TOPRA

THE ORGANISATION FOR PROFESSIONALS IN REGULATORY AFFAIRS

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

A European Network of Paediatric Research
The Contribution of Regulators

Daniel Brasseur
Chair PDCO

EU Paediatric Regulation[1]

Entered into force on 26 January 2007

The objective of the Paediatric Regulation is to improve the health of children in Europe by:

- facilitating the development and availability of medicines for children from birth to less than 18 years,
- ensuring that medicines for use in children are of high quality, ethically researched, and authorised appropriately,
- improving the availability of information on the use of medicines for children,

without:

- subjecting children to unnecessary trials,
- or delaying the authorisation of medicinal products for use in adults.

[1] Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, amended by Regulation (EC) No 1902/2006.

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Further information

'Medicines for children' section of the Agency's website:
http://www.ema.europa.eu/htms/human/paediatrics/introduction.htm

E-mail for questions on paediatrics issues:
paediatrics@ema.europa.eu

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Canary Wharf
London E14 4HB
Telephone +44 (0)20 7418 8400
Facsimile +44 (0)20 7418 8416
Website www.ema.europa.eu

Better medicines for children

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An agency of the European Union

Article 44

1. The Agency shall, with the scientific support of the Paediatric Committee, develop a European network of existing national and European networks, investigators and centres with specific expertise in the performance of studies in the paediatric population.

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Paediatric Investigation Plans

2. The objectives of the European network shall be, inter alia, to coordinate studies relating to paediatric medicinal products,

to build up the necessary scientific and administrative competences at European level, and to avoid unnecessary duplication of studies and testing in the paediatric population.

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PDCO

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EMA

REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2006

on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

What should the PDCO do?

(f) to support and advise the Agency on establishing the European network referred to in Article 44;

(g) to assist scientifically in the elaboration of any documents related to the fulfilment of the objectives of this Regulation;

(j) to advise the Agency and the Commission regarding the communication of arrangements available for conducting research into medicinal products for use in the paediatric population;

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European Medicines Agency

London, 15 January 2008
Doc. Ref. EMEA/MB/543523/2007

The Network of Paediatric Networks at the EMEA Implementing Strategy

2.2 EMEA level

Secretarial support to the activities of the network and the organisation of the meetings of the Coordinating Group are provided by the EMEA as requested by the legislation. Support is focussed on the coordination of exchange of information between the network partners, providing information to external partners and stakeholders, and facilitating the work of the Coordinating Group to ensure the objectives are met.

Members of the Paediatric Committee are involved in the Coordinating Group to advise on scientific issues and on the future strategy of the network. The Coordinating Group reports to the Paediatric Committee on a regular basis. The Paediatric Committee will act as the Scientific Committee of the network.

To assist in which domains?

- Formulations
- Pre-clinical
- Methodology (design, statistics, extrapolation…)
- Special populations (neonates, …)
- Special products (vaccines, Blood products…)
- Specific fields (rare diseases, ATherapies…)

What can PDCO offer?

- Guidance (science for regulation)
- Prioritise Needs & Products
- Evaluate and assess paediatric projects intended to bring new or old drugs on the market (e.g PUMA)
- Communicate with EMA on ‘ongoing’ Research (EudraCT)

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24 June 2010
EMA/CHMP/213057/2010
Committee for Medicinal Products for Human use (CHMP)

Paediatric addendum to CHMP note for guidance on clinical investigation of medicinal products in the treatment of lipid disorders

Draft

GUIDELINE ON CLINICAL EVALUATION OF NEW VACCINES

REFLECTION PAPER: FORMULATIONS OF CHOICE FOR THE PAEDIATRIC POPULATION

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)
AND
PAEDIATRIC COMMITTEE (PDCO)

GUIDELINE ON THE INVESTIGATION OF MEDICINAL PRODUCTS
IN THE TERM AND PRETERM NEONATE

GUIDELINE ON THE NEED FOR NON-CLINICAL TESTING IN JUVENILE ANIMALS OF PHARMACEUTICALS FOR PAEDIATRIC INDICATIONS

20 May 2010
EMA/CHMP/EWP/213972/2010
Committee for Medicinal Products for Human use (CHMP)

Paediatric addendum to CHMP guideline on the clinical investigations of medicinal products for the treatment of pulmonary arterial hypertension

Draft

Draft Agreed by Efficacy Working Party	April 2010
Adoption by CHMP for release for consultation	20 May 2010
End of consultation (deadline for comments)	30 November 2010

Guideline on missing data in confirmatory clinical trials

GUIDELINE ON THE ROLE OF PHARMACOKINETICS IN THE DEVELOPMENT OF MEDICINAL PRODUCTS IN THE PAEDIATRIC POPULATION

GUIDELINE ON THE NEED FOR NON-CLINICAL TESTING IN JUVENILE ANIMALS OF PHARMACEUTICALS FOR PAEDIATRIC INDICATIONS

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21 October 2010
EMA/CHMP/BPWP/94038/2007 rev. 3
Committee for Medicinal Products for Human Use (CHMP)

Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg)

'Guidance' in the « pipe-line »

- Gluco-corticoid induced osteoporosis
- Pulmonary Hypertension
- Insomnia
- Schizophrenia
- Asthma
- Hepatitis C
- …

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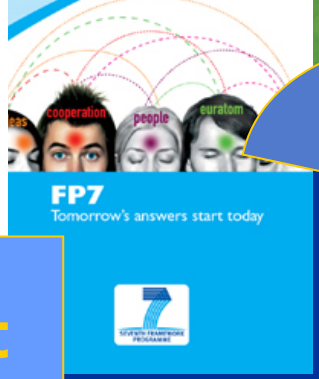
25 July 2010
EMA/480197/2010
Rev. 2010 – update 17/11/2010*
Human Medicines Development and Evaluation

Revised priority list for studies into off-patent paediatric medicinal products

for the 5th Call 2011 of the 7th Framework Programme of the European Commission

This priority list of off patent medicines is the basis only for the 5th Call 2011 of the 7th Framework Programme of the European Commission.

List



DG Research Project

Funded Project

DG Research

EMA

PDCO evaluation

PIP Procedure	Date	Procedure Da
Report version 0 from EMEA	01/08/2007	1
Report version 1 from Rapporteur	20/08/2007	20
Report version 2 from Peer-reviewer	28/08/2007	28
Report version 3 with co	13/09/2007	44
Report version 4 from E	25/10/2007	61
Report version 5 from R	23/11/2007	90
Report version	20/12/2007	120

PIP


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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STOP

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EMA

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DG Research

PDCO

EMEA

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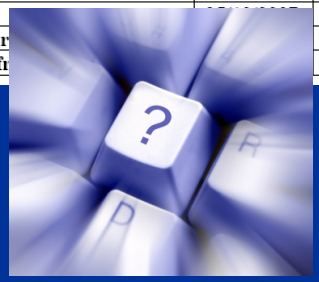
Report version 6 with comments fr		



List

PDCO

Plan

Define

Project

Deploy

DG Research

EMEA

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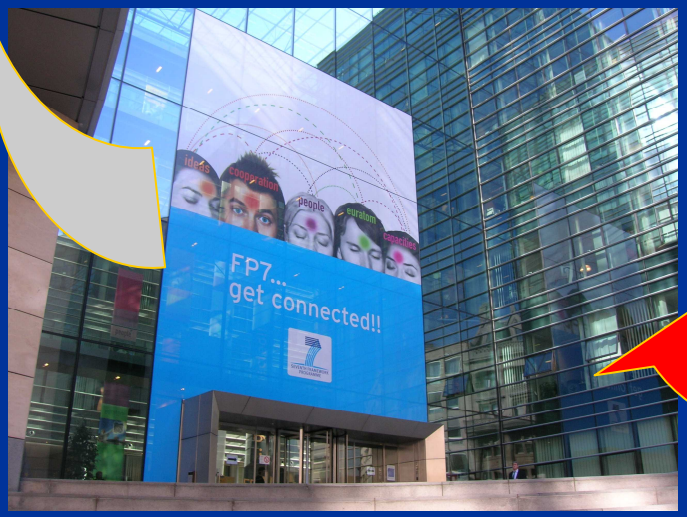

GO

All together…

PDCO can work with the Network
to define standard/models PIP
(methodology, formulations, designs….)
in defined areas where paediatric drug
development takes place
having in mind feasibility (ethics, access…)
and perception of patients (families…)

EudraCT

EudraCT v8 Information NEW
EudraCT v7 Documentation NEW

IMPORTANT

EudraCT Version 8 is expected to be released into production on **10 March 2011**.

EudraCT Version 8 incorporates the revised Clinical Trial Application form and the possibility for PIP Addressees to load information on trials conducted outside of the EEA.

The new release also includes a utility to convert EudraCT Version 7 XMLs to Version 8 XMLs, in order to allow XMLs already complete or in preparation to be used in Version 8.

This notice period respects the agreed "minimum of 15 calendar days' notice" to users as specified on the EudraCT website.

The production release date will be preceded by a period of system downtime to allow for data migration and the upgrade of the system to take place:

EudraCT systems will be unavailable from 17:00 (GMT +0.00) on Thursday 3 March 2011 until 09:00 on Thursday 10 March 2011.

Welcome to the Community Clinical Trial System Public Home Page

EudraCT is a database of all clinical trials commencing in the Community from 1 May 2004 onwards. It has been established in accordance with Directive 2001/20/EC.

This site is the sponsor interface which gives the sponsor access to the EudraCT application in order to:

- Get a EudraCT number
- Complete, save as a .xml file on your computer and print a pdf version of the clinical trial application form

Access to EudraCT v7 Application

You must save the xml files and the pdf files of your Clinical Trial Application Form to your own computer.

You are unable to save xml and pdf files to the EudraCT system.

Only the Member State Competent Authorities are able to do this when you send them your xml file.

