Consilium

Salmonson & Hemmings

Looking back to the way(s) taken by EU….

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Former chair, CHMP, EMA

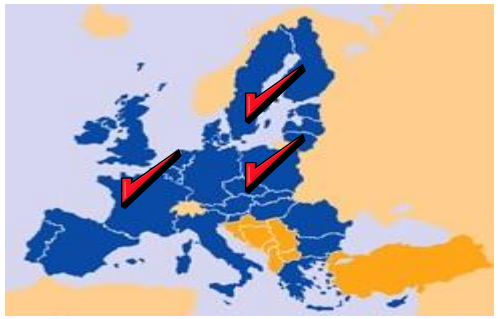
Regulatory Workshop, Moscow, October 2019

Post Nov 2005 Three European Systems

Centralised Procedure (via EMA)

Mutual Recognition procedure

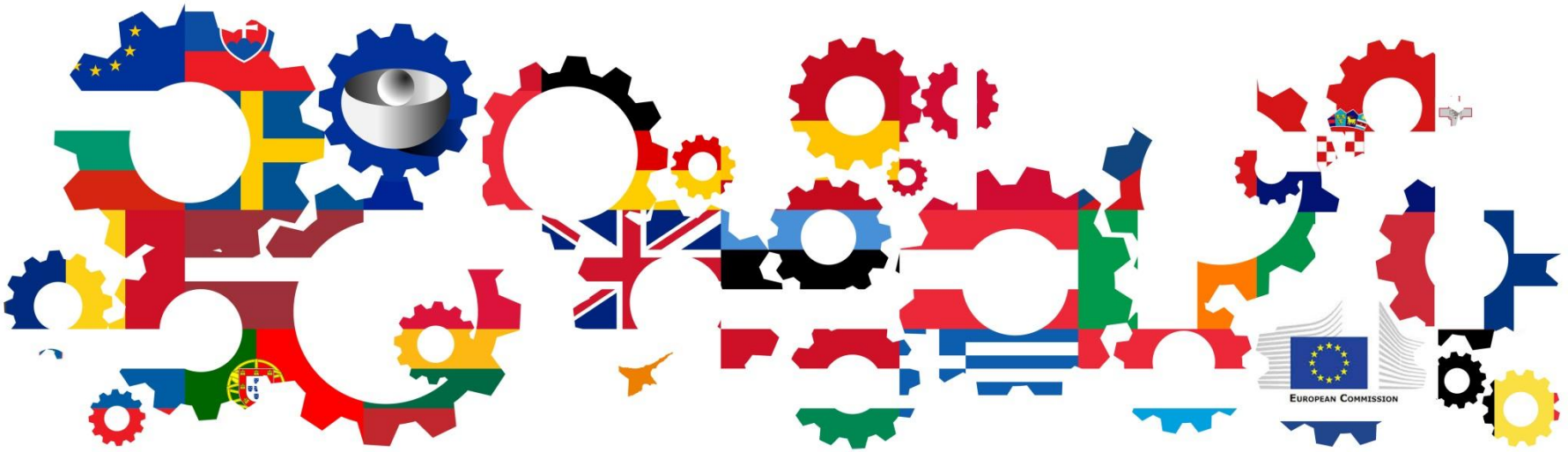
Decentralised Procedure



National MAs

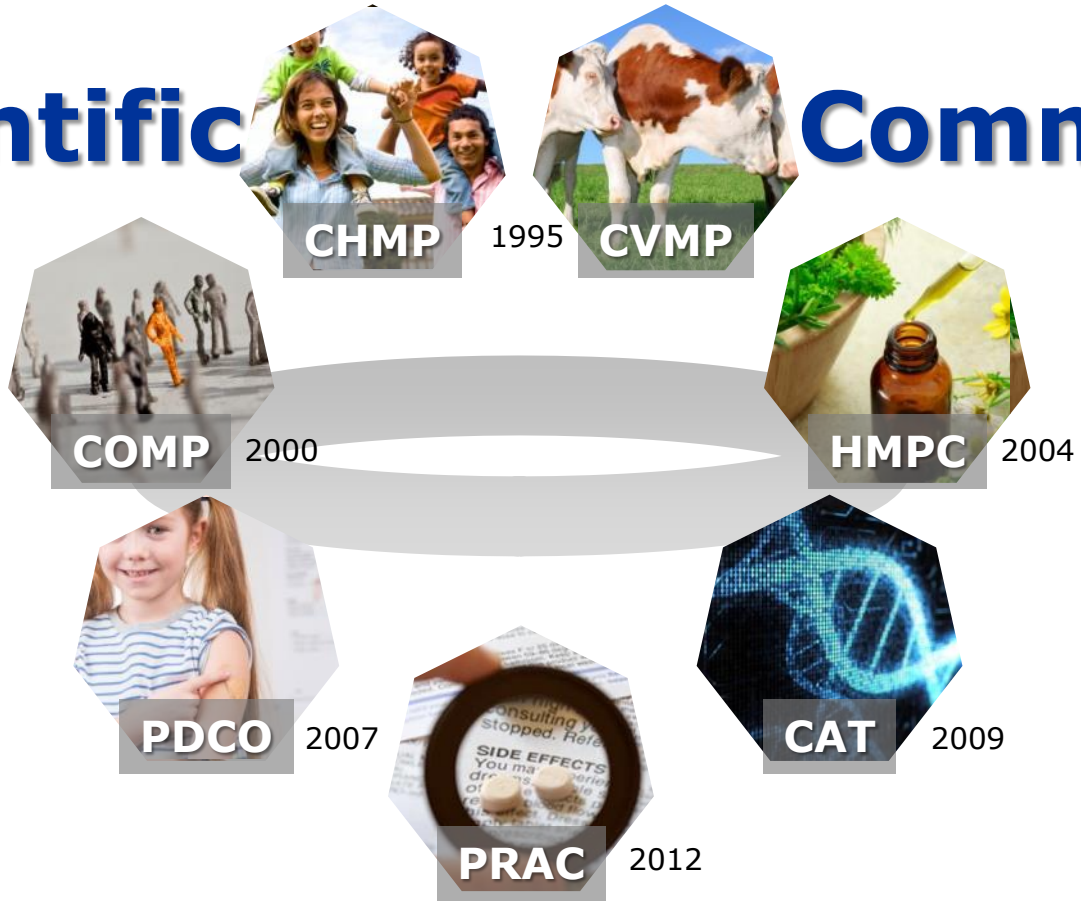
- Still possible for authorisation in a single MS

