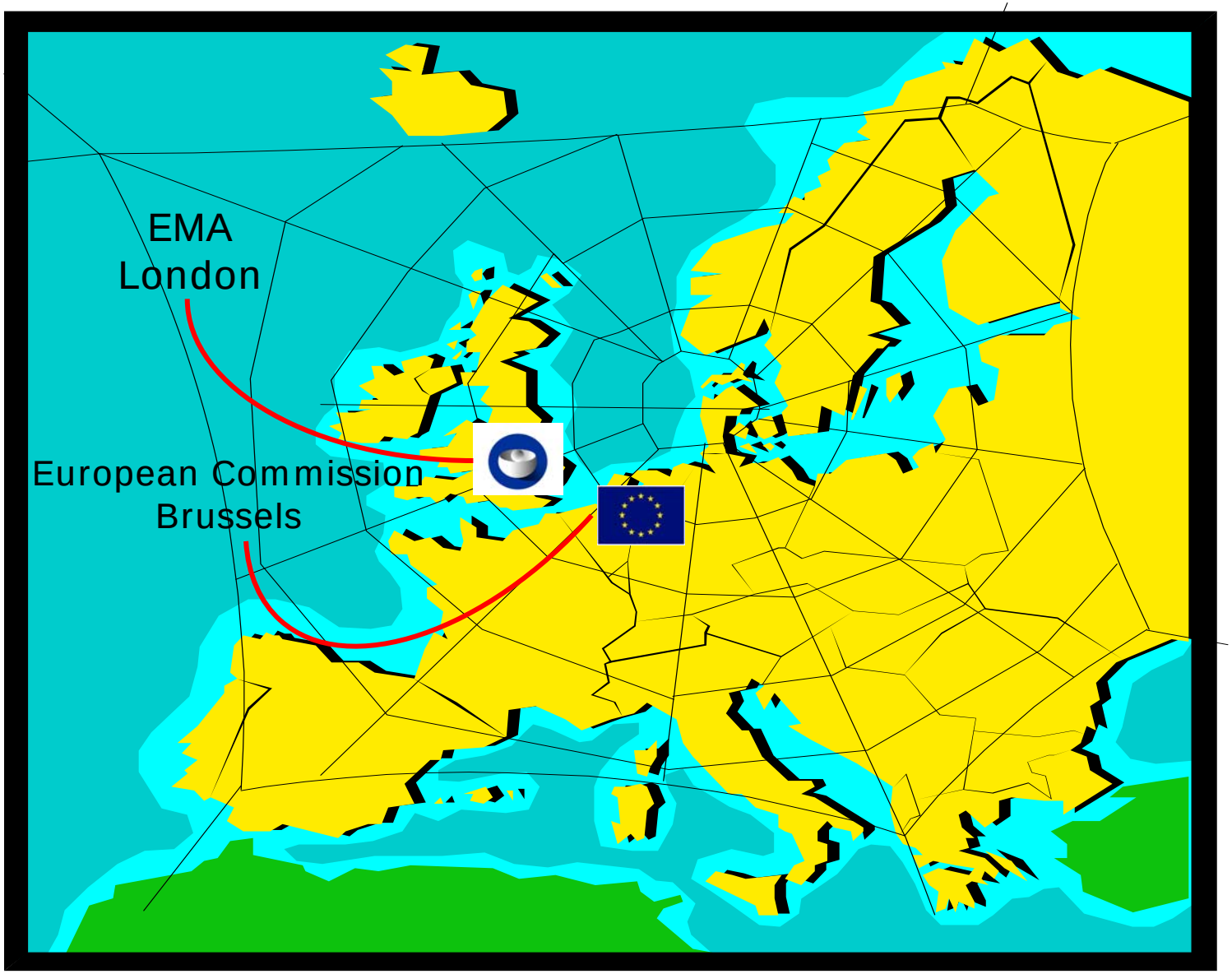
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Accession preparation - Phasing-in

Reinforcing patient safety in Europe
14-15 June 2011
Zagreb, Croatia

Presented by: Tony Humphreys
Head of Regulatory, Procedural and Scientific Committee Support

