EU Regulatory Network

Challenges and Opportunities for Croatia

5th ALMP Anniversary

13-14 November 2008, Rijeka - Croatia

Overview of Review Process Interactions

Tony Humphreys
EMEA
Head of Sector
Regulatory Affairs and Organisational Support (RAOS)

Post Nov 2005 Three European Systems

Centralised Procedure (via EMEA)

Mutual Recognition procedure

Decentralised Procedure

Centralised Procedure (via EMEA)

Mutual Recognition procedure

Decentralised Procedure

All Systems allow

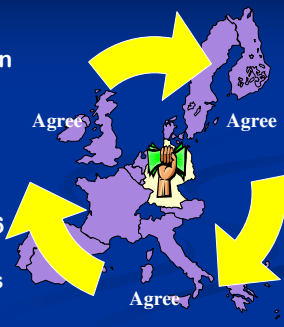
Better Resource Utilisation
Harmonised Scientific Opinions
Harmonised Information to Doctors / Patients

Mutual Recognition Procedure

1 National Authorisation issued by

1 National Regulatory Authority

recognised by up to 26 other National Regulatory Authorities



Decentralised Procedure Evaluation

Collaborative Evaluation MS level without any pre-existing National MA

Draft AR SPC, PL, Labelling

120 days RMS to prepare AR

90 days CMS to approve

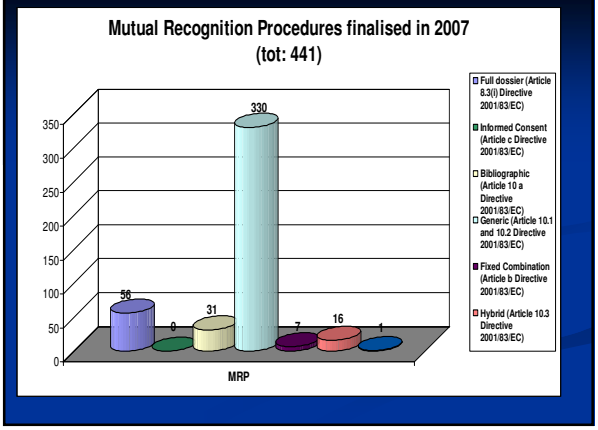
Agreement

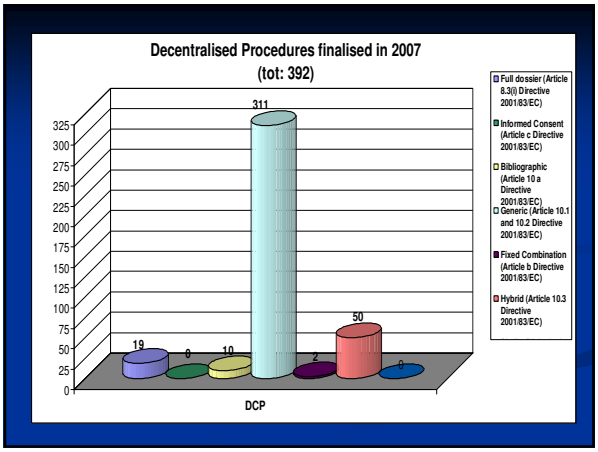
30 days for RMS/ CMS to issue National MA's

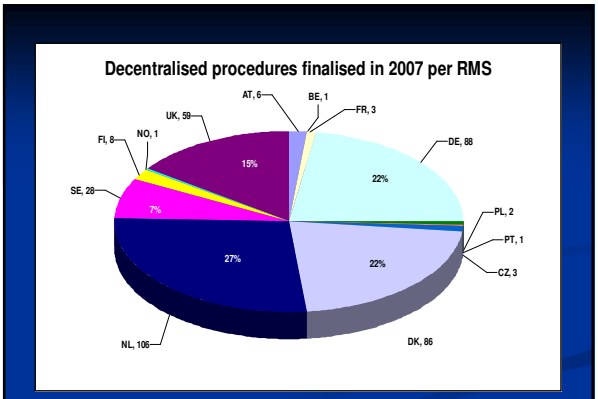
Serious risk to public health

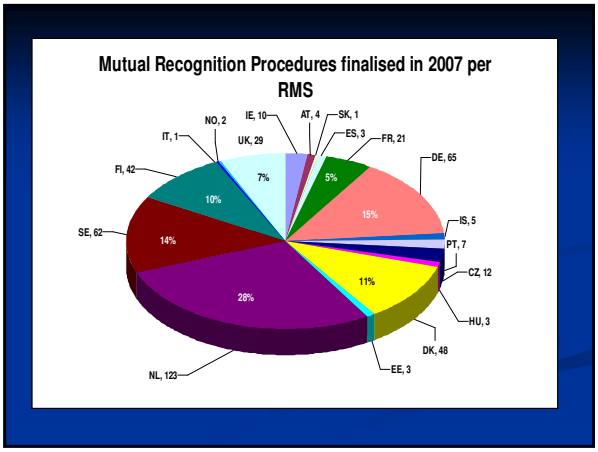
CMDh

REFERRAL







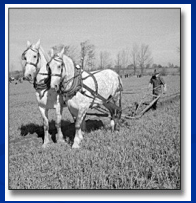


The Co-ordination Group CMD(h)