The European medicines regulatory network

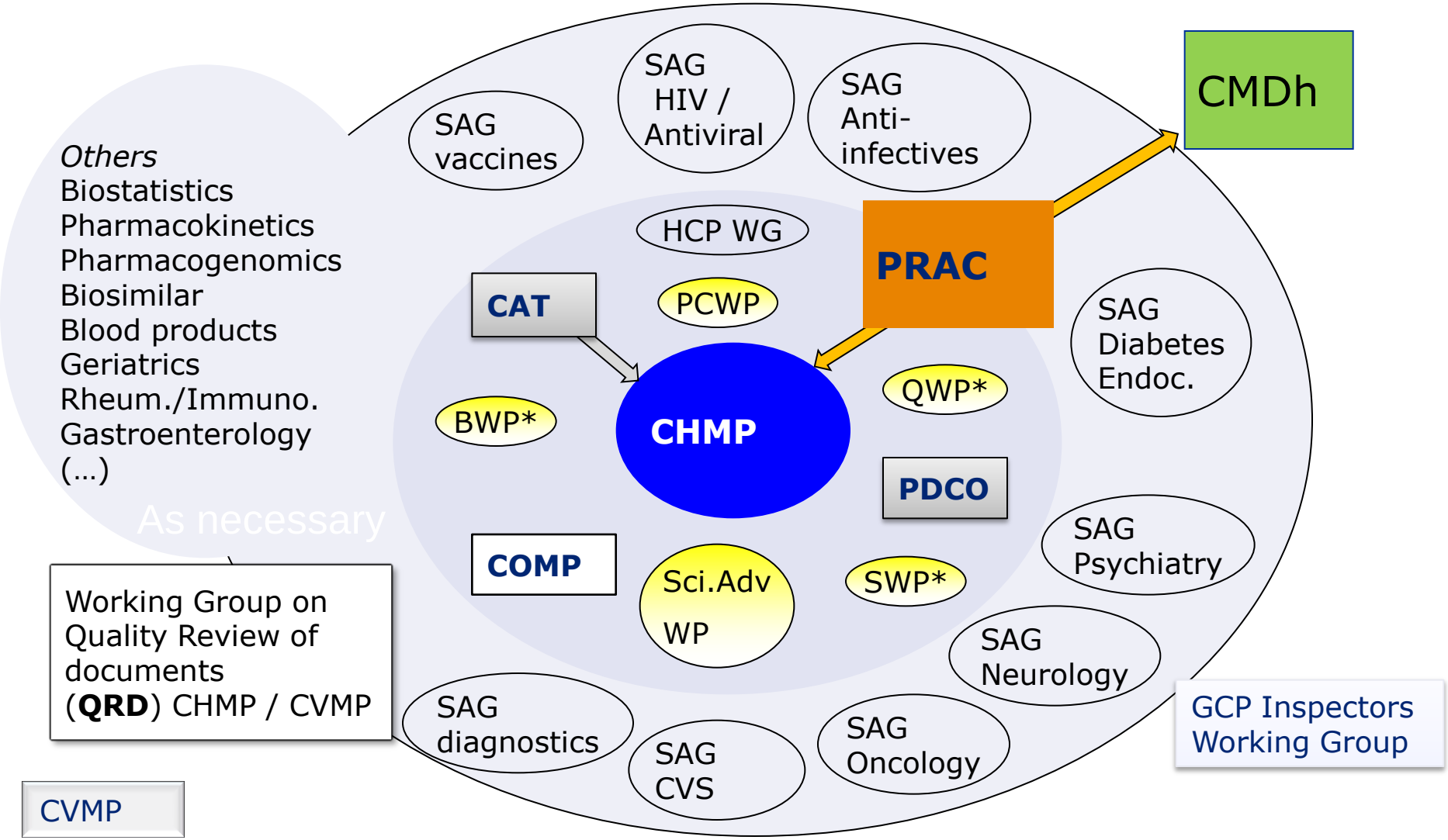


~ 50 national regulatory authorities European Commission European Medicines Agency

