



Paediatric Research in FP VI and FP VII

Dr. Fergal DONNELLY
Directorate Health
DG Research – European Commission



Framework Programme FP VI (2002-2006)

Call II (2003) Medicines for children – *NETWORK OF EXCELLENCE : TEDDY*.

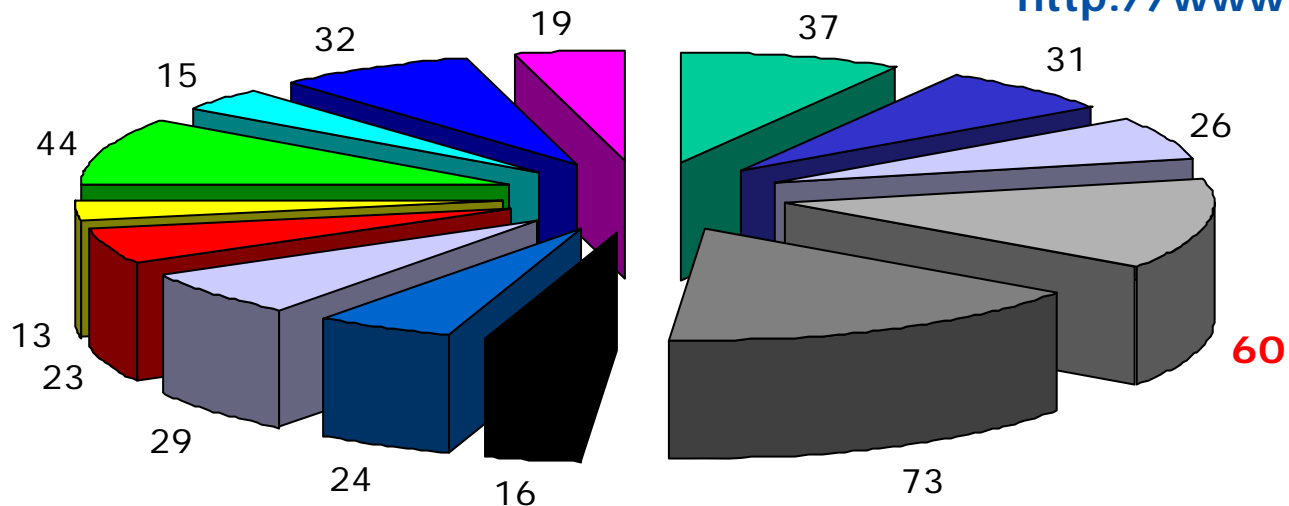
- Structuring of European efforts devoted to the development medicines for children.
- Close collaboration among academia, pharmaceutical industry, ethical bodies and regulatory authorities will be necessary.
- 8 main objectives
- Better use of medicines for children, define unmet needs, database establishment, ethical debate, build critical mass



