

EU The Role of the Paediatric Committee (PDCO)

**TOPRA, London
December 2006**

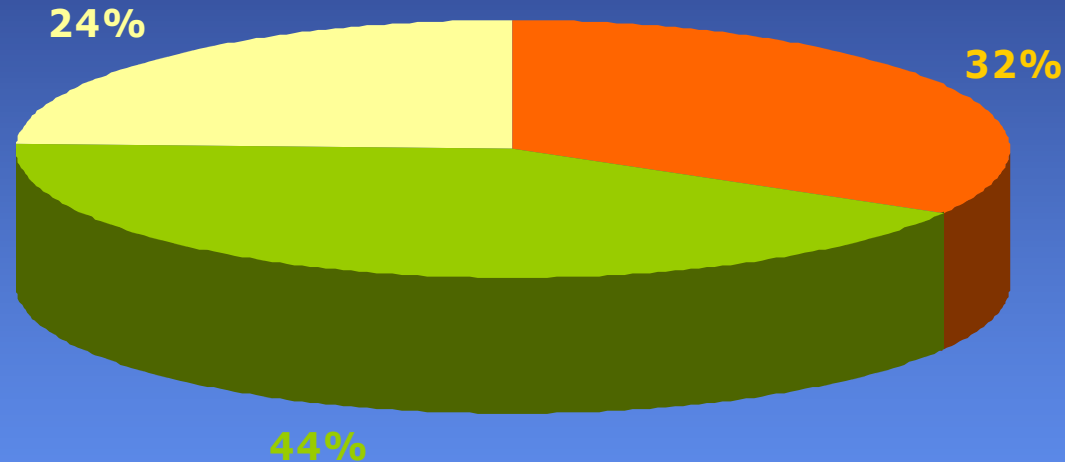
**Daniel Brasseur Chair
of the PEG at the EMEA**

Legislative Initiative

- **First European publications in the 80's**
- **European Commission Round Table, EMEA December 1997**
- **European Council Resolution in Dec 2000**
- **Consultation and Extended Impact Assessment 2000-2004**
- **Adoption of Draft Regulation by European Commissioners in September 2004**

Paediatric Medicines Were Still not Studied

Number of active substances: 258 (1995- January 2006)



- Paediatric indication
- Potential paediatric indication
- Not applicable

EMEA data



Legislative Process

- **First readings in European Parliament and Council 2004-5**
- **Second readings in European Parliament and Council, December 2005 to June 2006**
- **Vote in European Parliament, 1 June 2006**
- **Final steps in Council and Parliament Oct-Nov 2006**

- **Publication of Regulation expected December 2006**
- **Entry into force January 2007 but staggered implementation**

Objectives of the Regulation

- **Improve the health of children**
 - Increase high quality, ethical **research** into medicines for children
 - Increase **availability** of authorised medicines for children
 - Increase **information** on medicines
- **Achieve the above**
 - Without unnecessary studies in children
 - Without delaying authorisation for adults

Main Pillars

- **Creation of a Paediatric Committee at EMEA**
- **Measures for patented medicinal products**
- **Measures for off-patent medicinal product**

Main Pillars

- **Creation of a Paediatric Committee at EMEA**
- **Measures for patented medicinal products**
- **Measures for off-patent medicinal product**

For Yet Unauthorised Products

Patent-protected products

- Obligation to submit **results** of an **agreed** Paediatric Investigation Plan at the time of marketing authorisation, or variation (i.e. new indication, route of administration, or pharmaceutical form)
- Reward:
 - 6-month extension of the Supplementary Protection Certificate (= patent protection)

For 'Old' Products

Off-patent products not covered by a patent or supplementary protection certificate

- **Optional procedure**
- **Paediatric Use Marketing Authorisation (PUMA)**
 - **Paediatric Investigation Plan needed**
 - **Formulation + Paediatric indication(s) only**

Old products (2)