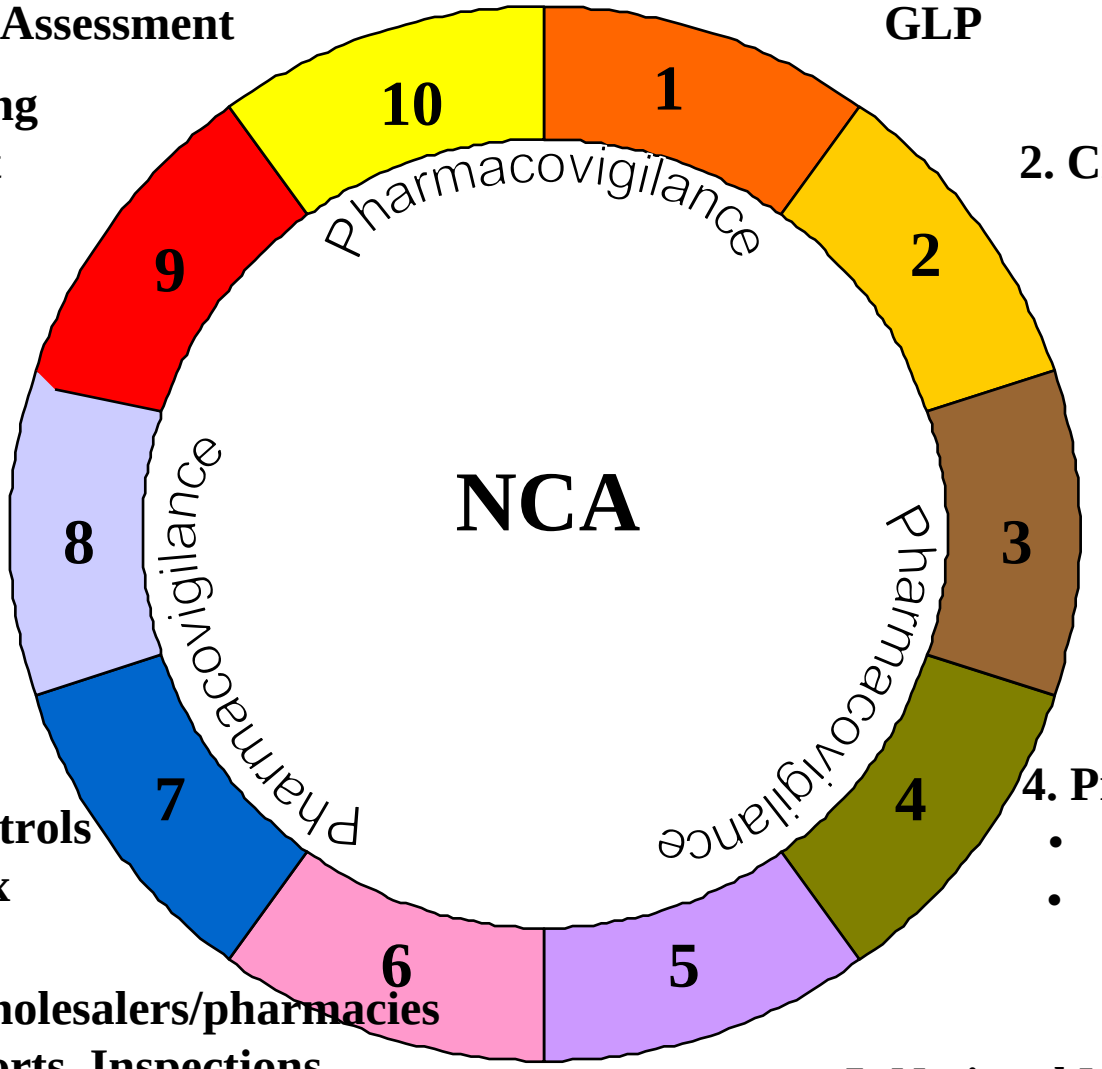

EMA
London
European Commission
Brussels

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



1. Animal Testing
GLP

2. Clinical Trials
GCP

3. Compassionate Use Programme

