EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Towards EU Accession: Serbia's Regulatory Challenges Expectations and Opportunities

Phasing in Issues – Impact on Nationally authorised products MA status from traditional herbal to advanced therapy medicinal products

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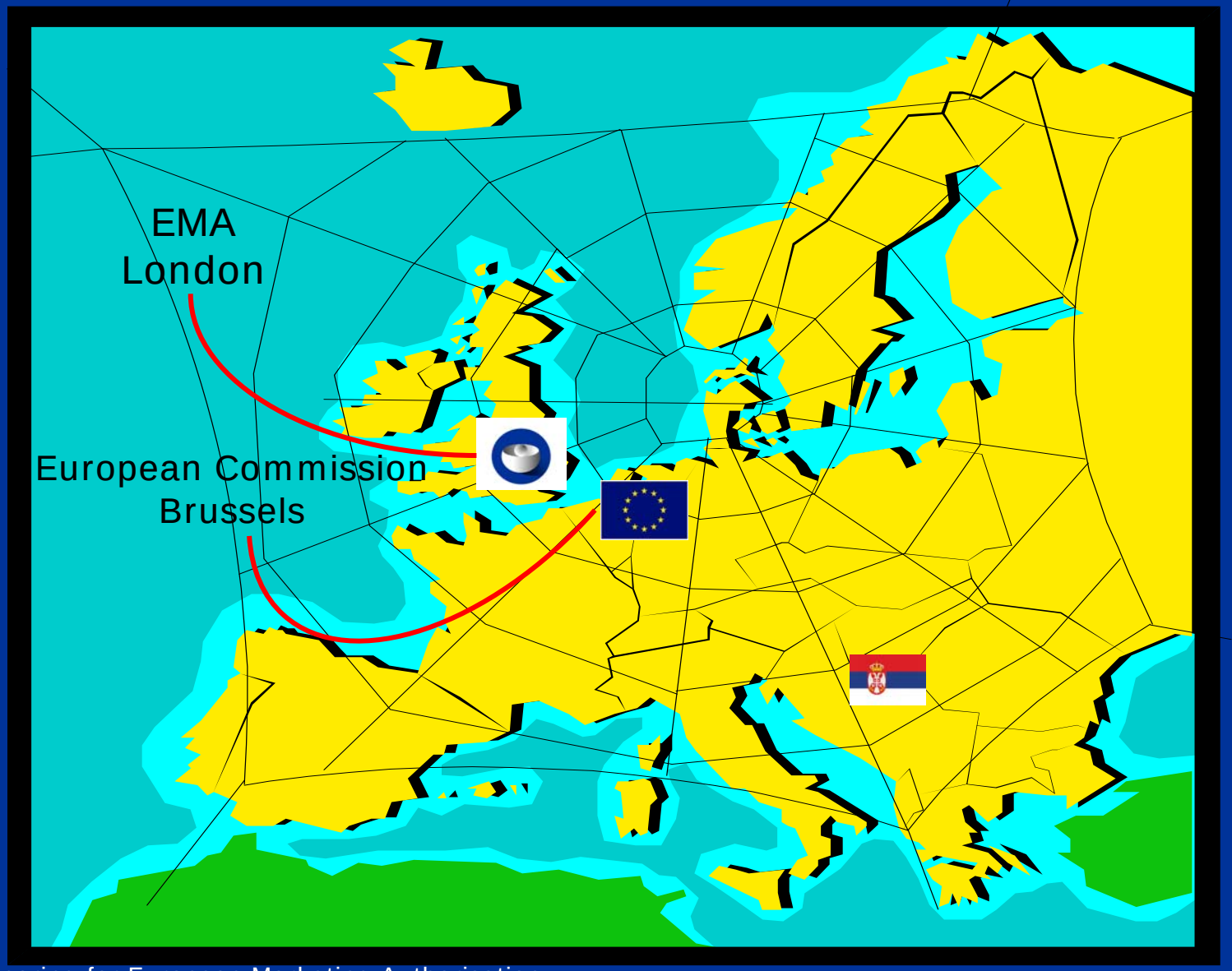
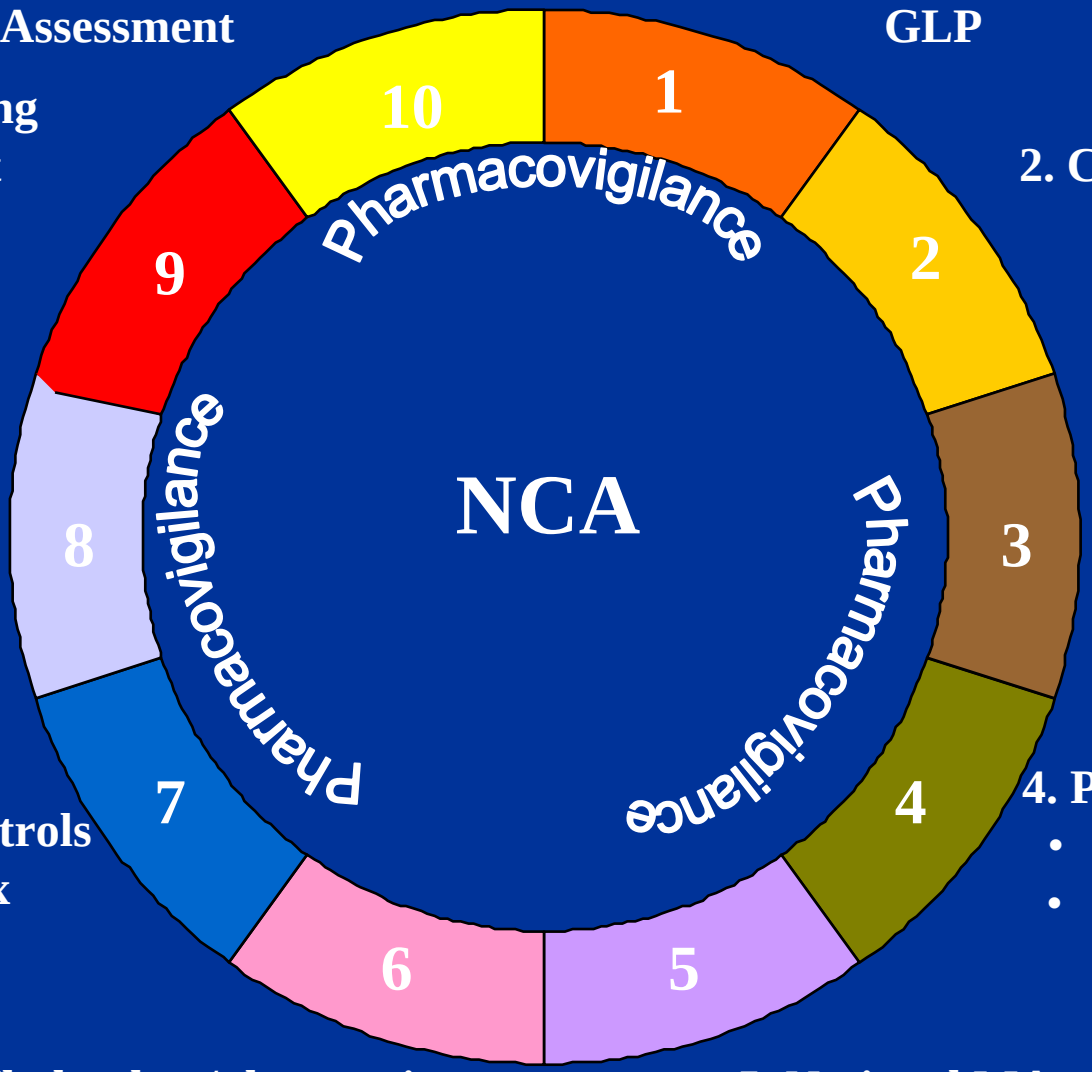
An agency of the European Union


