



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# PDCO perspectives & proposals

## Enpr-EMA coordinating group

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A. Siapkara, C. Male

29 – May - 2015



An agency of the European Union





# New PDCO representatives are happy to join

## **Angeliki Siapkara**

Paediatric orthopaedic surgeon, MSc in International Child Health

Paediatric unit manager at MRHA, UK PDCO delegate, CMDh/EMA Paediatric WP

Motivation: only collaboration of all stakeholders will achieve the aim of more licensed paediatric drugs; Enpr-EMA offers optimal platform

## **Christoph Male**

Paediatric cardiologist, academic clinical investigator (Medical University of Vienna)

Steering committee, Austrian Medicines for Children Research Network (OKIDS)

Austrian alternate PDCO delegate

Motivation: to bring investigators' perspectives into PDCO discussions



## PDCO needs for input from Enpr-EMA

- Paediatric therapeutic needs – prioritization of developments
- Methodological expertise
  - Target populations
  - Study designs
  - Outcome parameters
  - Extrapolation
  - etc.
- Standard-of-care
- Numbers of patients
- Relevance of PIPs for practice – acceptability >> feasibility
- Proactive involvement of disease-specific networks in strategic planning for respective therapeutic areas



## Need for a neutral platform for communication between

- **Sponsors** – who know most about their medicinal product
- **Academic clinical investigators** – who know most about the clinical setting and patients
- **Patient/parent groups** as possible – to express their needs
- **PDCO/EMA** – responsible for regulating the process, i.e. achieve optimal output within legal framework
  - For optimal *a priori* planning of PIPs according to best knowledge & consensus
  - Adaptation of PIPs and general strategies according to evolving data
  - To resolve unanticipated problems in PIPs
  - To prevent companies playing games



## Ways of interaction

- Involvement of Enpr-EMA/disease-specific networks in specific PIP discussions at PDCO
- Regular generic discussions of specific therapeutic areas at virtual PDCO meetings (ORGAM), involving networks and several companies (with products of interest)
- Workshops on specific therapeutic areas involving all stakeholders, hosted by Enpr-EMA, taking place e.g. at scientific conferences
- Etc.



## Issues to be resolved

- Declaration of interest
- Confidentiality agreements, contracts
- Logistics ('rooms & sandwiches')
- Technicalities (e.g. virtual meetings)
- Funding