4. Production Facilities
- **Active Substance**
- **Finished Product**

GMP

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

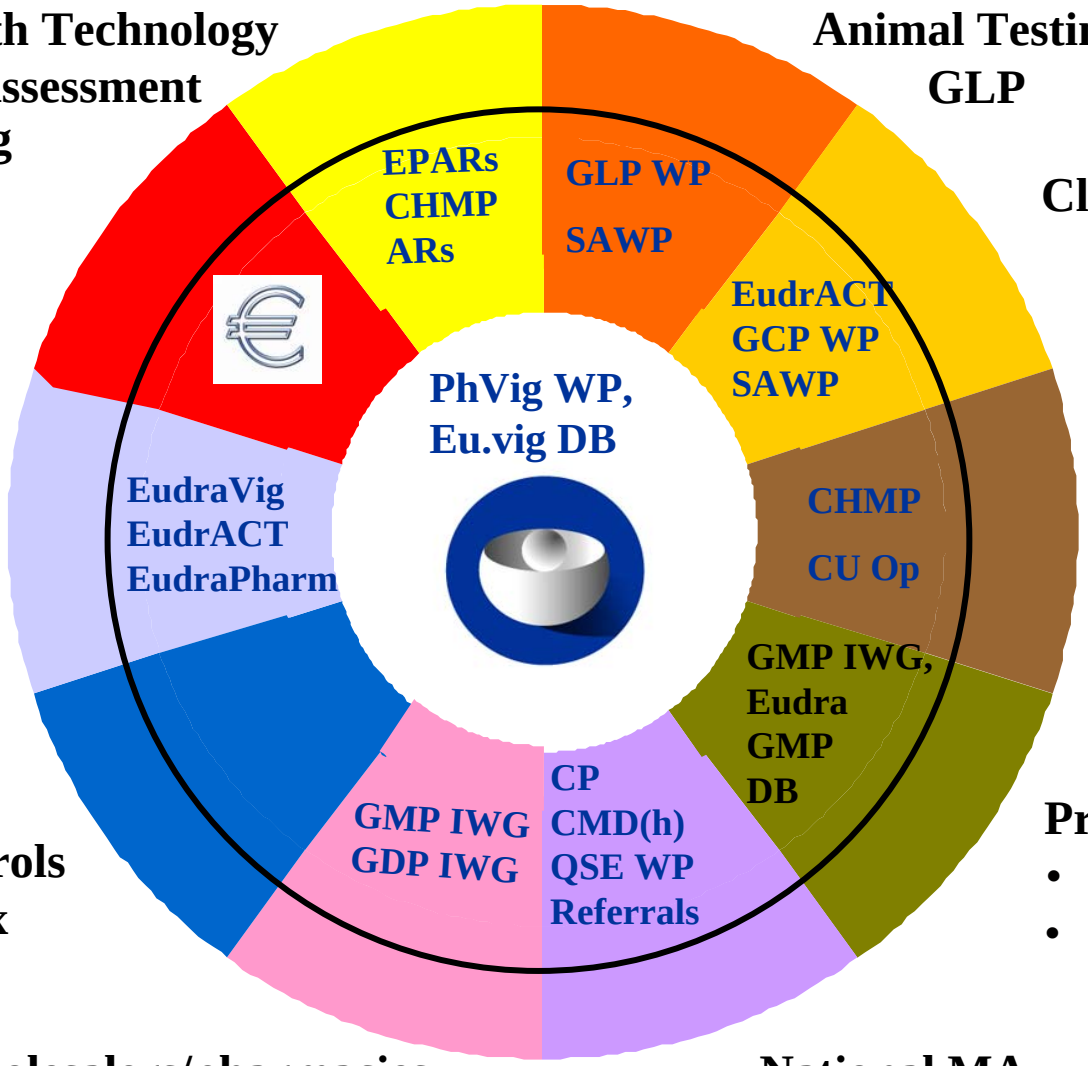
6. Distribution Wholesalers/pharmacies
Parallel imports, Inspections