EMA
London
European Commission
Brussels

- Operational roles and responsibilities within an enlarged EU
- Impact on National MAs as of Accession
- Expected Contribution to the Network
- Facilitating Operation of the Network



10. Health Technology Assessment

1. Animal Testing
GLP

9. HCPs Prescribing
Re-imbursement
Pricing
substitution

2. Clinical Trials
GCP

8. Independent
Information
Sources

3. Compassionate
Use Programme

7. Advertising Controls
Rx and Non Rx

4. Production Facilities
- Active Substance
- Finished Product
GMP

6. Distribution Wholesalers/pharmacies
Parallel imports, Inspections

5. National MA
+ve risk/benefit / SPC label +leaflet

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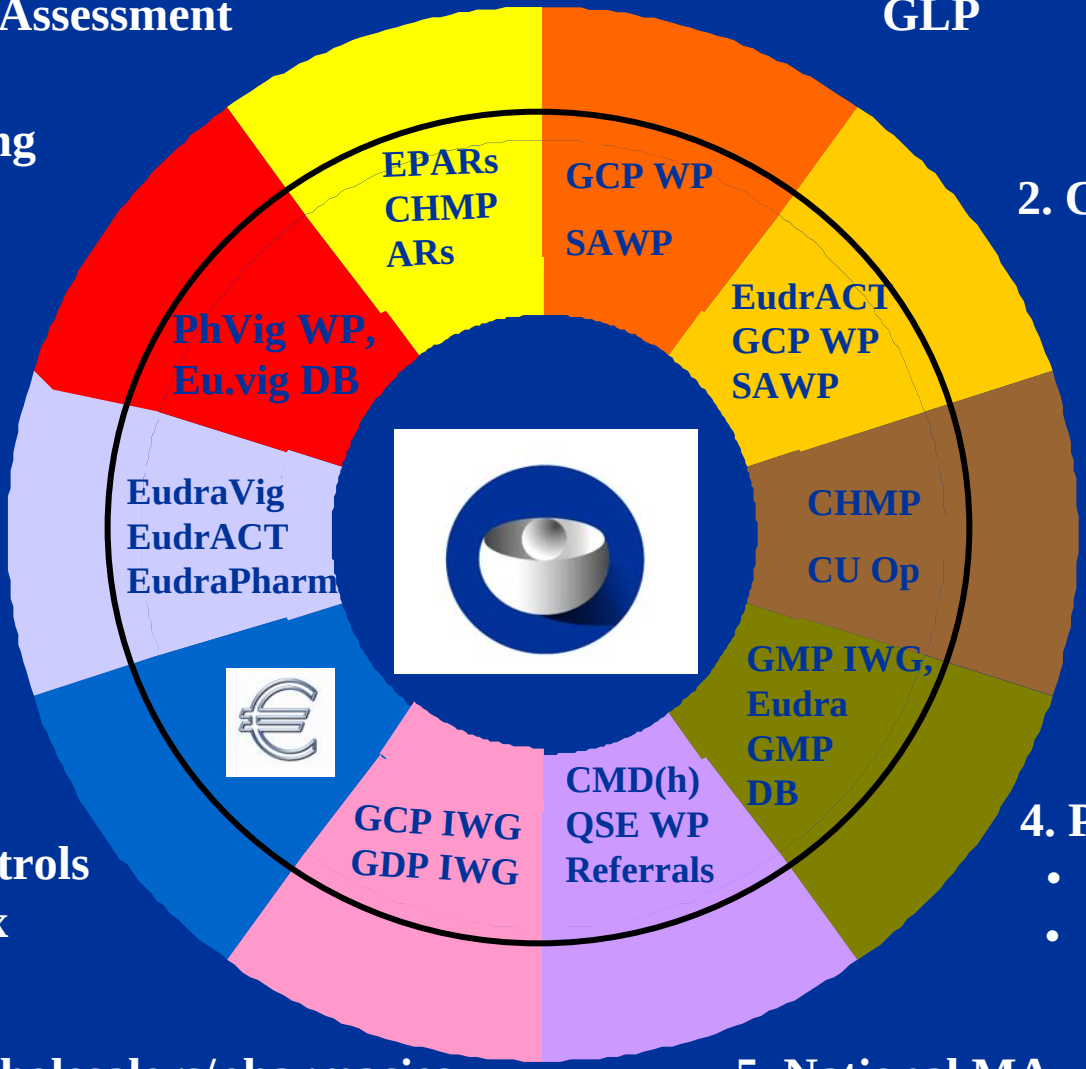

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Impact on National MAs as of Accession

