
Medicines for children in Belgium: the way forward



BELGISCHE VERENIGING
VOOR KINDERGENEESKUNDE
SOCIÉTÉ BELGE DE PÉDIATRIE

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What the paediatricians know

- **Studies on medicines in adults not sufficient**
 - Specificity disease
 - Effects on growth, development, maturation
 - Specific adverse reaction

Child... not a small adult

Infant... not a small child

Preterm...not a small newborn



Medicines for children

- Barriers to paediatric medicine development ?

- It takes at least...7 partners

- Challenges to European societies, clinical centres, research units, paediatricians

Position paper EAP on the proposal

European Journal of Pediatrics

May 2005

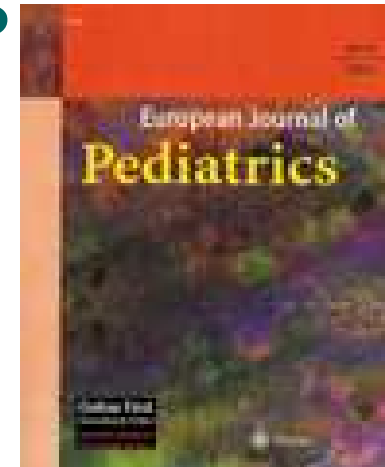
volume 164, Issue Number 5

pages: 263 – 265

Special Article

What the paediatricians need - the launch of paediatric research in Europe

Ramet J et al.