7 Scientific Committees

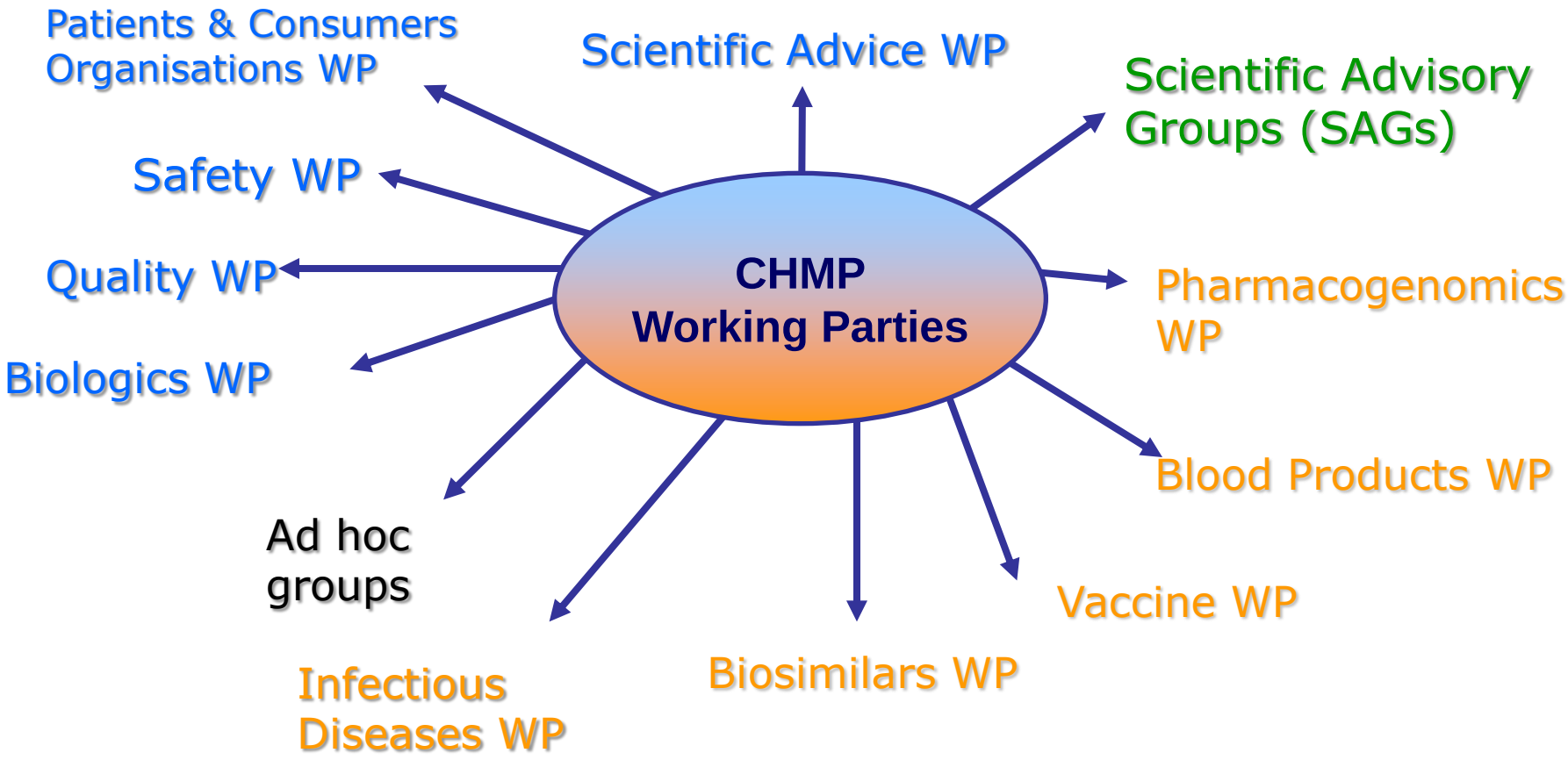


Working Parties and other Groups

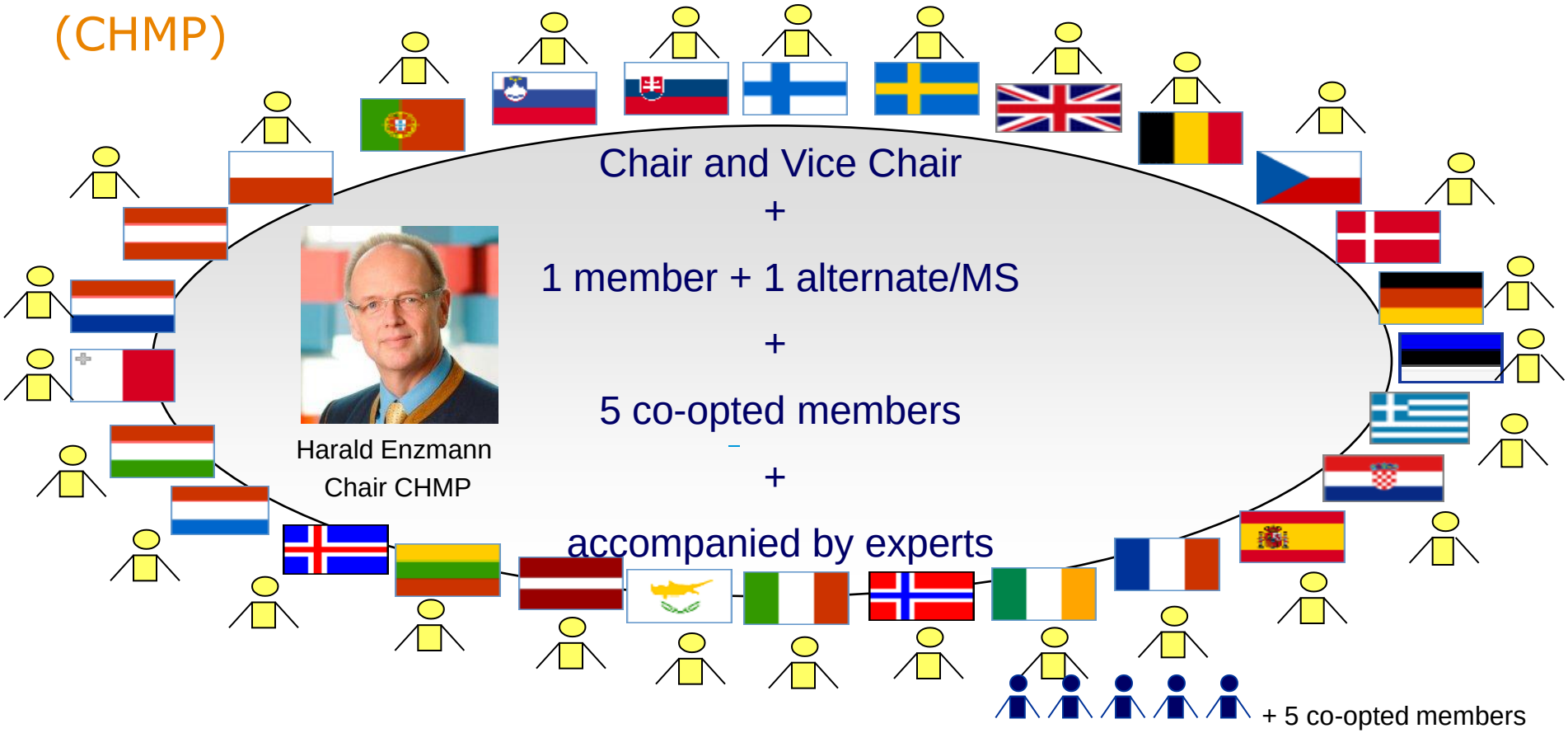


* 1 / MS representation

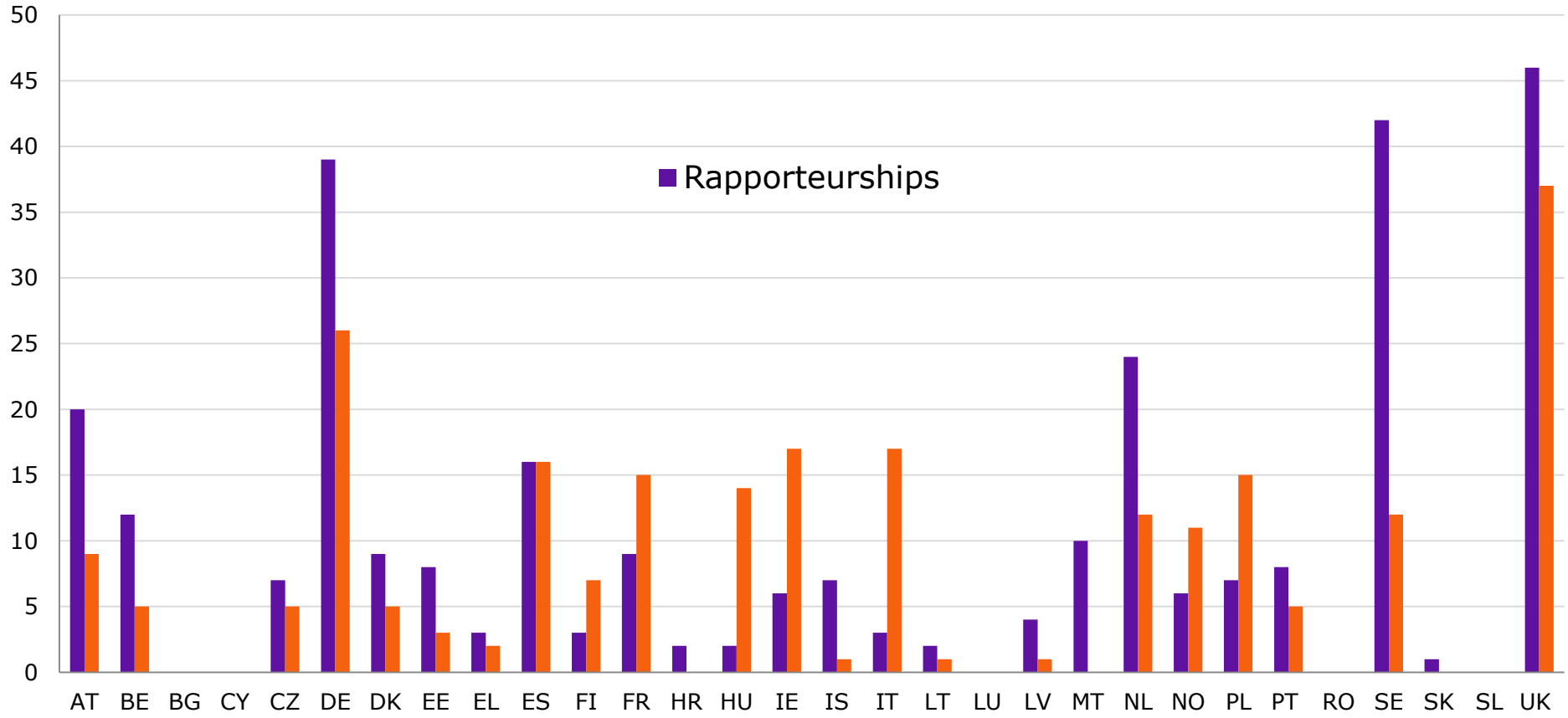
CHMP Working Parties and Expert Groups

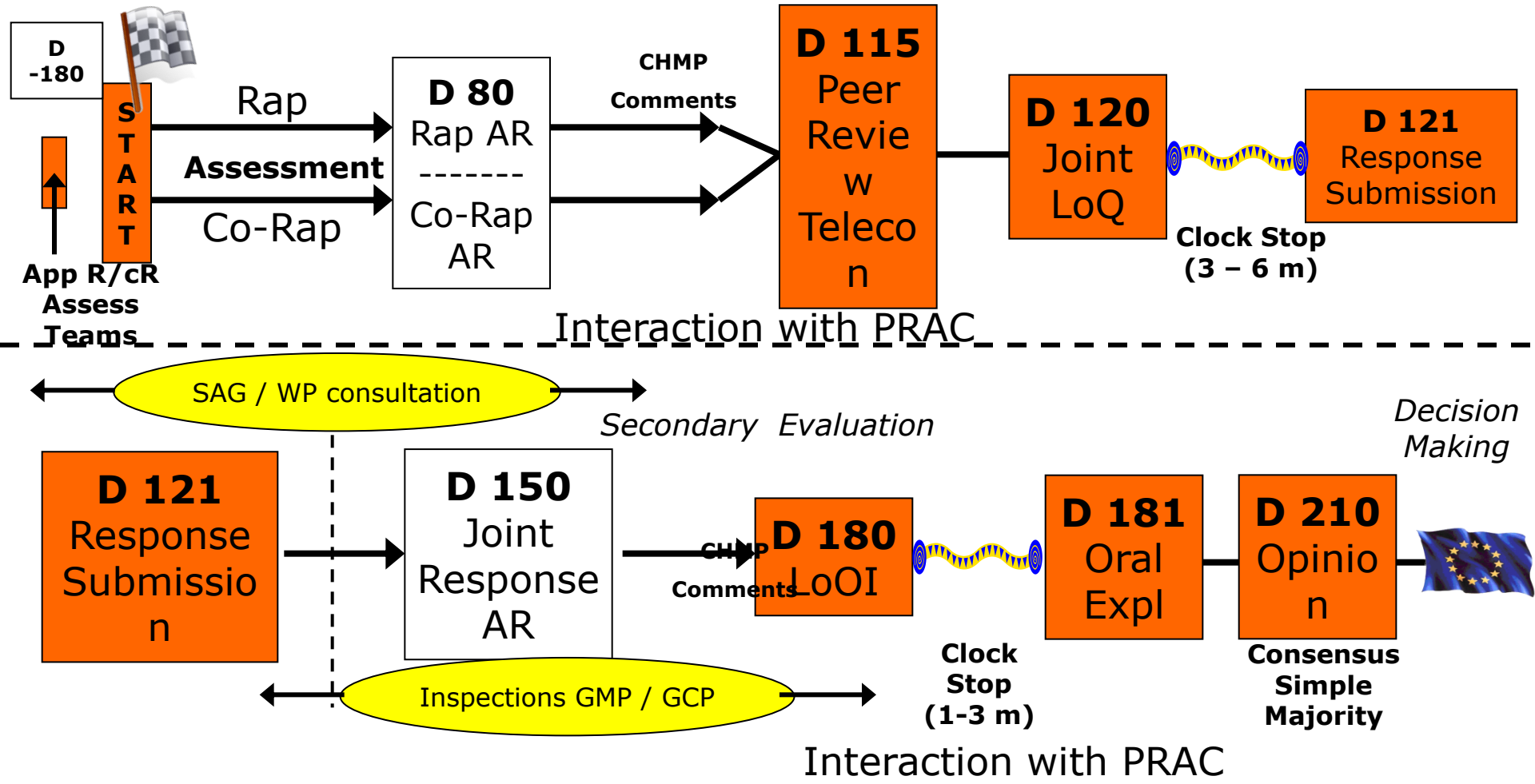


Committee for Human Medicinal Products (CHMP)



Rapporteurships 01/2015 – 02/2017




D -180
START
App R/cR Assess Teams
Rap
Assessment
Co-Rap
D 80
Rap AR