Incentive

- 10 years data protection/exclusivity (as for new products)
- Possible use of existing brand name (brand recognition)

Orphan Drugs

- **15-20% of rare diseases affect children only, 55% affect adults and children**
- **Reward**
2 years of market exclusivity added to existing 10 years, if development in accordance with Paediatric Investigation Plan

CHMP - Committee for Human Medicinal Products

COMPOSITION

5 CHMP Members + 22
to reach
1 member per Member State
inclusively Norway and Iceland

+

6 Members of Patients/Family
& Health Care Professionals

Each member has an alternate

Paediatric Committee

- **6 months to establish (i.e. before July 2007)**
- **Expertise in all aspects related to medicines for children**
 - **Pharmaceutical development**
 - **Paediatric medicine**
 - **General practitioners**
 - **Paediatric pharmacy**
 - **Paediatric pharmacology**
 - **Paediatric research**
 - **Pharmacovigilance**
 - **Ethics and public health**

Tasks of PDCO (1)

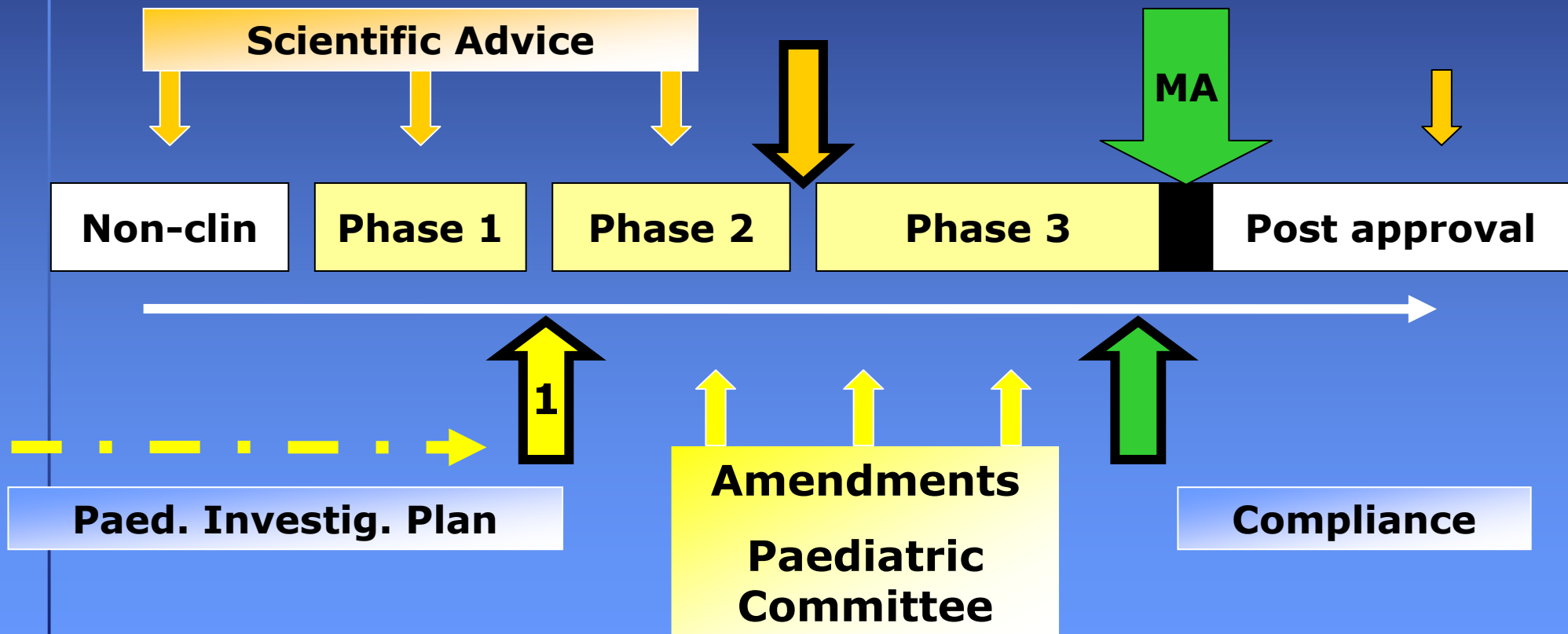
- Paediatric Investigation Plans (more than 200 announced in 2007)
 - Assessment (on basis of EMEA summary report)
 - Deferrals
 - Modifications