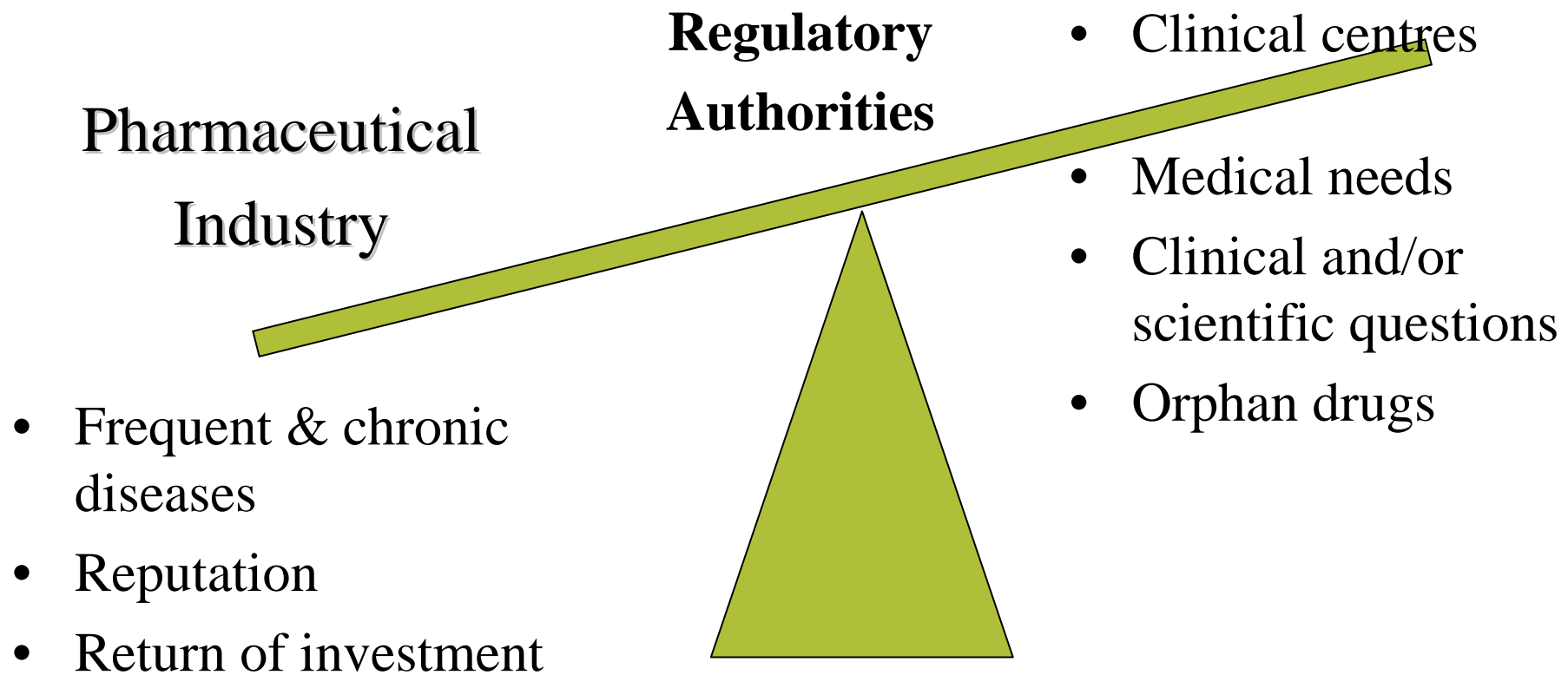


- Partners
 - Balance 3 main stakeholders
 - Ethical concerns
-

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- Children / parents
- Paediatricians and allied physicians
- Academic centres
- Industry
- Regulatory Agencies
- Scientific Societies
- Ethic committees


- Partners
- Balance 3 main stakeholders
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- Partners
 - Balance 3 main stakeholders
 - Ethical concerns

- The principles:the paediatric population should
 - not be exposed to unnecessary hazards
 - not be tested too early in drug development
 - not be tested unnecessarily in clinical trials
 - The reality:
 - do receive off label products
 - may get a wrong dose
 - no adequate galenical form
 - no data on safety : **adverse events : rarely reported**
-

The proposal

 COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, xxx
COM(2004) yyy final
2004/aaaa (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on medicinal products for paediatric use and amending Council Regulation (EEC)
No 1768/92, Directive 2001/83/EC and Regulation (EC) No 726/2004

(presented by the Commission)

EN EN

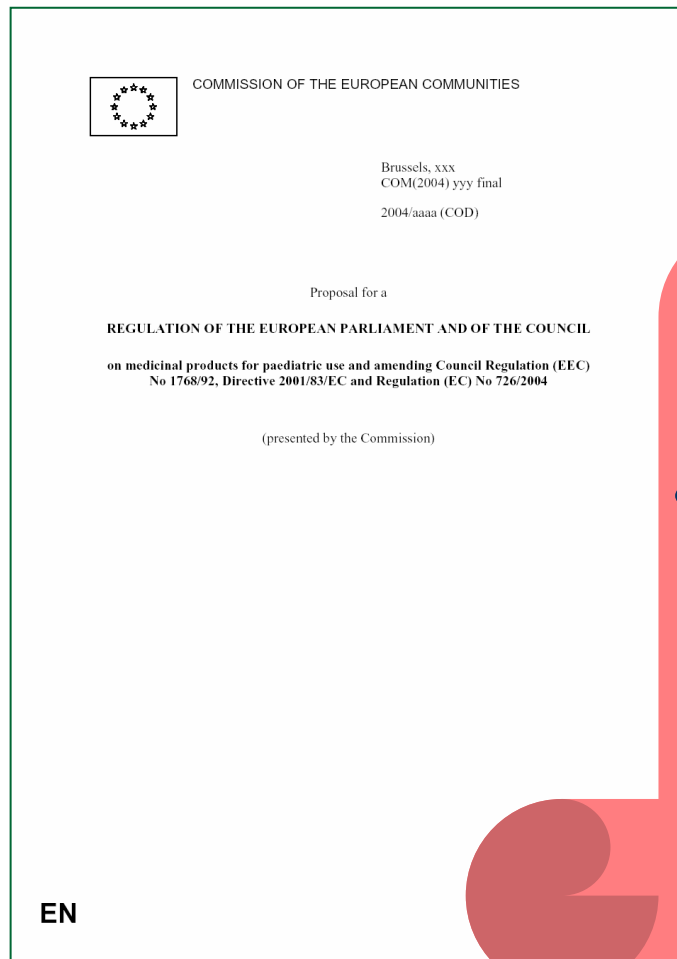
Objectives

- ❑ Increase high quality research into medicines for children
- ❑ Increase availability of authorised medicines for children
- ❑ Improve the information available

Key elements of the proposal

- **Paediatric Committee (PC) in EMEA**
 - Experts in e.g. development, pharmacology, research & ethics
 - **All new products:**
 - **Paediatric Investigation Plan (PIP)**
 - Development plan to ensure availability of data on use of medicinal product in the paediatric population
 - **Established products:**
 - Paediatric Use for off-patent products
-

The way forward ...