TEDDY Expert groups activities

14 Therapeutic areas - 442 drugs

<http://www.teddynoe.org>

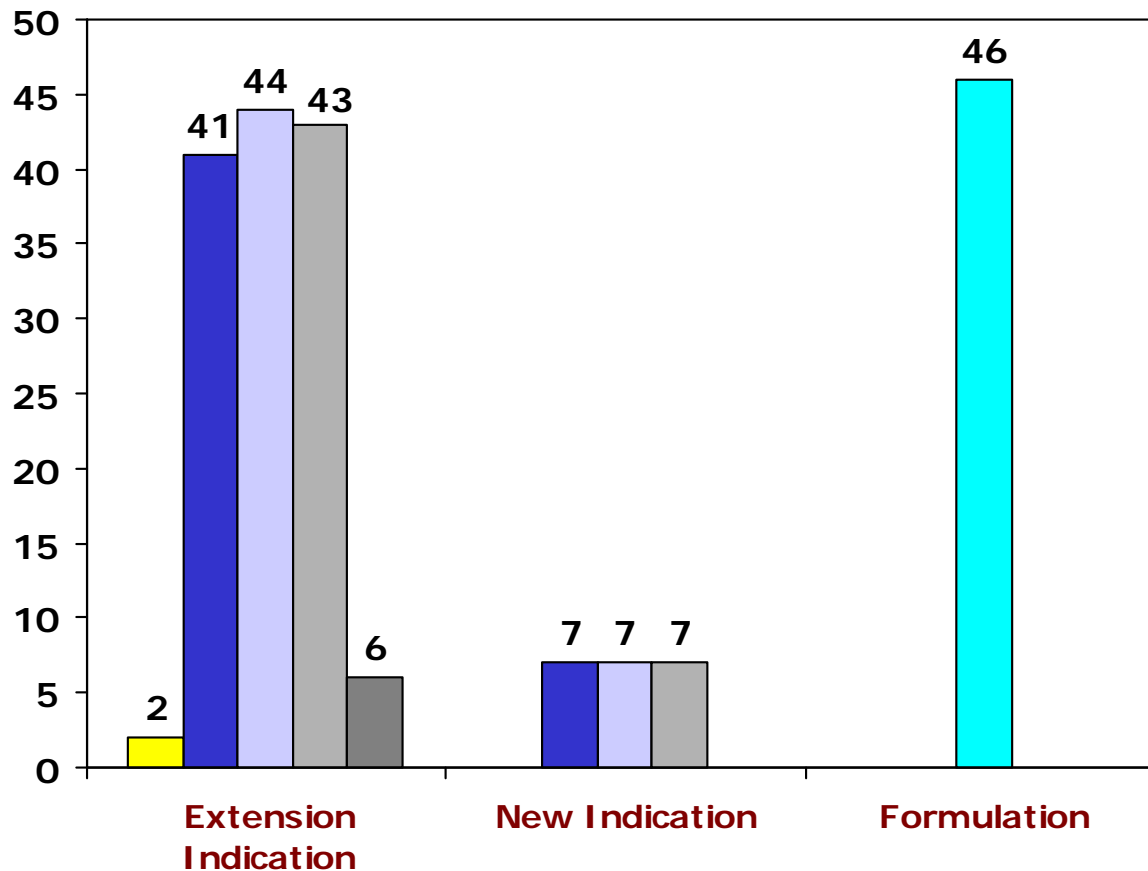


- | | | | |
|-----------------|-----------------|------------------|------------------|
| Anaesthesiology | Infectious dis. | Respiratory dis. | Cardiology |
| Oncology | Diabetes | Epilepsy | Gastroenterology |
| Immunology | Migraine | Nephrology | Pain |
| Psychiatry | Rheumatology | | |

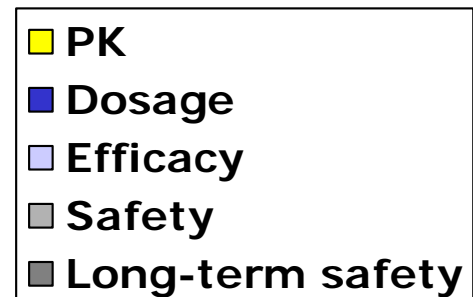


New studies needed in cardiology (60 drugs)

Total studies to be done: 203



<http://www.teddynoe.org>





Collaborative research in the Health theme (FPVII)

Main policy drivers:

- **Improving health** of European citizens
- **Increasing competitiveness** of European health-related industries and businesses
- **Addressing global health issues**, including emerging epidemics

- Budget:

- **€6.1 billion over 7 years (2007-2013)**



Funding schemes for research in FPVII

Warning: these are eligibility criteria !

	min.	max.*
➤ Small- or medium-scale focussed research project (FRP)		€3m
➤ Large-scale integrating project (IP)	€6m	€12m
➤ Projects targeted at (SMEs & SICA)		€3m
➤ Coordination action (CA)		
➤ Support action (SA)		
➤ ERA-Net (for cancer topic)		€2m

*except where otherwise stated in work programme, e.g. Off-Patent Medicines for Children (max. €6m).



Minimum conditions for participation in FP7

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"You'll experience denial, anger,
bargaining, depression, acceptance,
and finally, stuffing."