Co-Rap AR
CHMP Comments
D 115
Peer Review Teleco n
D 120
Joint LoQ
Clock Stop (3 – 6 m)
D 121
Response Submission
Interaction with PRAC
SAG / WP consultation
Secondary Evaluation
Decision Making
D 121
Response Submissio n
D 150
Joint Response AR
CHMP Comments
D 180
LoOI
D 181
Oral Expl
D 210
Opinio n
Clock Stop (1-3 m)
Consensus Simple Majority
Inspections GMP / GCP
Interaction with PRAC

CHMP Voting Rules

33 members eligible to vote (28 MS/NCAs + 5 co-opted)

Norway and Iceland recorded separately

Quorum = 21

Abstention!

Voting

Simple Majority: 17 to sustain a positive or negative opinion

No pre-determined MS position CHMP capacity scientific member, hence vote personal / individual

CHALLENGES FACING REGULATORS TODAY….

- New drugs are often considered expensive
  - Hep C – scientific success, public health…
  - Expensive drug development. Why? GCP?
  - Combinations
  - Due to cost, drugs are often used in a more restricted population than the entire indication
- Involvement of "health care providers"
- Who provides information to patients and prescriber today? Dr GOOGLE? YouTube?
- Involvement of patients

INVOLVMENT OF PATIENTS…
(NOT AN EASY STORY…)

- Why?
  - Transparency?
  - PROs (Patient reported outcomes)
  - Input in decision making?
  - Quality Assurance of information?
- How?
  - Members of Committees?
- Conflict of Interests?