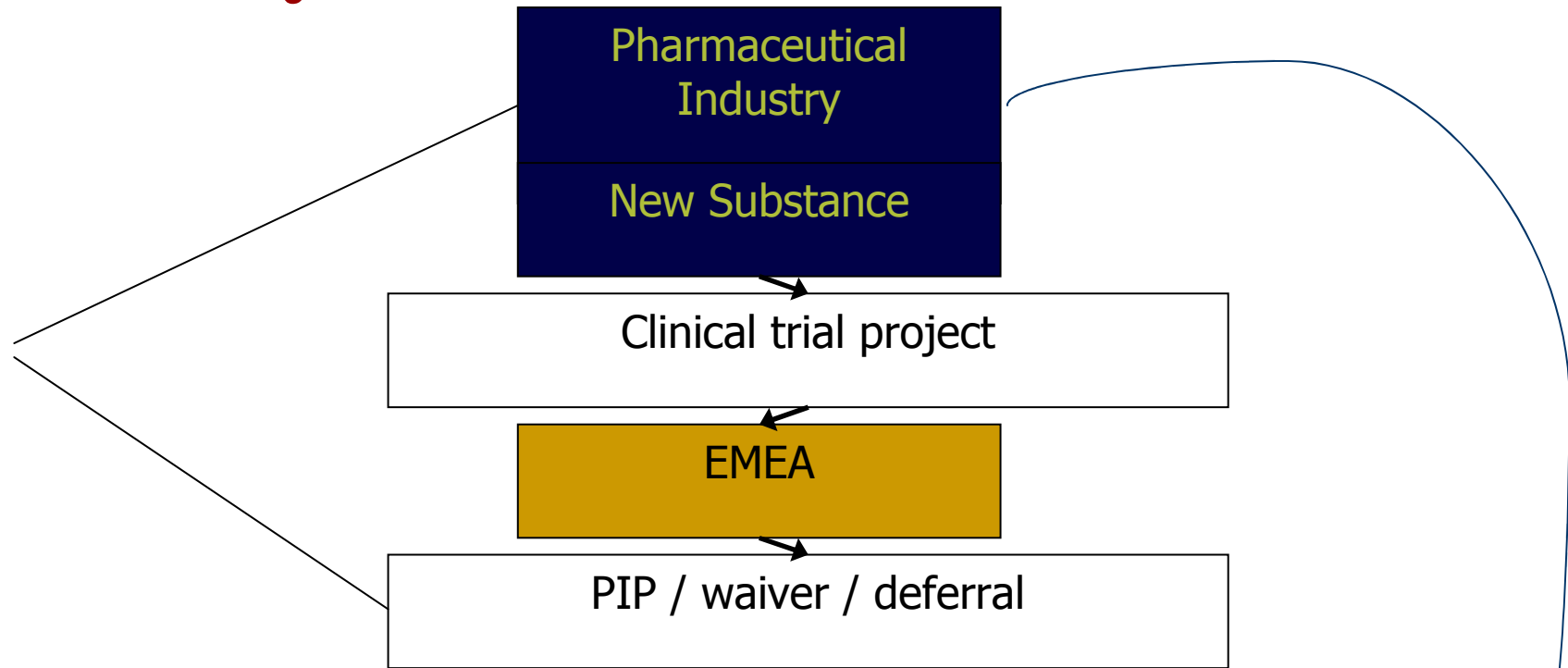
EMEA

Tasks:

- examine & agree PIP
 - therapeutic benefit to children?
 - may request modifications
 - may grant waiver or deferral