- Nature of medicinal product concerned

= vast majority stay national

= “update in compliance with Acquis” exercise

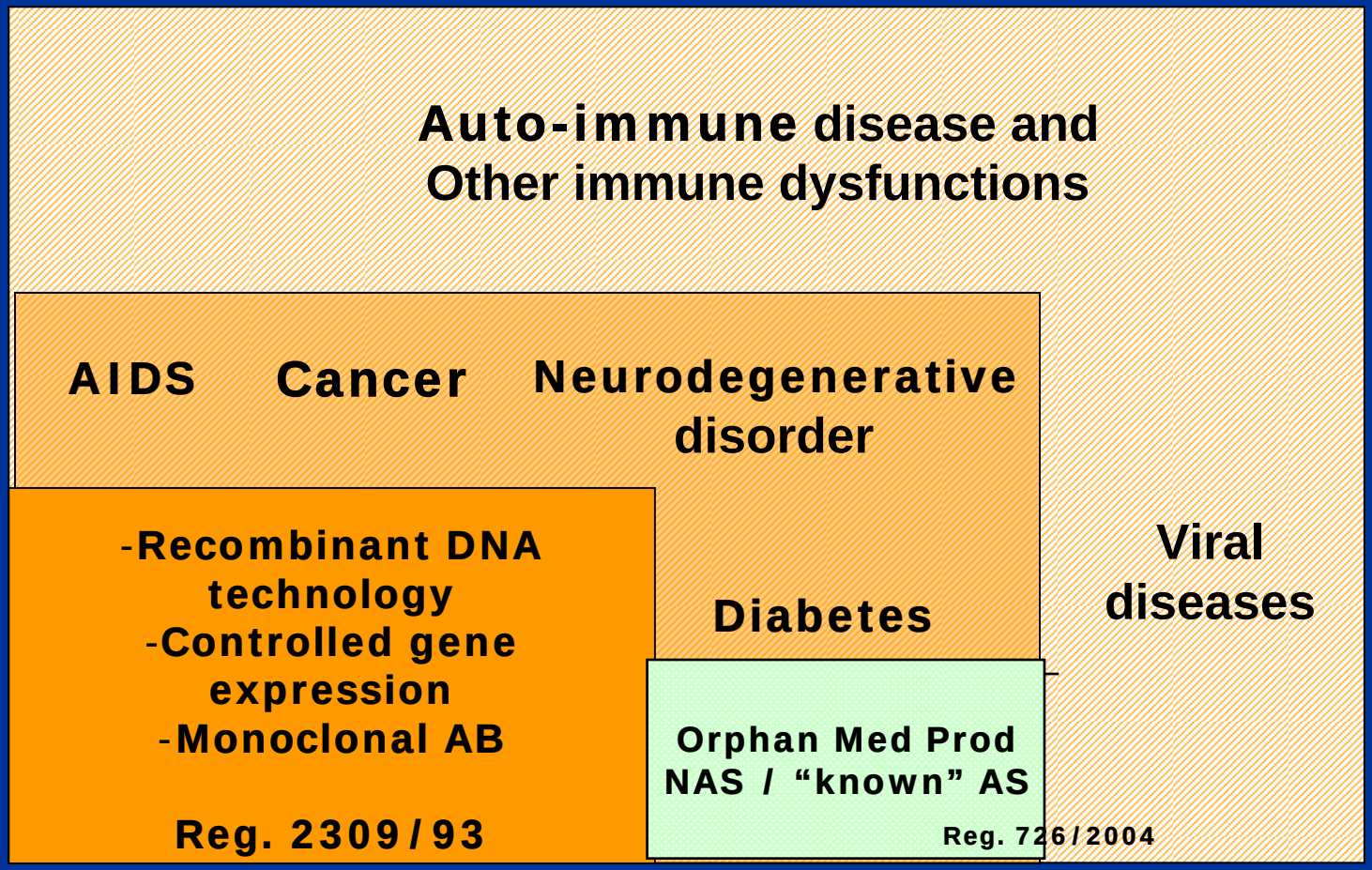
- Certain product types suitable for MR/DCP = but will lead to National MA = but linked and harmonised
- Select product types obligatory CP

Access to Medicines

Mandatory Scope

NAS

NAS / "known" AS?



Access to Medicines

Optional Scope

Art. 3(2) of Regulation (EC) No 726/2004

Art. 3(2)(a)

New Active Substances

Art. 3(2)(b)