7. Advertising Controls
Rx and Non Rx

8. Independent Information Sources

9. HCPs Prescribing
Re-imbursement
Pricing
substitution

10. Health Technology Assessment



Health Technology Assessment

HCPs Prescribing Re-imbursement pricing substitution

Animal Testing GLP

Clinical Trials GCP

Compassionate Use Programme

Production Facilities
- **Active Substance**
- **Finished Product GMP**

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

Distribution Wholesalers/pharmacies
Parallel imports, Inspections

Advertising Controls Rx and Non Rx

Independent Information Sources

Impact on National MAs as of Accession

Nature of medicinal product concerned

= vast majority stay national

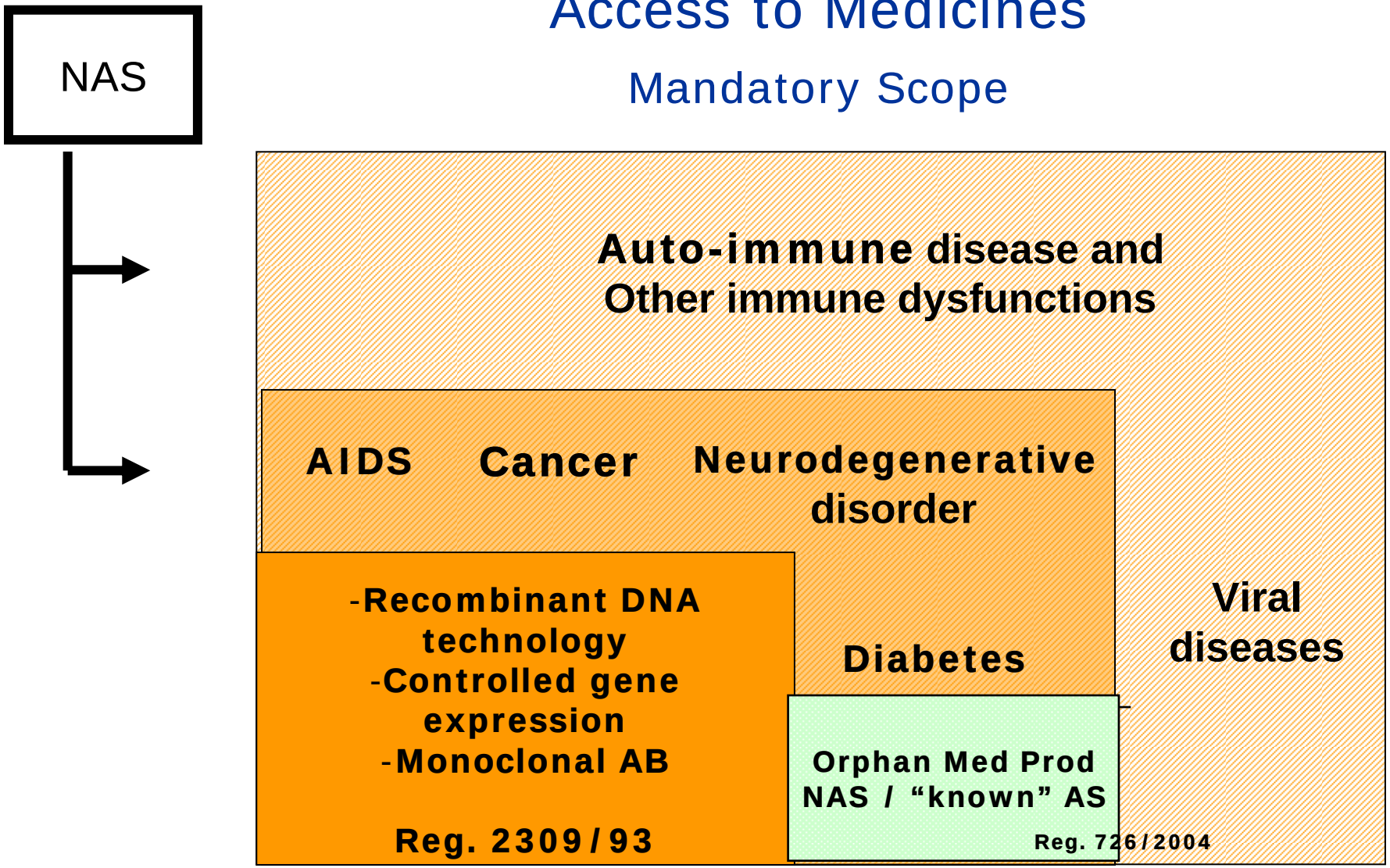
= “update in compliance with Acquis” exercise

❖ Certain product types suitable for MR/DCP = will lead to National MA = but linked and harmonised

❖ Certain product types obligatory CP

Access to Medicines

Mandatory Scope



Access to Medicines

Optional Scope

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

Art. 3(2)(a)