**gives
positive / negative
opinion**

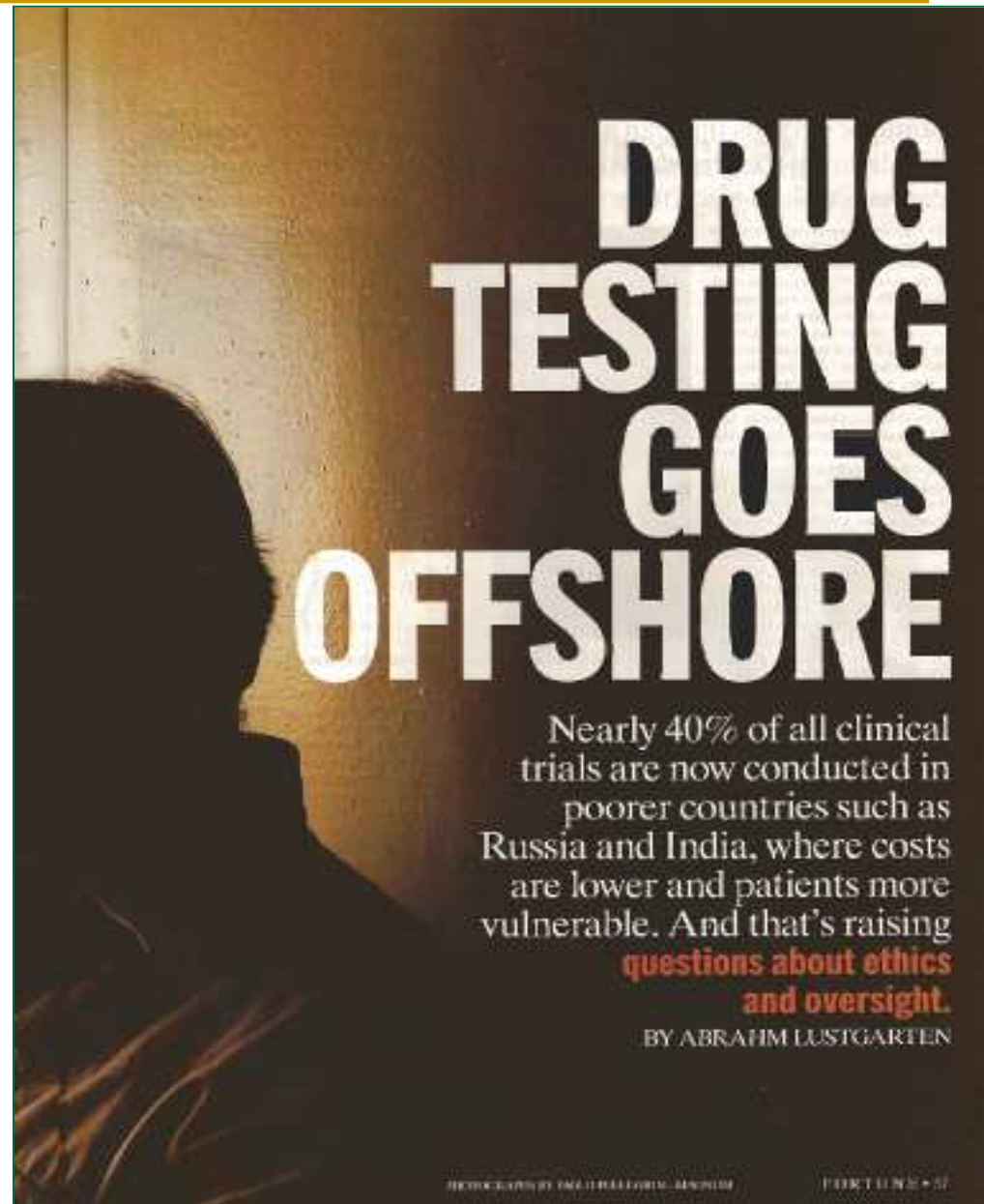
The way forward in ...



How to find competent Paediatric centres
to conduct & evaluate
the clinical trials of a new substance
in...?

Where?

The
globalisation of
clinical trials



Who?

