



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# 10 Year Report to the European Commission on the public health effects of the Paediatric Regulation: request for data collection from the Enpr-EMA networks

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An agency of the European Union





# Regulatory background

- **Art. 50** of Reg. (EC) No 1901/2006
  - By Jan 2017 the Commission shall present a report to the Parliament on the experience from Articles 36, 37 and 38 (rewards and incentives)
- **Measuring the 10 year impact** on paediatric research, availability of authorised medicines and better information on medicines
- Based on data collected from EMA and MS
- Report to EC on the **public health effects** of the Paediatric Regulation



# Project overview



## ➤ Report key messages :

- High quality research
- Availability of medicines for children
- Informing on paediatric use of medicines



# Identification of Performance Indicators (PIs)

- By PIs Working Group (EMA-PDCO): to establish a list of PIs to measure outcomes of the work done by PDCO in achieving objectives of the Regulation (EC) 1901/2006
- Comprehensive list of PIs (n=51)
- As part of this comprehensive list, identification of 2 PIs related to Enpr-EMA networks:
  - **Indicator 1:** Number of contacts each network has had with industry re PIP trials only
  - **Indicator 2:** Input from the Network on paediatric treatment/care guidelines
- Preparation of **questionnaires for data collection** by the Enpr-EMA networks on these 2 PIs. Questionnaires have been updated further to Enpr-EMA chair review.



# Indicator 1: Number of contacts each network has had with industry re PIP trials only

PIP AND CLINICAL TRIAL RELATED INFORMATION					ORIGIN OF REQUEST	TYPE OF INVOLVEMENT OF THE NETWORK				CHILDREN, PARENTS OR FAMILIES INVOLVEMENT
Year <small>(start of the trial: must be between 2007-2016)</small>	Trial title	EudraCT number	PIP number (if known)	Name of trial sponsor (i.e. name of pharmaceutical company/SME)	Request for Network involvement coming from Industry directly or via the Enpr-EMA secretariat  Please specify	Advice given by Network to industry re PIP design (e.g. definition of therapeutic needs, standard of care)  Please specify	Advice given by the Network to industry re PIP implementation (e.g. feasibility of requested trials)  Please specify	Advice given by Network to industry re trial protocol design of a PIP (e.g. acceptability of clinical endpoints)  Please specify	Active participation of Network in conduct of clinical trial through enrolment of patients  Please specify	Involvement of children, parents or families in the trial design, development of informed consent forms, or other?  Please specify



## Indicator 2: Input from the Network on paediatric treatment/care guidelines

	Impact on paediatric treatment / care guidelines				
When did this occur? Year	Title of paediatric clinical treatment / care guideline	This guideline was newly-created?	This guideline makes reference to a study(ies) that are ongoing in the context of a PIP?	This guideline makes reference to results / data from a completed study(ies) that is a PIP?	In case the guideline made reference to results / data from a completed study(ies) that is a PIP:  Which level of evidence was assigned to the results / data?



# Additional free text question – not part of 10 Y Report

	CONDUCT OF PAEDIATRIC CLINICAL TRIALS BY NETWORKS				
	Funding	Support	Access to clinical expertise	Access to information from the Regulatory Setting	Any other aspects you wish to report; please specify
It works well Please specify					
It can be improved Please specify					

This info is not directly relevant for the 10 year report but the questions have been designed with a benefit for the networks:

- It could help them to document their achievements / performance
- It could help them to analyse lessons learnt and make concrete proposals not only on how to potentially improve the Paediatric Regulation but also to improve their performance, structure and organisation



# Timelines

- Post Enpr-EMA members meeting: spreadsheets to be sent out to all Networks
- By **mid November 2015**: Networks to complete spreadsheets for the 2 defined PIs, for the period 2007 to 2015
- EMA to analyse data provided and draft 10 year qualitative report to EC by April 2016
- By **mid November 2016**: Networks to complete same spreadsheets for the 2 defined PIs, for the year 2016
- EMA to analyse data provided for year 2016 and draft update to 10 year qualitative report to EC, by April 2017





**Many thanks in advance for your  
contribution to this project !**