TODAY….

- Regulators are part of a health care system
  - Different regulatory agencies have different tasks.
  - Links to HTA/Payers and other stakeholders
- Drug development is global, information is available to everyone.
- Regulatory output: an approval with a SmPC (including an indication) is not enough. The package leaflet is….EPARs!!!
- Structured B/R section in the CHMP Assessment report.
- Uncertainties are more clearly identified and recognizes today.

Benefit-Risk structure – a part of transparency

5.1Therapeutic context

- 5.1.1 Disease or condition
- 5.1.2 Available therapies and unmet medical need
- 5.1.3 Main clinical studies

5.2 Favourable effects

5.3 Uncertainties/limitations of favourable effects

5.4 Unfavourable effects

5.5 Uncertainties/limitations of unfavourable effects

5.6 Effects Table

5.7 Benefit-risk assessment and discussion

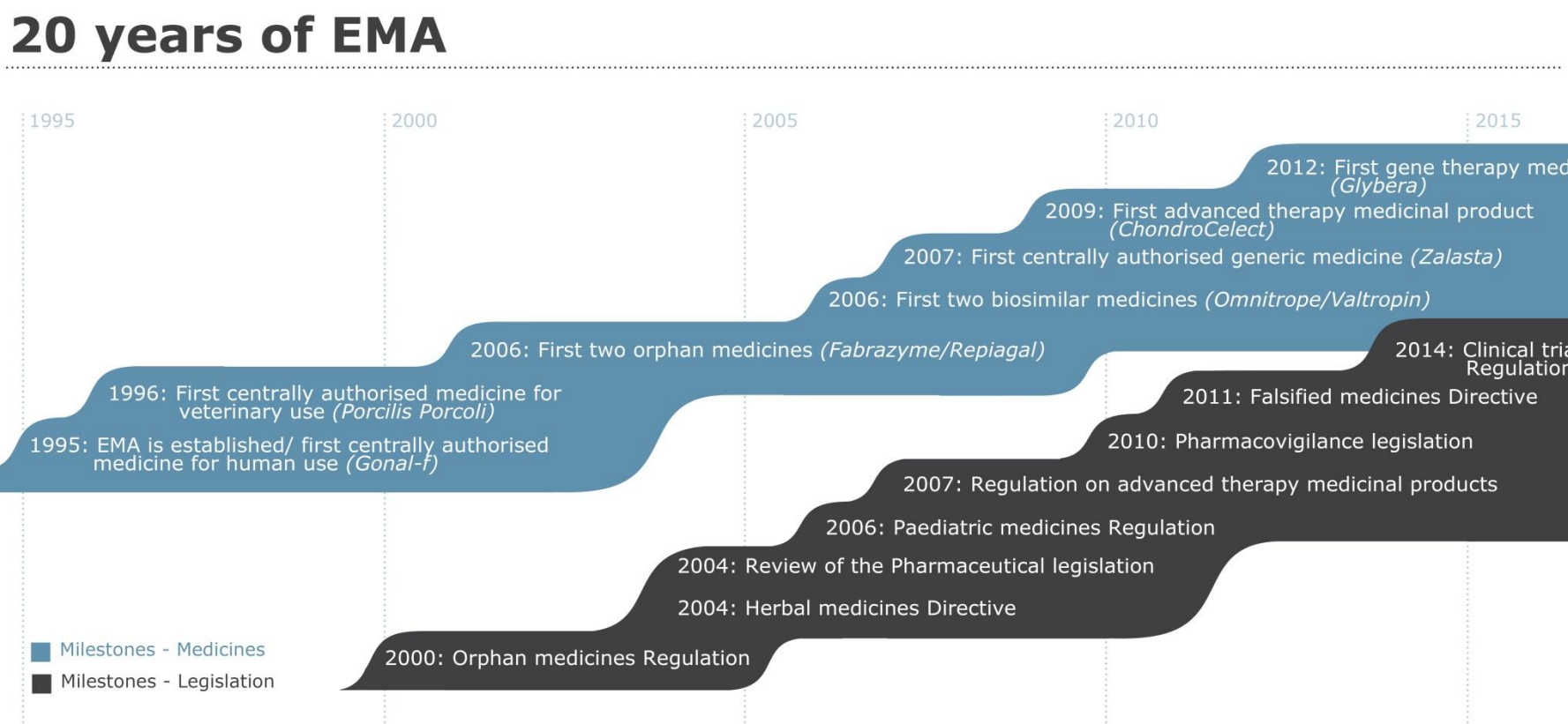
- 5.7.1 Importance of favourable and unfavourable effects
- 5.7.2 Balance of benefits and risk
- 5.7.3 Additional considerations

ALL THIS IS GOOD BUT…….