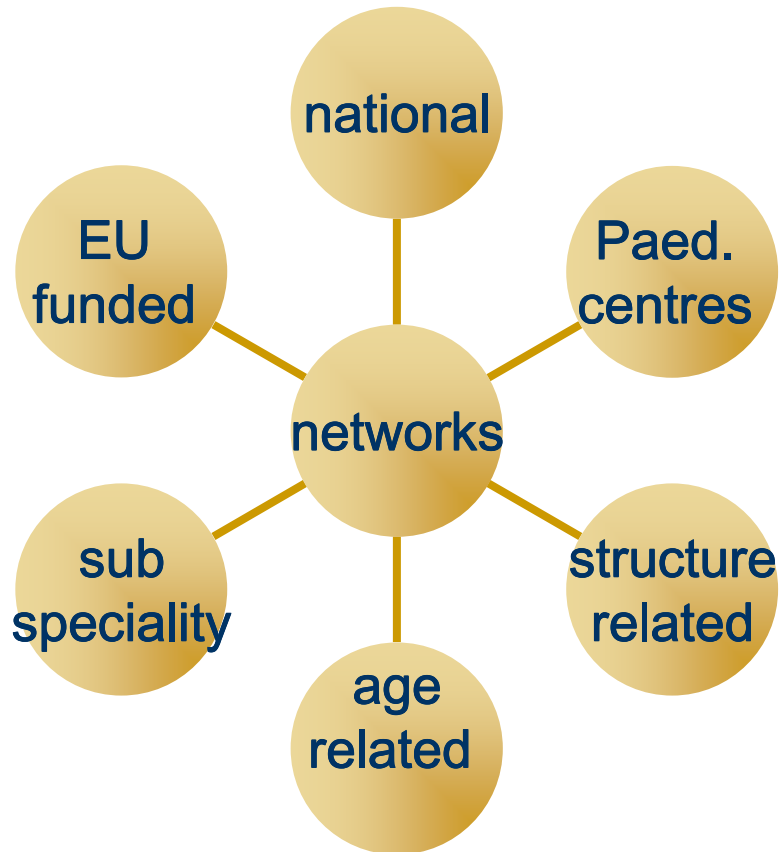
‘Maybe me, but not my child!’



Stakeholders



Existing EU paediatric networks



■ 7 national networks

- public funding
- FR, NL, IT, DE ,..

■ EU funded

- TEDDY

■ sub speciality

- ESPNIC, ESPN...

■ age related

- neonatal

■ structure related

- Pharmacovigilance networks

■ paediatric centres

- dedicated clinical research centres

Advantages networks

- complementary scientific & administrative competences
- avoid duplication
- efficient use of facilities
- developing common working
- sharing best practices