- Waivers (more than 80 announced in 2007)
 - Product and condition (severity?)
 - Public list of waivers

About 300 procedures from questionnaire to EMEA MAH/MAA, but likely to be more as not all companies have grasped the scope

- Compliance checks

Timing Consultation of Paediatric Committee



Tasks of PDCO (2)

Use as Expert Group by and for CHMP

- **Scientific Advice (158 announced in 2007)**
 - No paediatric expertise in SAWP
 - Duplication of expertise to be avoided
 - *Use of PEG has proved useful but limited number of experts for areas covered, and workload*
- 'SAG' or expert source for marketing authorisation applications (60-70% of new products with paediatric interest)

Tasks of PDCO (3)

- **Paediatric Needs Inventory: Criteria for survey of use (off label) by Member State**
- **Support and Advice on the European Network establishment**
- **Experts for DG Research? (FP7 funding)**

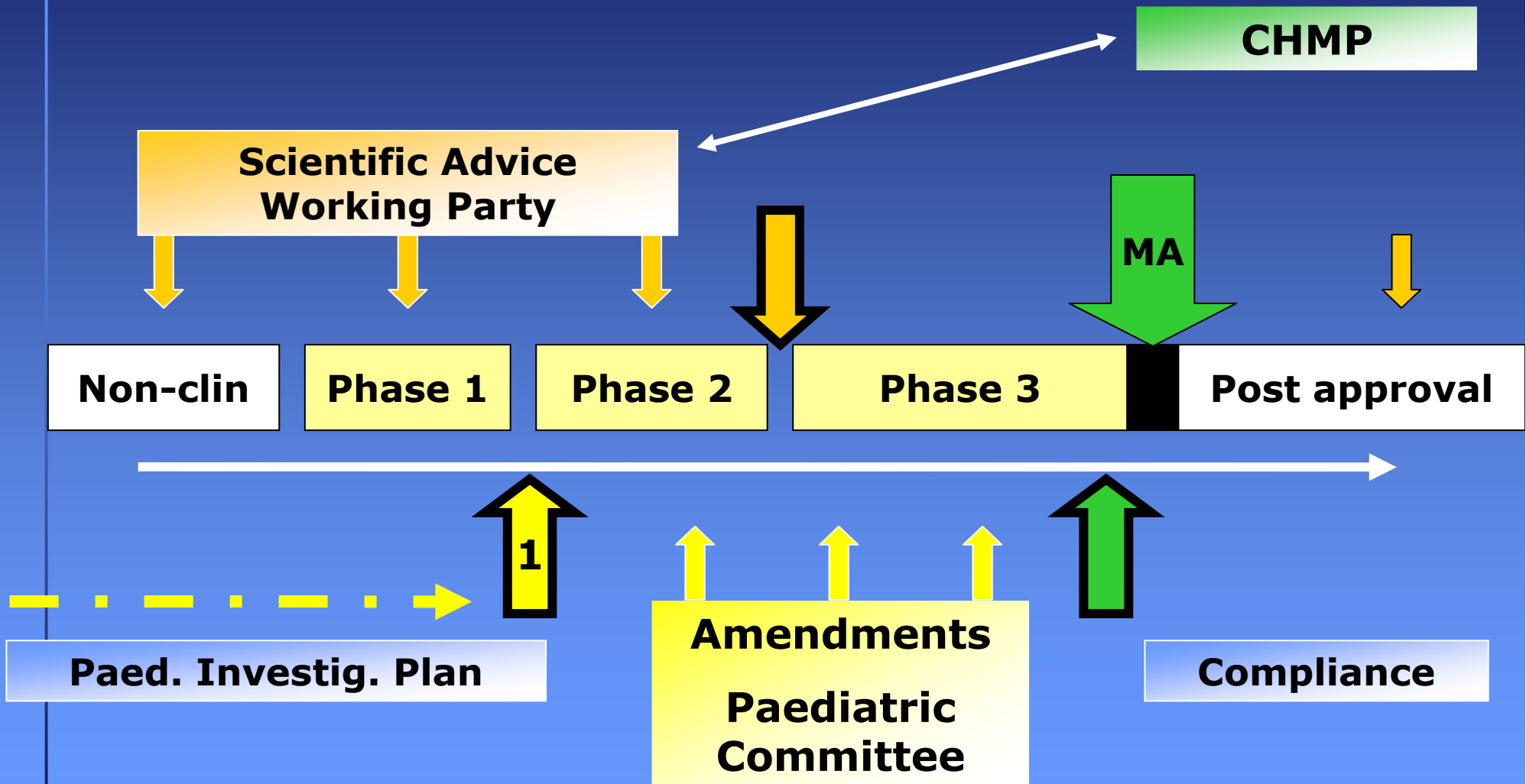
Tasks of PDCO (4)