New Active Substances

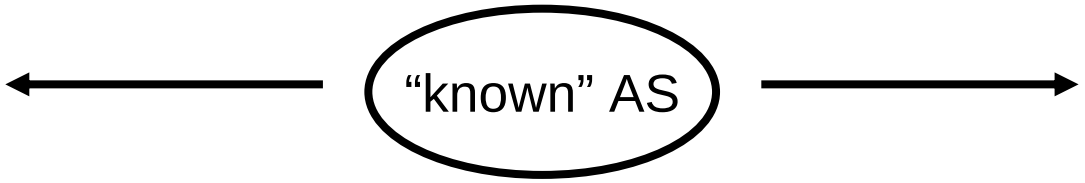
Art. 3(2)(b)

Significant Innovation

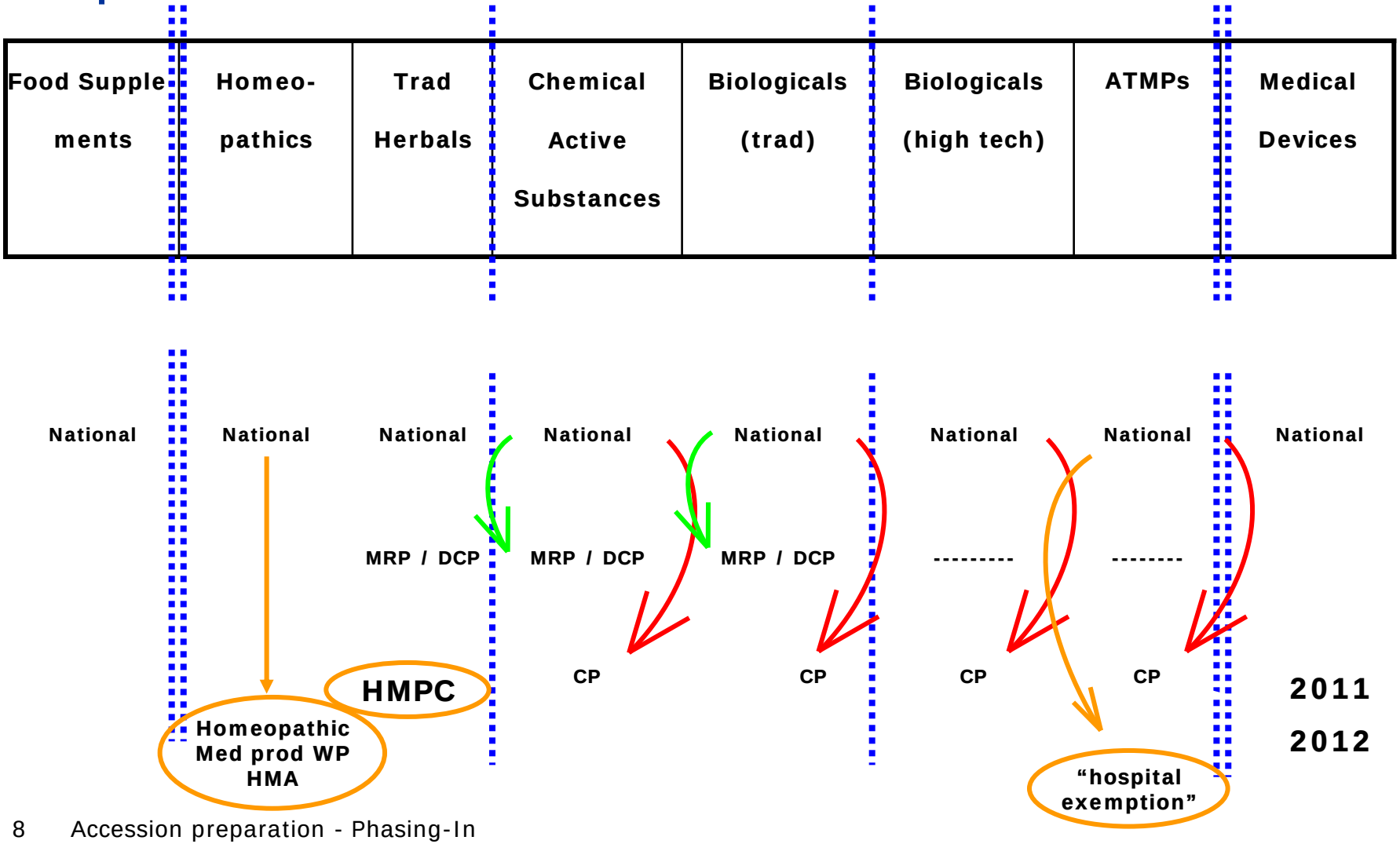
-Therapeutic &/or Scientific &/or Technical

