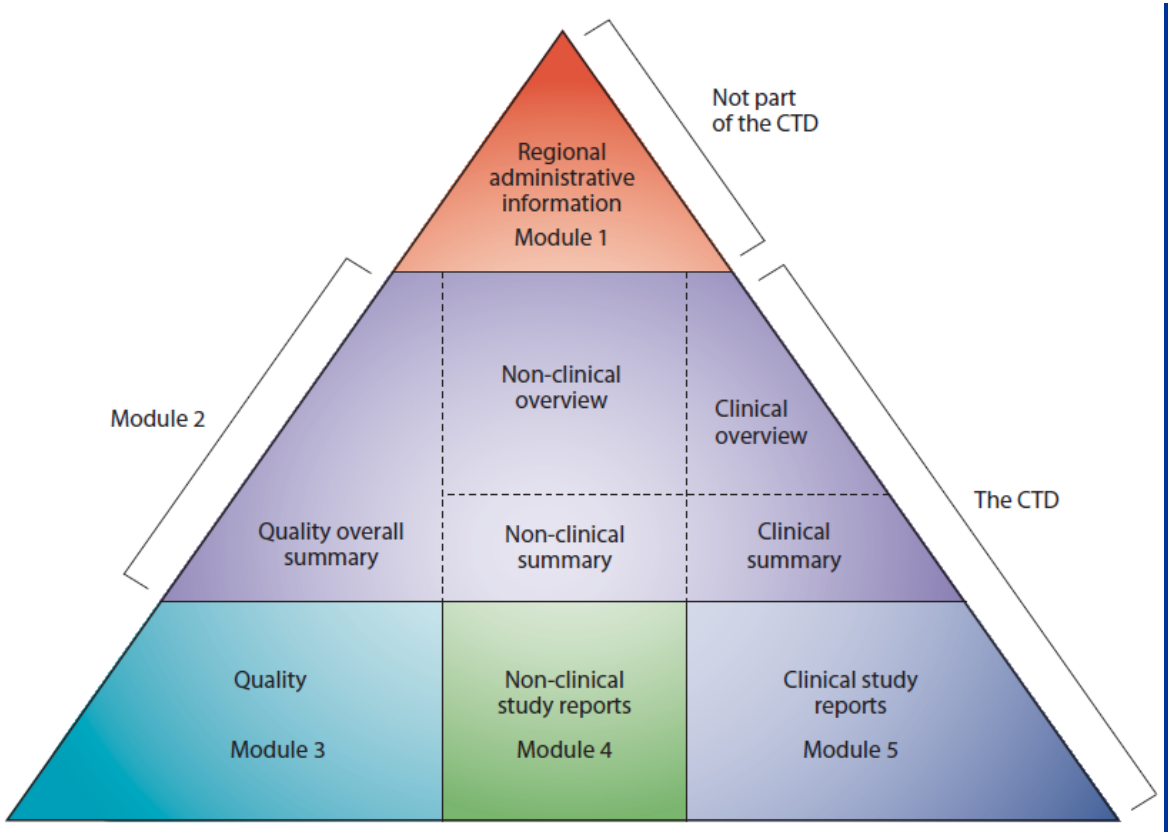
- Therapeutic Areas covered by **SAGs**: **Vaccines, Oncology, Neurology, Cardiovascular, Infectious diseases, Immune and Inflammatory Diseases**; rest of areas are covered by AHEGs.
- Deliver **answers to specific questions** asked by the Committees; these bodies are not responsible for establishing 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



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

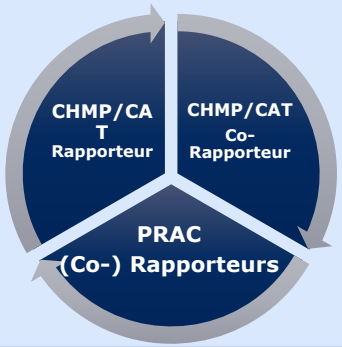


EMA support and product team

Network

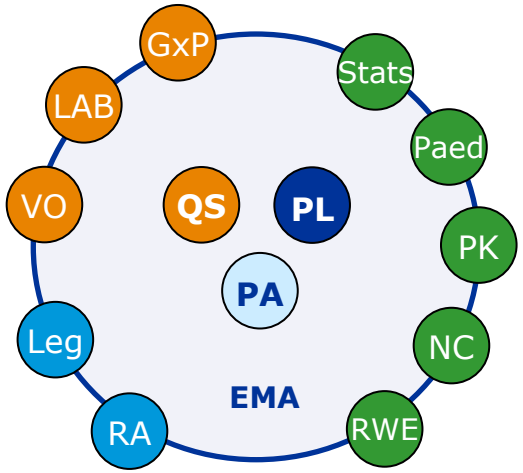
QWP

BWP



Rapporteur

- Lead the scientific assessment and evaluation
- Represent the CHMP, CAT and PRAC in liaison with applicant
- Presentation to committees