- Advice on “communication of arrangements available for conducting research into medicinal products for paediatric use”, which corresponds to Eur. Parliament’s wish for PDCO to promote participation in /educate on clinical research
- Advice to Commission, or to EMEA Executive Director on an ad-hoc basis
- Opinion on symbol for paediatric products

PDCO Main Interactions

- **With Scientific Advice Working Party**
- **With Quality Working Party and Biologicals Working Party (formulations)**
- **With Safety Working Party (juvenile animals)**
- **With Efficacy Working Party (guidelines)**
- **With COMP (orphan designation)**

Scientific Advice WP vs. Paediatric Committee



SAWP and PDCO

- Scientific Advice: non binding ↔
- Adults and children development ↔
- Fee attracting procedure (adults, non orphan) ↔
- Reduced fee for SME
- Free for orphan (Protocol Assistance) & paediatric indication
- PIP decision is binding on Company
- Paediatric development only
- No fee

SAWP and PDCO

- Voluntary ↔ • Requirement to consult (PIP or waiver request)
- Request at any time,
• Usually... End of Ph 2 ↔ • Submission at 'completion of Adult PK studies' at the latest,
i.e. End of Ph 1, unless justified

SAWP and PDCO

- Agreement on strategy
 - Deviation possible
 - Covers only population targeted by applicant
 - Greater chances of success at MA stage if followed
- ↔
- Binding Decision on key elements of development
- ↔
- Covers all subsets of paediatric population (incl. possible waivers)
- ↔
- Compliance checked (for a valid application)
 - Determines the right to reward

Conclusions

- **A 7-year process but real achievements**
- **Regulatory framework for Europe**
- **A major change in the way medicines are developed**
- **Better Medicines for the Children of Europe**

Abbreviations

- **EMA: European Medicines Agency**
- **EU: European Union**
- **ICH: International Conference on Harmonization**
- **Council: Council of Ministers (Council of European Union)**
- **PIP: Paediatric Investigation Plan**
- **CHMP: Committee on Medicinal Products for Human Use**
- **PUMA: Paediatric Use Marketing Authorisation**
- **PK: pharmaco-kinetics**
- **EUDRACT: European Database of Clinical Trials**
- **FP7: 7th Framework Programme**

European Medicines Agency

www.emea.europa.eu

DG Enterprise website

pharmacos.eudra.org

- Paediatric regulation proposal and explanatory texts
- Latest version (link)
- Guideline on Ethics



Thank you