**efficient networks
&
stakeholder
collaboration**

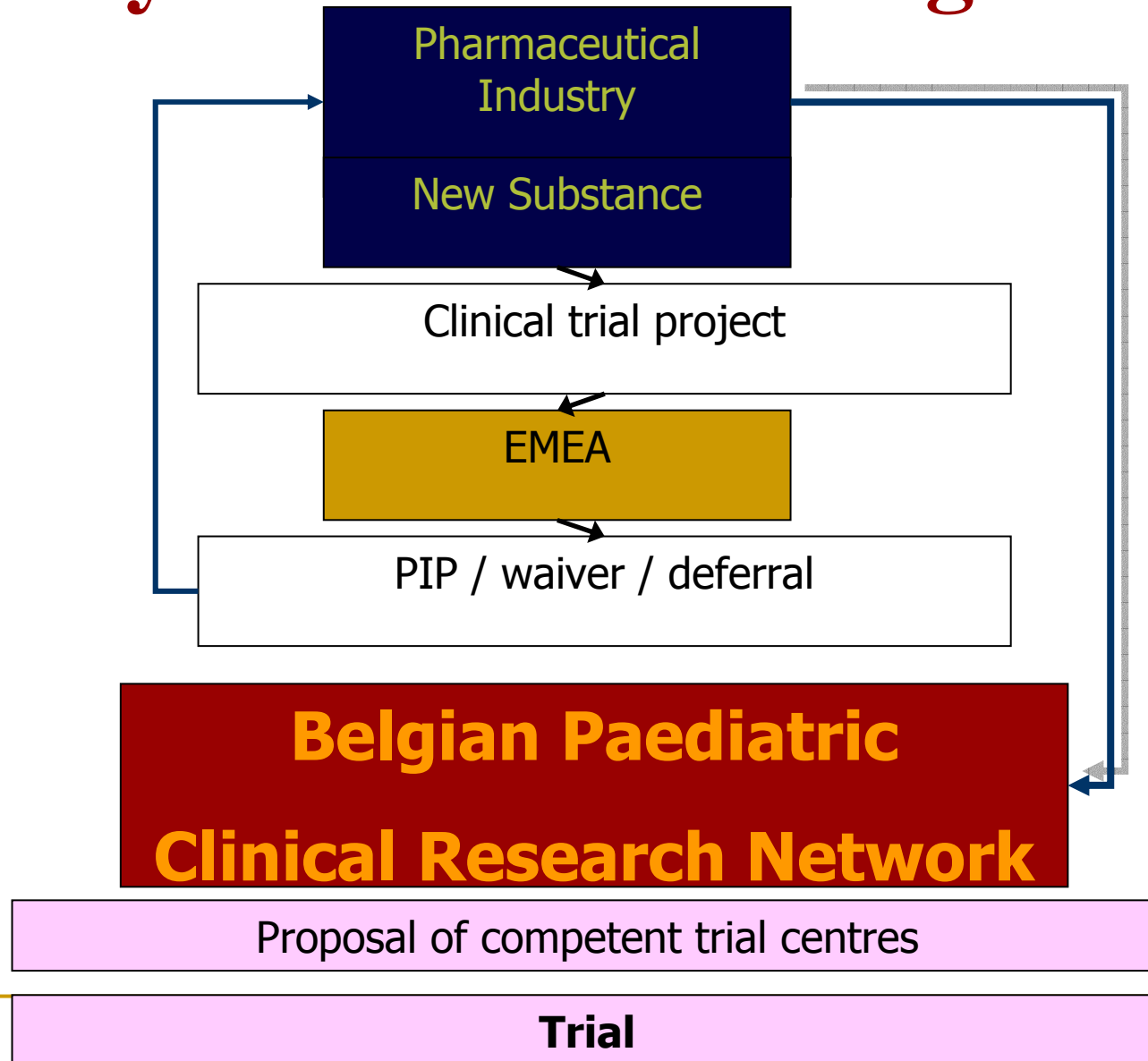
The way forward in Belgium

Development of a paediatric network

Objective of the network:

Coordination of clinical studies on medicines for children

The way forward in ...Belgium?



The way forward in Belgium

Development of a paediatric network

Belgian Paediatric Clinical Research Network

- Coordination & networking activities
 - studies related to medicinal products
 - create updated database
 - national sub-specialty expertise in various fields
 - experienced investigators
 - centres with specific expertise : performance of paediatric studies
-

Belgian Paediatric Clinical Research Network & BVK-SBP

- **Network supported by “neutral” scientific organization**
 - Good knowledge of existing expertise & stakeholders
 - Database on clinical investigators
 - Coordination of recruitment on Belgian level
 - avoiding unnecessary studies
 - sharing information
 - develop multidisciplinary research partnership
-

BVK-SBP

Subsection- overruling field

subsections

- Neonatology
- Neuropaediatrics
- Paediatric Respiratory Medicine
- Paediatric Infectious Diseases
- Paediatric Gastroenterology, Hepatology and Nutrition
- Paediatric Endocrinology & Diabetes
- Paediatric Nephrology
- Paediatric Allergology
- Paediatric Cardiology
- Paediatric Intensive Care
- Paediatric Haemato-Oncology
- Paediatric Metabolic Medicine
- others

Objectives of a Belgian Paediatric Clinical Research network :

■ Database

- existing networks, experience, investigators, local facilities...

■ Reference for

- health care professionals & pharmaceutical industry

■ Interaction

- all stakeholders
- between networks

■ Training & education

- new centres & investigators

■ Information

- annual meeting stakeholders
- printed report of clinical research activities in various fields

role
as
« facilitator »

« facilitator »

□ **recruitment**

- in various and/or dedicated centres
- attainment of required sample sizes

□ **increased performance of trials**

- through inter-investigators exchange of experience

□ **circulation of information**

- consolidated effort of all stakeholders to communicate
- practitioners in the field : aware of those new opportunities

□ **develop scientific excellence**

- stimulate gifted medical students: consider careers in paediatric research
- support major international research projects

□ **act on education , training , research stimulation**

Example of a clinical trial network

cooperation



EAP

(European Academy of
Paediatrics)

&

ERS Paediatric Assembly
(Paediatric subspeciality
formation)