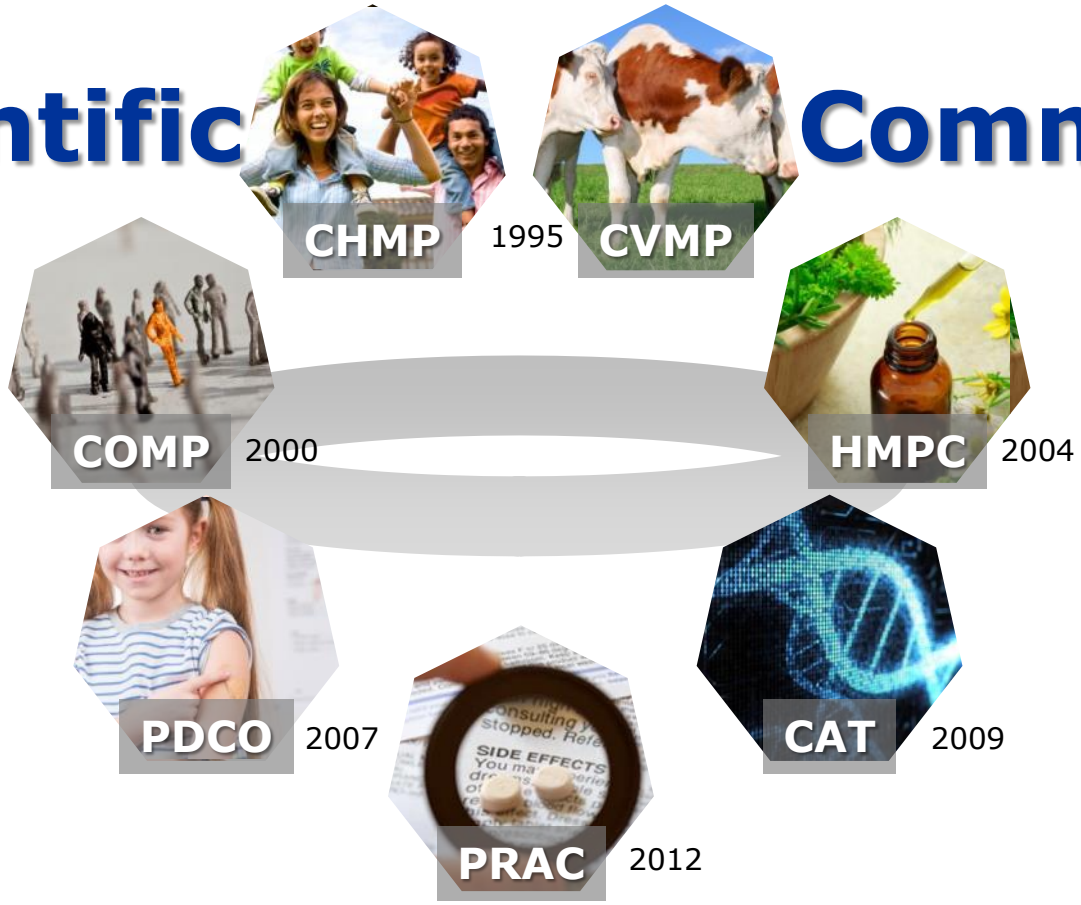
THE SITUATION TODAY…..

- Drug development – a recognized joint venture (”private-public partnership”)!
- Science continues to deliver new drugs
  - ATMPs, biologics, small molecules
  - Combinations of drugs
  - Disease modifying/cure rather than symptomatic relief
- Many (!) new drugs fall within the scope of the Orphan legislation
- Some drugs are (initially) approved with narrow indications …
- The post-approval development is more and more important
  - Conditional, “Annex II” conditions
  - How well is the PIP working?

20 years of EMA



7 Scientific Committees



CONCLUSIONS…..(FROM THE EU EXPERIENCE)

- MS responsible for scientific assessments
  - Joint scientific standards (Scientific advice, guidelines (EU and ICH)
  - Topic specific "Working parties"
  - Benefit-Risk structure – transparency
  - Two assessment reports
- All MS taking part in the decision-making process
- Patchwork of legislations…..need to update:
  - Orphan including COMP?
  - Pediatrics including PDCO?
  - Conditional Marketing Approvals?
  - Advance therapies?
- Challenge the value of other regulatory tools such as:
  - Accelerated timetable
  - "PRIME"
  - Content of PIP:s
  - etc

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?Questions?