Significant Innovation

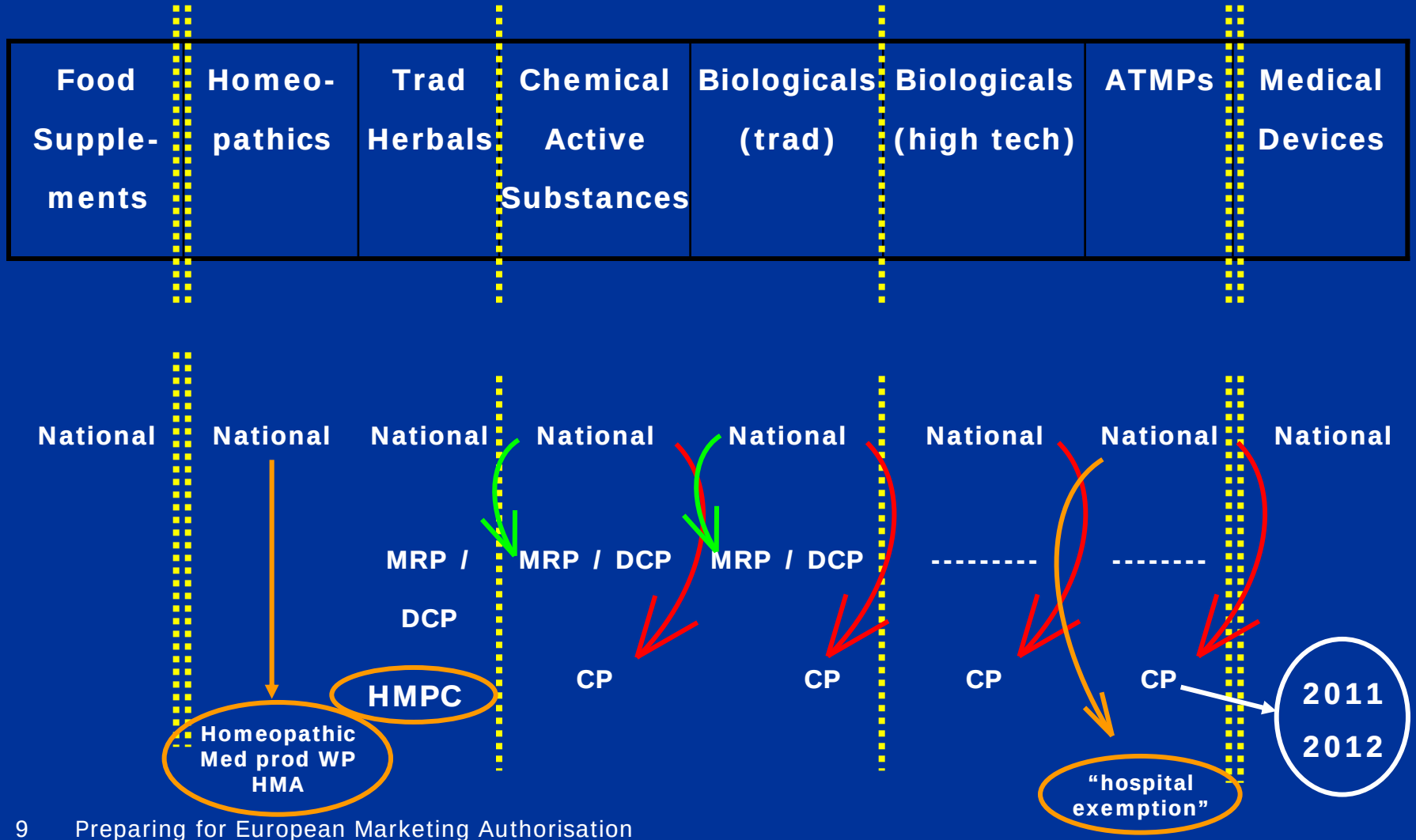
-Therapeutic &/or Scientific &/or Technical

OR

Interest of Patients at Community Level

← "known" AS →

Impact on National MAs as of Accession



Levels of harmonisation drive impact

A. Centralised Medicinal Product

= No national equivalent MA allowed

= Central MA effective as of Accession

B. Community Referral Procedure with partial / complete SPC harmonisation

= “expected” to be implemented into National MA

C. MRP / DCP Medicinal Products

= “invited” to be implemented into National MA (repeat use procedure)

National MAs: Continued Independence of action?

It depends….