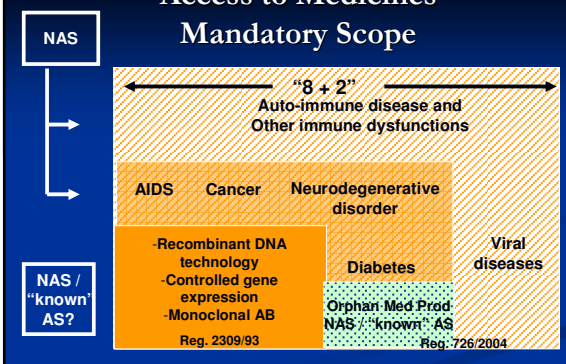
- The Co-ordination Group started in November 2005.
- Truus Janse-de Hoog, Medicines Evaluation Board (NL), Chair of the CMD(h)
- Vice-Chair appointed by the MS which has the Presidency of the Council of the EU.
- The Group is meeting on a monthly basis at EMEA.
- The Rules of Procedures and Guidance Documents published on the HMA website (http://heads.medagencies.org/)
- Sub-groups/Working Groups: Harmonisation of SPCs, CTS WG (h+v), Joint CMD(h)/PhVWP WG

Mutual Recognition Procedure

- Workhorse of the EU Regulatory System
- 100 000's National Marketing Authorisations across EU
- Risk flooding Centralised Procedure if free access granted



Access to Medicines Mandatory Scope



Access to Medicines Optional Scope

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

Art. 3(2)(a)	Art. 3(2)(b)	
New Active Substances " 8 + 2 "	Significant Innovation -Therapeutic &/or Scientific &/or Technical	OR Interest of Patients at Community Level "0" vs "8 + 2"

"known" AS

Article 1

- "The provisions of this Regulation shall not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions.
- In particular, Member States shall be free to choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies. "

A Networking Decentralised Agency

- Member States have pooled their sovreignity for authorisation of medicines
- EMEA is designed to coordinate the existing scientific resources of Member States
- EMEA is not an FDA for Europe
- A 'virtual' agency, interfacing between all partners
- All parties linked by an IT network (EudraNet)
  - eCTD/Eudrapharm/Eudravigilance/EUDRACT etc

Objectives

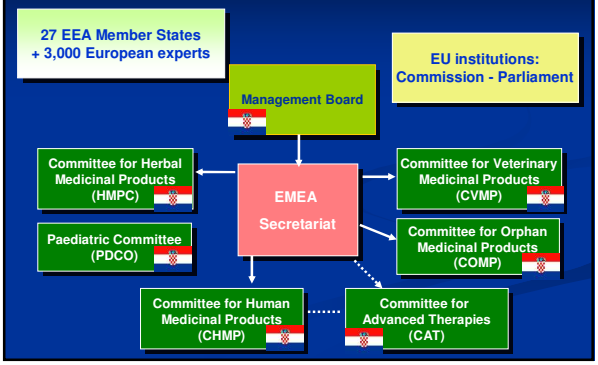
- Rapid Access by users to safe and effective innovative medicines through single EU Marketing Authorisation
- Controlling safety medicines through pharmacovigilance network
- Facilitate innovation and stimulate research and contribute to competitiveness of EU based Pharmaceutical Industry

Objectives (cont.)

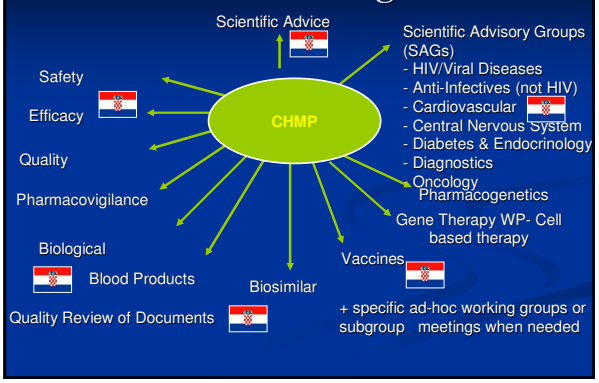
Mobilise and co-ordinate EU Scientific resources to provide high quality evaluation of medicinal products