New Features in EudraCT v7

Version 7 of EudraCT contains three important additional pieces of functionality as well as an updated Clinical Trial Application Menu, to accommodate these new options. This new functionality has been developed on the basis of requests from stakeholders:

- **Validate XML** - Check and ensure that a Clinical Trial Application form has been completed prior to submission.
- **Compare XML** - Compare two Clinical Trial Applications and view the differences between them onscreen.
- **Prepare Submission Package** - Create a zipped file containing EudraCT documentation for a Clinical Trial Application (CTA): the CTA XML, the corresponding pdf of that CTA, and the validation report for that CTA form.

For more details, see the Supporting Documentation page.

Access to EudraCT v7 Supporting Documentation

This section includes the latest EC directives, guidelines and forms on EudraLex and EudraCT user and technical documentation, as well as monthly statistics.

Resources include:

- New EudraLink Request Form
- New functionality walkthroughs
- Release Notes for the latest version of EudraCT (patch v7.0.3)
- Business Rules Schematron
- Updated user manuals and FAQs

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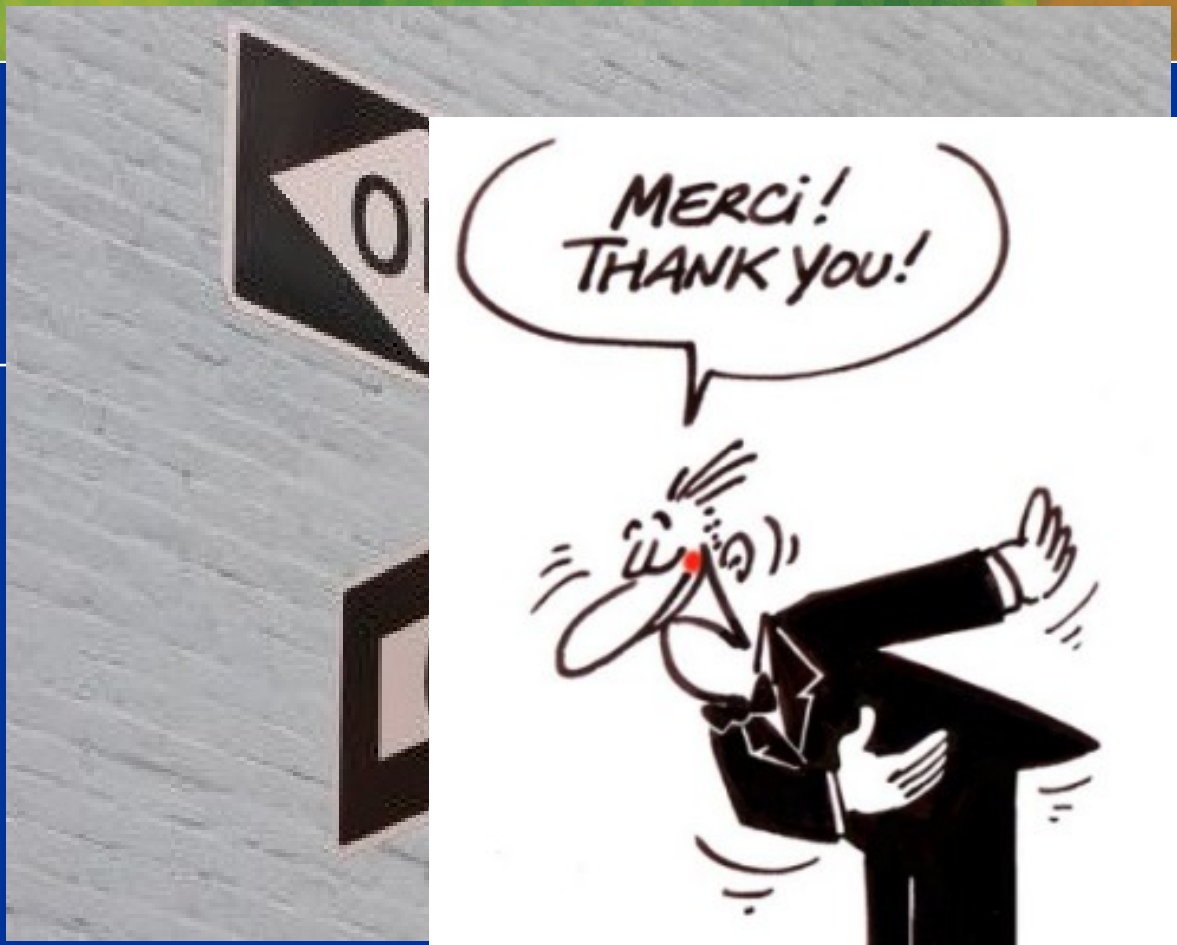
PDCO can offer ‘services’ to the system/networks

1/advice on methodology, formulations… guiding research and facilitating development with the view to register a paediatric drug…but

2/needs to receive input from all stakeholders to fit with relevance and reality


ONE
ONE WAY


ONE
ONE
WAY



MERCI!
THANK YOU!
FRAPAR.