- MRP / DCP → fully linked for all regulatory actions
- Quality defects; Emerging safety issues → rapid communication through network → NuI / ~~RAS~~
- Pharmacovigilance safety actions ; suspension triggers Art. 107 Procedure → takes issue to EU level
- Community Interest Art. 31 referrals impacts on national MA

National MAs Continued Independence of Action? Case studies

Art. 107 –

Ketoprofen gel = phototoxicity

Nimesulide = Hepatotoxicity

Art. 31 –

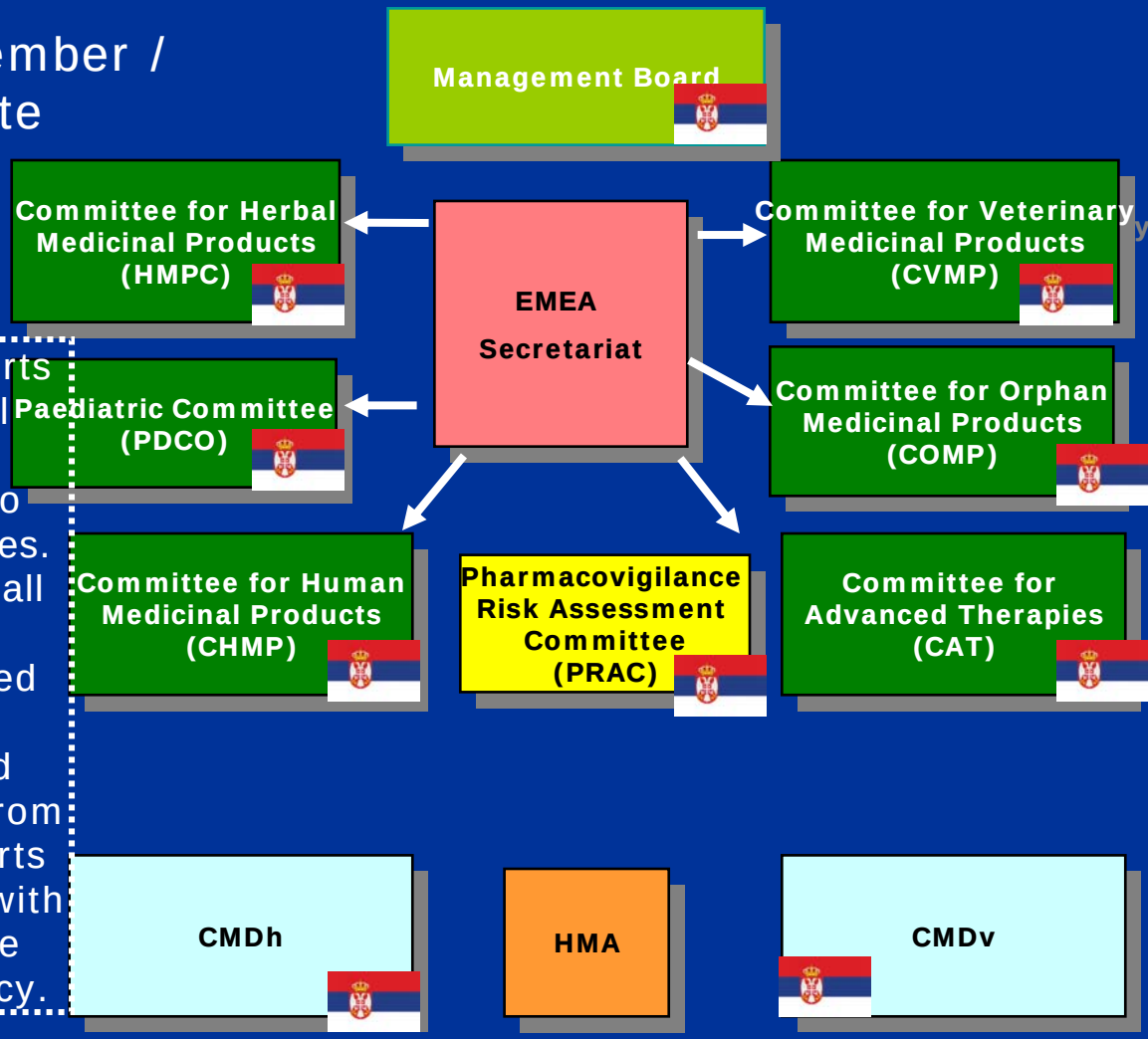
Dextropropoxyphene = risk of accidental overdose and death