OR

Interest of Patients at Community Level



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 / Rapid Alert System (RAS)

- Pharmacovigilance safety actions ; suspension triggers Art. 107 Procedure → takes issue to EU level
- Community Interest Art. 31 referrals impacts on national MA
- NCA can take interim suspension of use action for all products regardless legal basis approval

National MAs Continued Independence of Action? Case studies

Art. 107 –

Ketoprofen gel = phototoxicity

Nimesulide = Hepatotoxicity

Art. 31 –

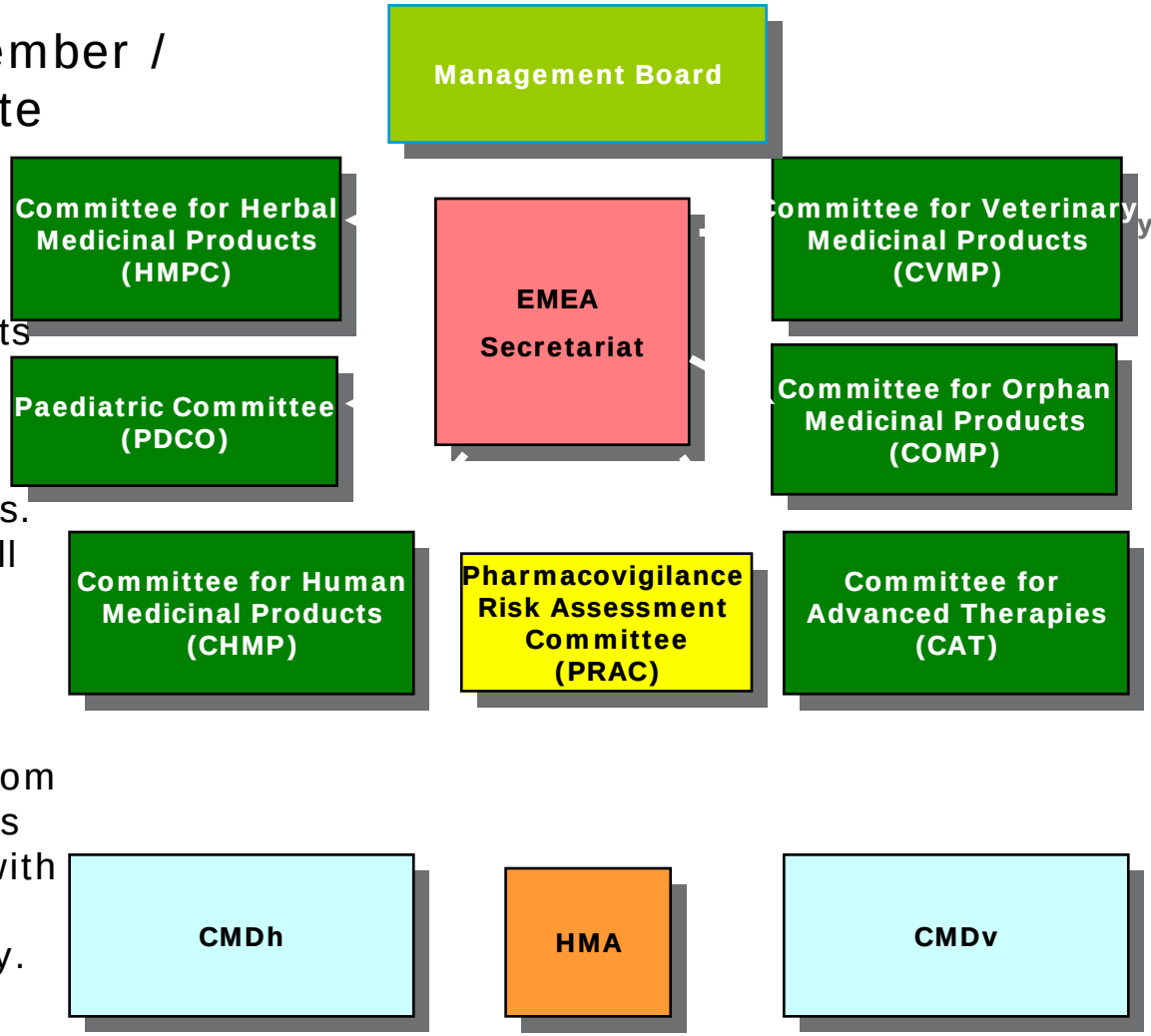
Dextropropoxyphene = risk of accidental overdose and death

