



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Early paediatric interaction meeting

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Initial consultation on paediatric development



Presented by Early paediatric interaction meeting team on 11 May 2015  
Paediatric Medicines

An agency of the European Union





# Early interaction meeting – Background

## In some PIPs

- Paediatric needs not considered appropriately for certain conditions
- No sufficient link between paediatric studies and adult development
- Extrapolation could have been proposed
- Improbable waiver requests
- PIP application problems → Complex Request for Modification

## Consequences

- Negative Opinions or long clock stops → delay in getting medicines to children
- Waste of Industry resources



# Early interaction meeting – Why?

- Foster efficient development of safe and efficacious medicines for children
- Facilitate and encourage early dialogue and constructive discussion with PDCO/EMA
- Assist applicants early and favour streamlined, integrated adult/paediatric development
- Provide recommendations for drug development that address paediatric needs
- Improve the quality of some PIP applications
- Decrease PIP withdrawals



# Early interaction meeting – What is it?

- It takes place in the early phase of drug development
- It focuses on overall development strategies
- To discuss potential paediatric needs and scope of development for paediatrics
- Not intended for evaluation of data to support PIP application



# Early interaction meeting – Format

- Pilot phase for 6-12 months
- Conducted preferably as a video conference
- It lasts up to 1 hour



# Early interaction meeting – organisation

- Applicant submits request ~1-2 months and briefing documents ~1-2 weeks before video conference
- PDCO and EMA representatives nominated
- Video conference / meeting takes place
- Applicant provides minutes (within 2 weeks of meeting)
- Minutes to include main outcomes of the discussion



# Early interaction meeting – Considerations

- Records will be kept and considered at the time of PIP application
- PIP application expected according to outcome of meeting, and consistent with legal requirements
- In exceptional cases justification for later application may be agreed and will be evaluated at the time of PIP submission



## Early interaction meeting – Benefits

- It takes place at an early stage of product development
  - ✓ Early planning
  - ✓ Optimise resources
- Possibility to discuss global approach to paediatric development and timelines
  - ✓ Integrate with adult development
  - ✓ Avoid unnecessary studies in children
  - ✓ Early discussion on possible extrapolation
  - ✓ Early discussion on appropriateness of waiver
  - ✓ PIPs more likely to meet children's needs and PDCO requirements



# Thank you for your attention

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# Back-up slides





# Difference between early interaction and pre-submission meetings

## Pre-submission

- It takes place shortly before submission of PIP application
- Intended to ensure a smooth validation
- Pre-assessment of the scientific documents is not the aim of this meeting

## Early interaction

- It takes place at an early stage of product development
- To discuss global approach to paediatric development and timelines
- To discuss scientific issues related to paediatric development