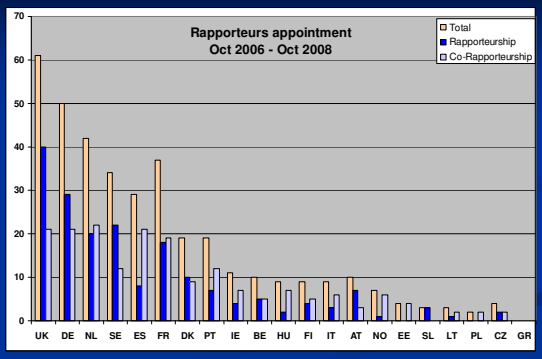
- ✓ To advise on research and development programmes
- ✓ To perform inspections (GXP)
- ✓ To provide useful and clear information to users and healthcare professionals

How is the EMEA Organised?



CHMP Working Parties





Management Board

Chairman: Mr Pat O'Mahony

Vice Chairman: Mrs Lisette Tiddens – Engwira

The Management Board is responsible for the Agency's budget and work programme.

One representative per Member State
Two representatives of the European Parliament
Two representatives of the European Commission
Two representatives from patients' organisations
One representative from doctors' organisations
One representative from veterinarians' organisations
One observer per EEA Member State

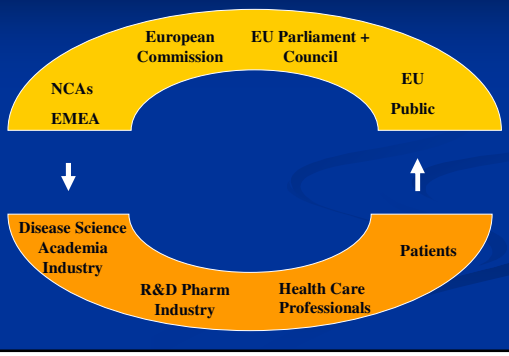
Heads of Medicines Agency (HMA)

- = 2 meetings under each presidency
- = focus for leadership within the Community system of medicines
- = forum for exchange of news on issues of Community Interest

HMA
Heads of Medicines Agencies

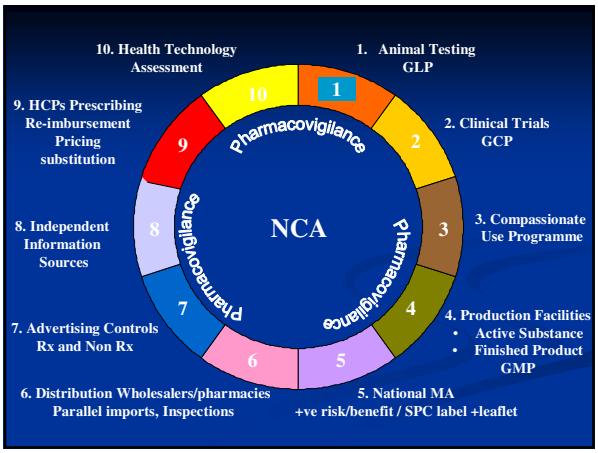
Jean Marimbert

"Virtuous Cycle"



"Blanka's knee"

- Available medicines?
- How effective?
- Side effects?
- Fast access? (especially innovation)
- Trust highest standard development
- Trust identity product supplied
- Trust Information supplied


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
NCA
Pharmacovigilance
Pharmacovigilance
Pharmacovigilance
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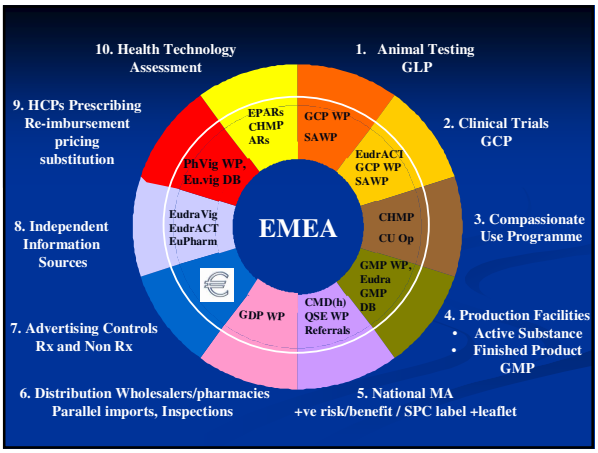
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EMEA
EPARs CHMP ARs
GCP WP
SAWP
EudrACT GCP WP SAWP
CHMP CU Op
GMP WP, Eudra GMP DB
CMD(h) QSE WP Referrals
GDP WP
EudraVig EudrACT EuPharm
PhVig WP, Eu.vig DB