Expected Contribution to the Network

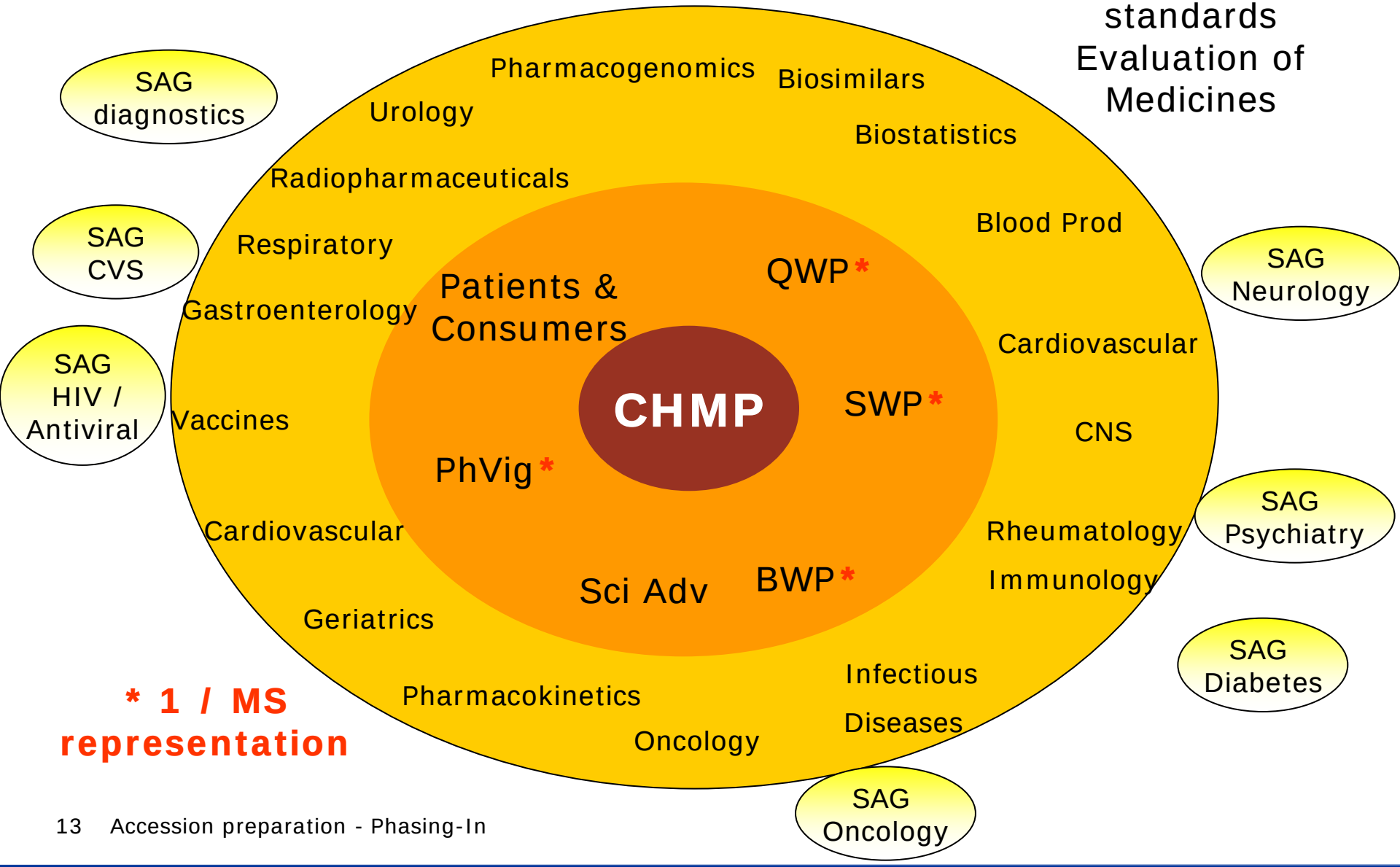
Legislatively Mandated One Member / One Alternate per Member State