Expected Contribution to the Network

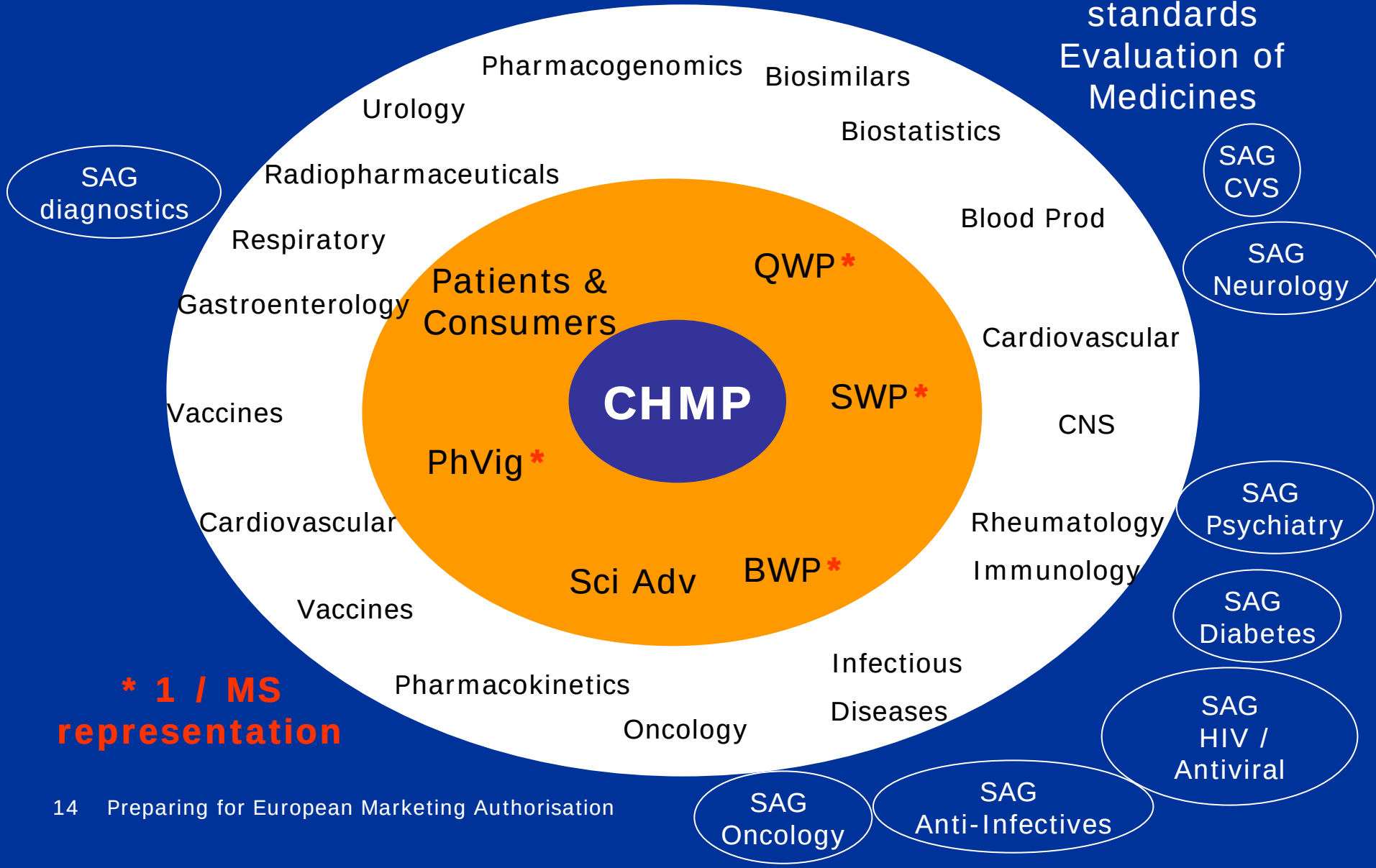
Legislatively Mandated One Member / One Alternate per Member State

Role: Rapporteur/ Peer Reviewer/Voting Member

Members of the committees and experts responsible for evaluating medicinal products shall rely on the scientific evaluation and resources available to national marketing authorisation bodies. Each competent national authority shall monitor the scientific level and independence of the evaluation carried out and facilitate the activities of nominated committee members and experts. Member States shall refrain from giving committee members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.