Minimum conditions for participation in FP7

General:

- 3 independent participants from 3 different Member States (MS) or Associated countries (Ac)
- Natural persons may participate
- Additional conditions can be established by the work programme (WP) or specific programme (SP) (e.g. number or type of participant, place of establishment)



Important definitions in FP7

- **Public body** means any legal entity established as such by national law, and international organisations.
- **Research organisation** means a legal entity established as a non profit organisation which carries out research or technological development as one of its main objectives.
- **Higher and secondary education establishments** = Term used by Financial Regulation / Implementing Rules, includes universities, schools for applied sciences and similar.
- **SMEs** mean micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC in the version of 6 May 2003 (OJ L 124, 20.5.2003, p. 36).
- **International cooperation partner countries** = FP6 INCO countries – three categories according to income per capita (low-income, lower-middle-income, or upper-middle-income); will be identified as such in the work programmes.



SMEs : Commission Regulation (EC) No 2049/2005

- Administrative and procedural assistance from the SME Office at EMEA;
- Fee reductions for scientific advice, inspections and (for veterinary medicines) establishment of maximum residue limits;
- Fee exemptions for certain administrative services of the EMEA;
- Deferral of the fee payable for an application for marketing authorisation or related inspection;
- Conditional fee exemption where scientific advice is followed and a marketing authorisation application is not successful;
- Assistance with translations of the product information documents submitted in the application for marketing authorisation.



SMEs

To determine which companies are eligible for SME incentives, the EMEA will apply the definition of micro, small and medium-sized enterprises provided in ***Commission Recommendation 2003/361/EC***



***EMEA : <http://www.emea.eu.int>
E-mail : smeoffice@emea.eu.int***



Results from 2nd Call

- 15 Proposals received
- 8 proposals over all evaluation thresholds
- 6 retained for funding

- Good coverage of the ages and conditions listed.
- Good coverage of malignant diseases, infectious diseases, neonatology
- Limited attention given to ophthalmology, gastroenterology or psychiatry, only one proposal in cardiovascular medicine.
- New Member States significantly under-represented.



Results from 2nd Call

- **Commitment to seeking a PUMA (Paediatric Use Marketing Authorisation) was not clearly articulated.**
- **In many proposals, over-ambitious objectives, not matched by budget!**
- **Some investigators appeared in more than one project.**
- **Lack of clarity was apparent between the EMEA Priority List of Molecules and the Paediatric (Clinical) Needs List.**
- **Lack of familiarity with the realities of the drug development process.**



4.2 – Responding to EU Policy needs 3rd call

Proposed topic for 3rd call :

Adapting off-patent medicines to the specific needs of paediatric populations:

- Studies dedicated to provide evidence for specific paediatric use of off-patent medicinal products currently used off-label
- PK (as well as data analysis and extrapolation by means of *in silico* models), efficacy, safety and formulations.
- Must take account of the updated Priority List of EMEA and of Paediatric Medicines' Regulation

US centres welcome!!

Objectives :

- Aims at better use of off-patent medicinal products in paediatric populations and Paediatric Use Marketing Authorisations (PUMAs).

Funding scheme:

- Small or medium-scale focused research projects, max. EUR 6 000 000.



Application Procedures

- **Electronic submission (on line) via Electronic Proposal Submission Service (EPSS)**
- **Administrative forms (Part A)**
- **Technical Content (Part B) (.pdf format only - 3rd version or higher),**
- **Exclusion criteria :**
 - **Incomplete**
 - **Illegible**
 - **Infected**
 - **In other ways (e-mail, fax, CD-ROM, etc)**

http://cordis.europa.eu/fp7/epss_en.html



Useful contact details

- **TEDDY :**
<http://www.teddynoe.org>
- **Community Research & Development Information Service :**
<http://cordis.europa.eu/en/home.html>
- **Calls for Proposals :**
<http://cordis.europa.eu/fp7/dc/index.cfm>
- **Health :**
http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.CooperationCallsPage&id_activity=1
- **Work Programme, incl. Paediatric Medicines :**
http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.CooperationDetailsCallPage&call_id=10
- **Independent Expert registration**
<https://cordis.europa.eu/emmp7/index.cfm?fuseaction=welcome.welcome>



**“Eighty percent of
success is showing up.”**

Woody Allen