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)

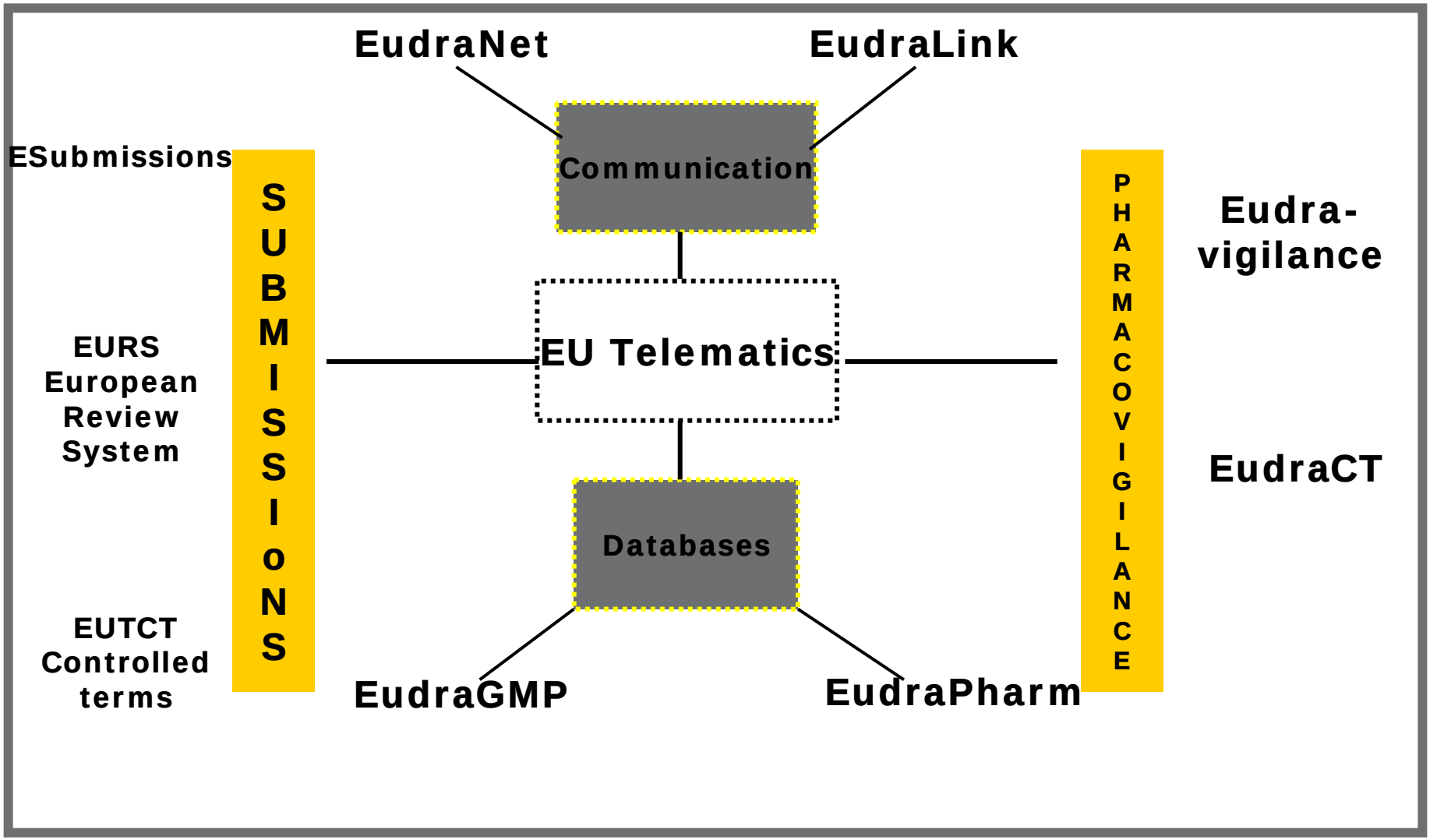
Inspections

Clinical Trials

GMP IWG
GCP IWG
GDP IWG

CTFG

Communication system



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