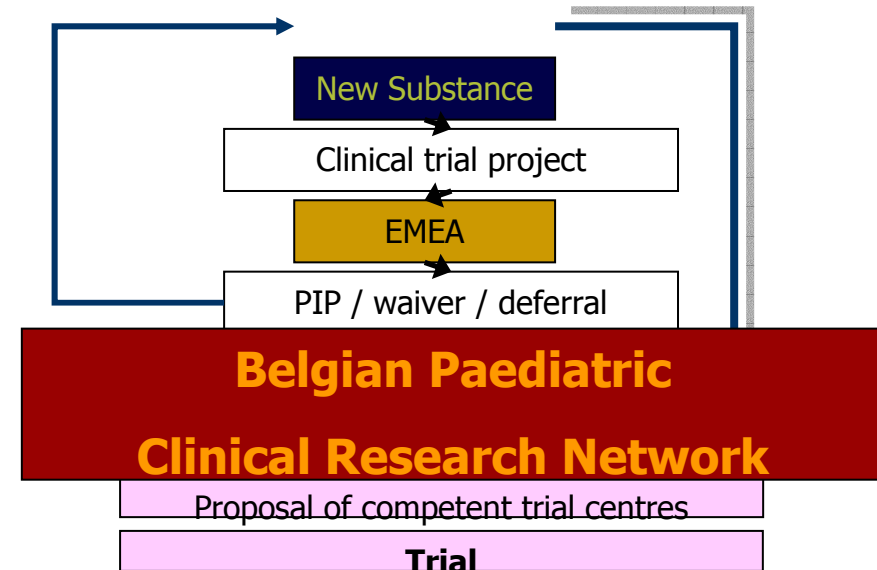
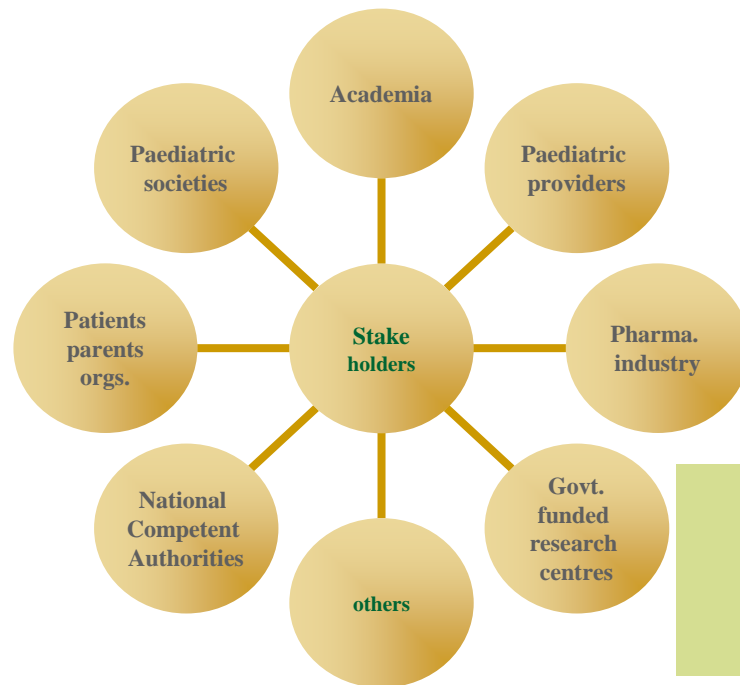
PAEDIATRIC RESPIRATORY MEDICINE

List of centres competent in and equipped
sufficiently for clinical drug investigations
in children with respiratory disorders

Comment:

This list was compiled by a survey conducted by the Paediatric Assembly of the European Respiratory Society in the second half of 2007. As such, it not only includes centres in European or EU-countries but rather reflects the more global membership of the ERS Paediatric Assembly. The survey was initiated and run by the Head of the Paediatric Assembly (Prof.Dr.Andy Bush, London, UK) upon request by the President of the European Academy of Paediatrics/UEMS-Section of Paediatrics (Prof.Dr.Max Zach, Graz, Austria).

Conclusion



Objectives of the network
« facilitator »



To do list

define interested stakeholders

proposal of procedure

find support of the network: 2 years

first things first: database