Working Party Constellation



MS Co-ordination structures

Mutual Recognition and De-centralised Procedures

MRFG <1995> (h/v) → **CMDh <2005> (h/v)**

Inspections

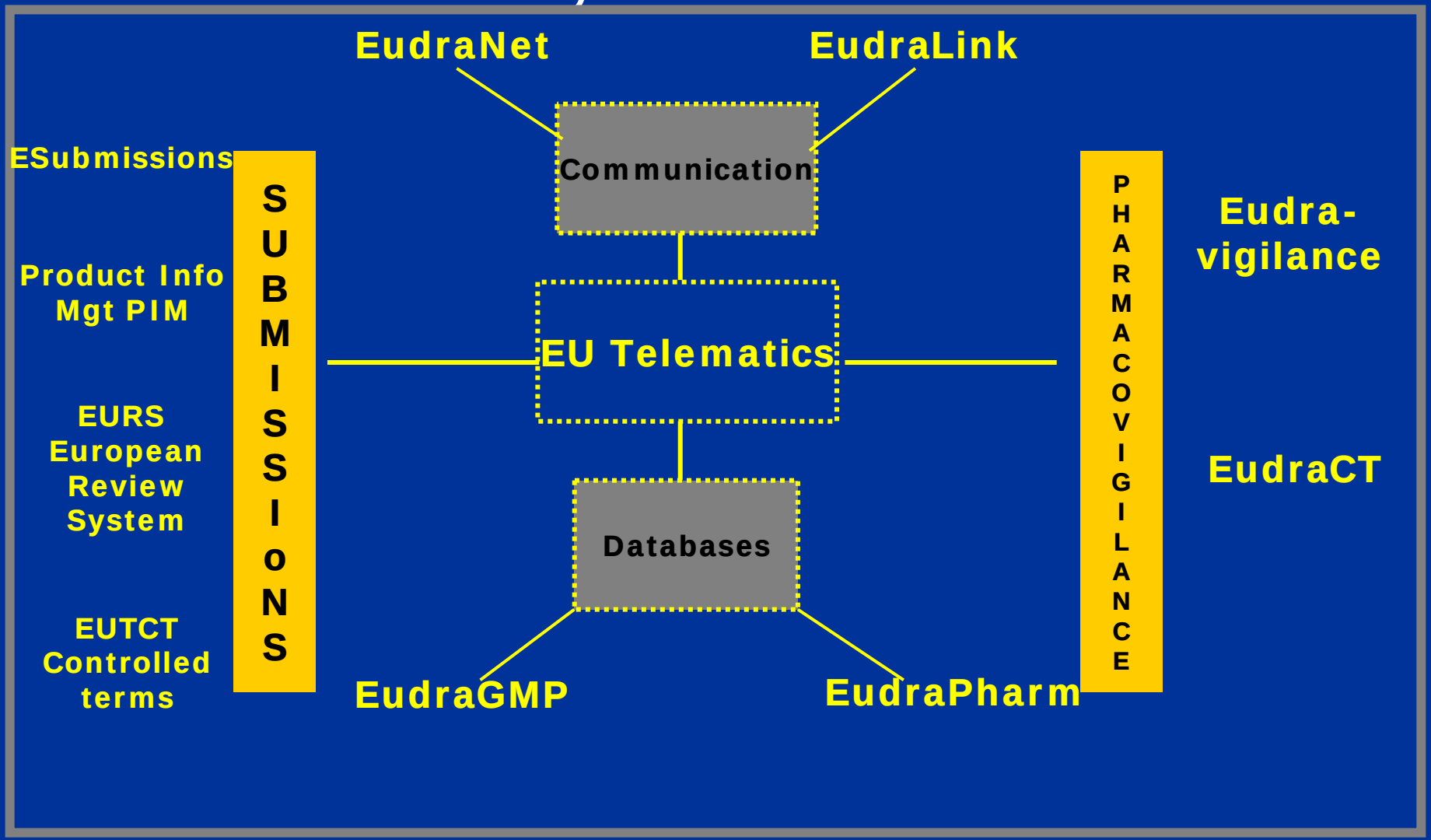
GMP IWG
GCP IWG
GDP IWG

Clinical Trials

CTFG

Communication system

EudraData Warehouse



Financing the system

23.1 % EU Subsidy (2009)

PDCO
COMP

HMPC
CMD(h/v)

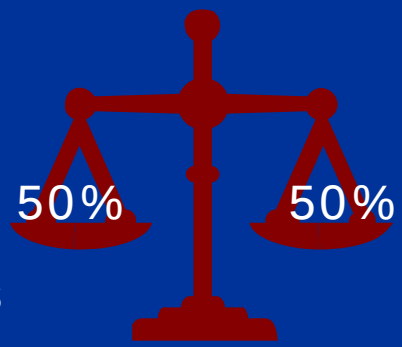
SAWP

CHMP

CAT

PRAC

National
MR / DCP



Rapporteurs

(NCAs)

- Staff
- Meeting facilities
- Members / Experts travel exp
- EU telematics