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

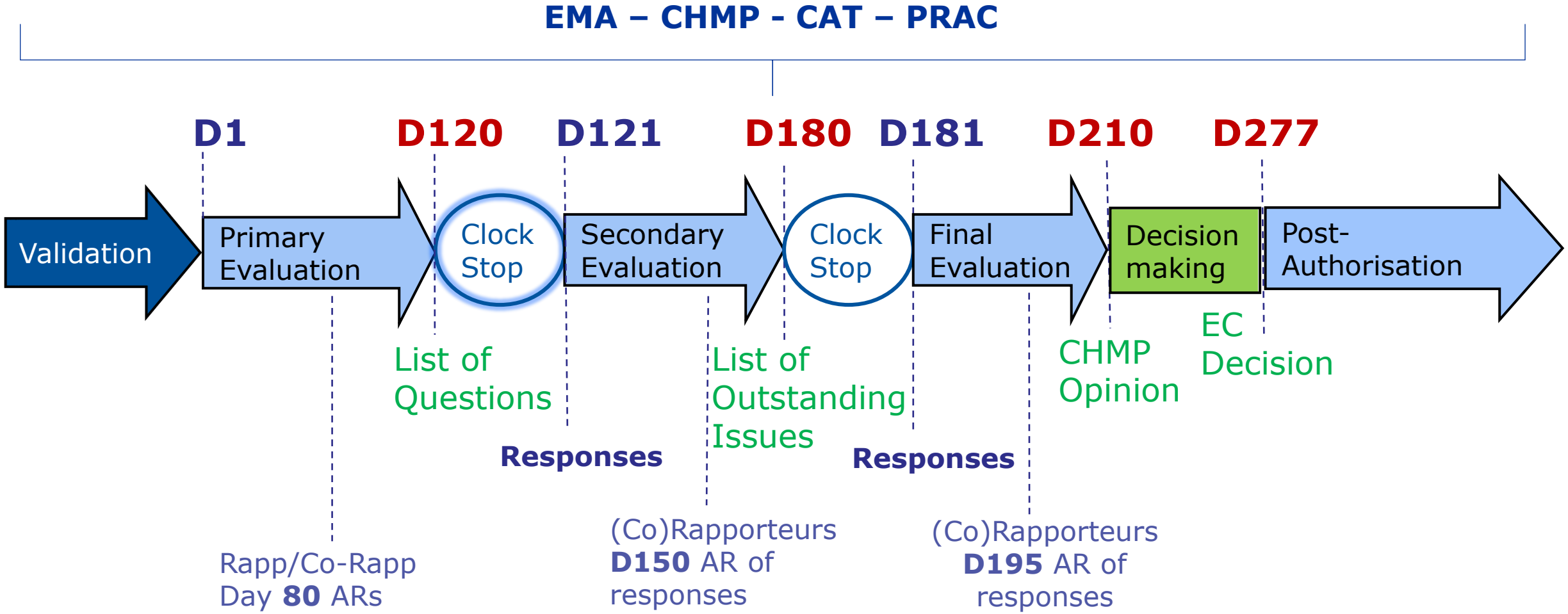
*LAB – labelling
*VO – validation officer
* leg – legals

*NC – non-clinical

*Paed – paediatrics

*Stats - statistics

Overview of the assessment process for initial MAA



Potential additional steps:

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

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*

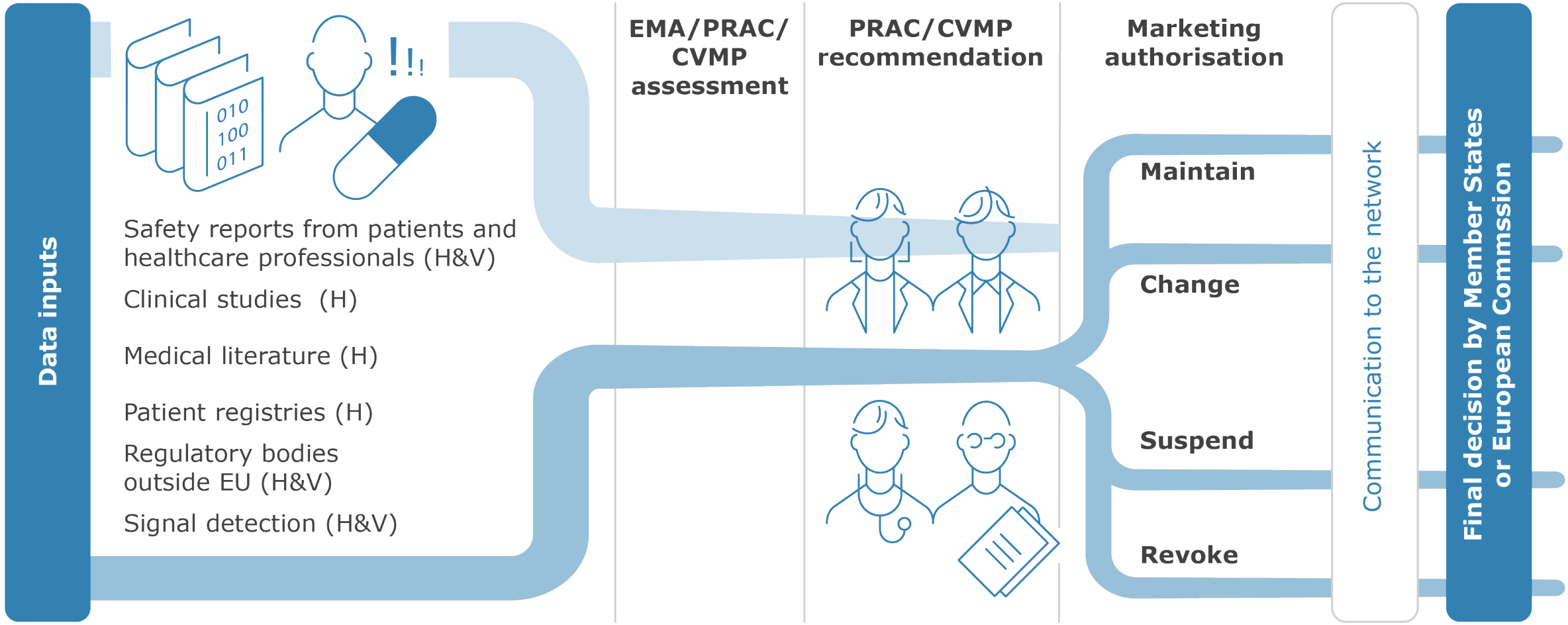
Annex 127a: Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states*

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

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