



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Early dialogue for paediatric development plans

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Review of the pilot phase

1<sup>st</sup> industry stakeholder platform on research and development support  
(EMA, London)

Presented by Gunter Egger on 25 April 2017  
Scientific officer / Paediatric medicines





## Early paediatric interaction meeting (EPIM)

- Based on wish by industry for early dialogue with the Paediatric Committee (PDCO)
- Pilot initiated in June 2015 to explore concept
- Takes place at early phase of drug development
- Focuses on overall development strategies
- To discuss potential paediatric needs and scope of development for paediatrics
- Not intended for evaluation of data to support a PIP application



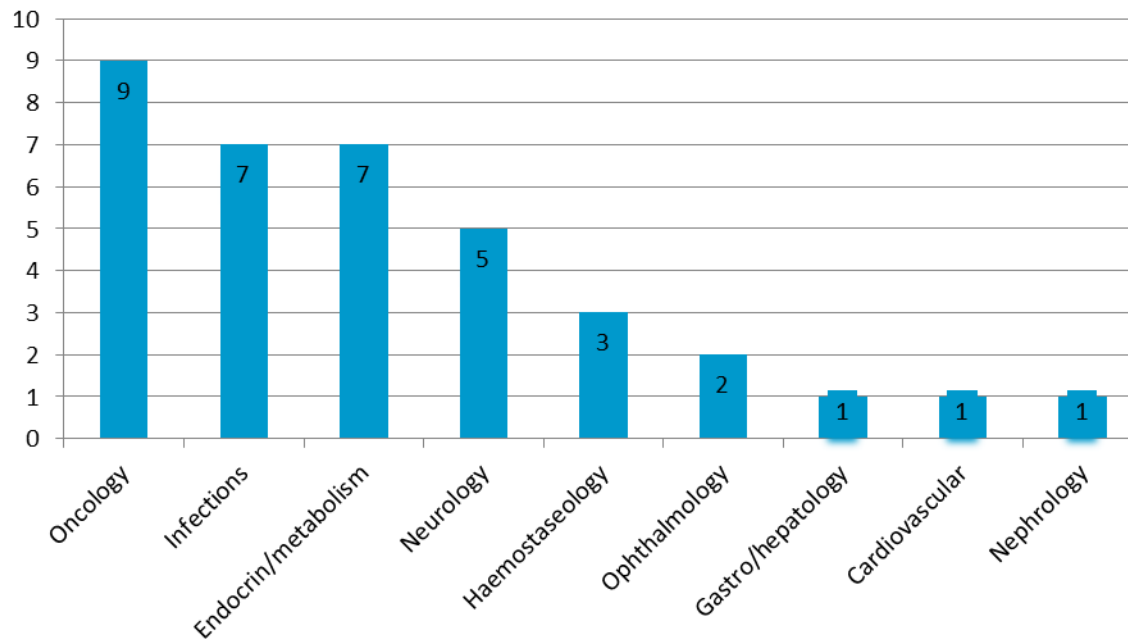
## Early interaction – Intended benefits

- Early contact with the PDCO
  - Early planning
  - To optimise resources
  - Helpful to applicants and beneficial to later PIP process
- To discuss approach to paediatric development and timelines
  - Integration with adult development
  - Avoiding unnecessary studies in children
  - Possible extrapolation
  - Appropriateness of waiver
  - PIPs more likely to meet PDCO requirements and children's needs



# Applications for early interaction by therapeutic area

June 2015 – March 2017 (pilot phase)



total: 36



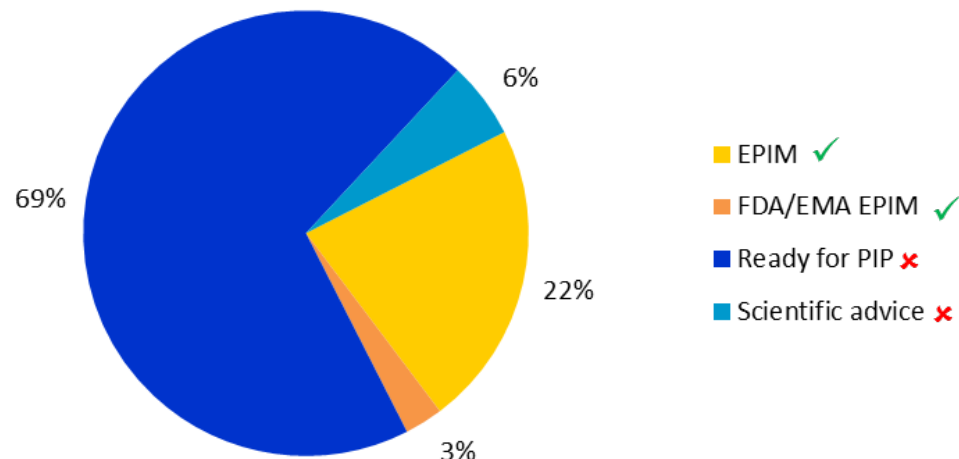
# Applications received/accepted for early interaction

Total number received <sup>1</sup>	36
Ready for PIP <sup>2</sup> ✗	25
For Scientific advice (SA) ✗	2
Early interaction (EPIM) <sup>3</sup> ✓	8
Early interaction (EPIM) <sup>3</sup> EMA/FDA ✓	1

<sup>1</sup> 5 (14%) from SMEs (1 for SA, 4 ready for PIP)

<sup>2</sup> 9 have now submitted a PIP

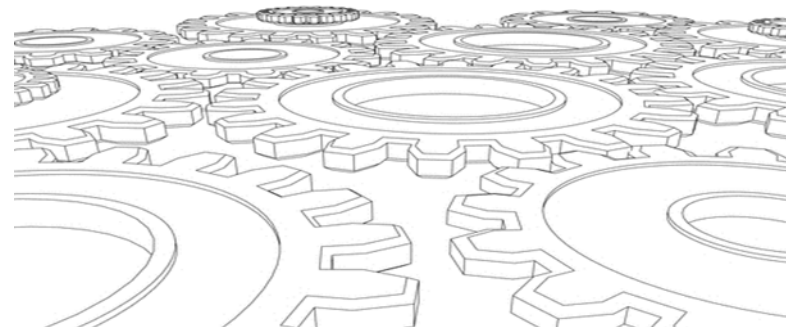
<sup>3</sup> EPIM = Early Paediatric Interaction Meeting





## What the data tell us

- Most applications submitted at legal PIP submission stage (69%)
- Specific questions asked which are usually addressed during PIP review process or SA (e.g. primary EP ok?, sample size ok?)





## Examples of topics discussed at early interaction meetings

- Condition/indication/scope of PIP
- Paediatric age-groups/waiver
- Approach to modelling/simulation & extrapolation
- Type of clinical studies



## Feedback from applicants\*

	<b>Very much</b>	<b>Somewhat</b>	<b>Not so much</b>	<b>Not at all</b>
Overall satisfaction	xxx	xxx		
Better integration of paediatrics likely	xx	xxx	x	
Improved PIP procedure likely	xxx	x	xx	
Scope of EPIM clear	xxxxx	x		
Scope of PSM clear	xxxxxxx			

*\*Feedback was only sought from applicants who had taken part in an early interaction meeting (total feedback received: n=6)*



## Feedback from applicants

### Pros:

- Overall experience positive and deemed useful
- Good to get early interaction, preliminary view of PDCO
- Good to discuss PIP condition
- Good to also get input from beyond PDCO (e.g. members of CHMP, PDCO-working groups, SA, EMA staff)

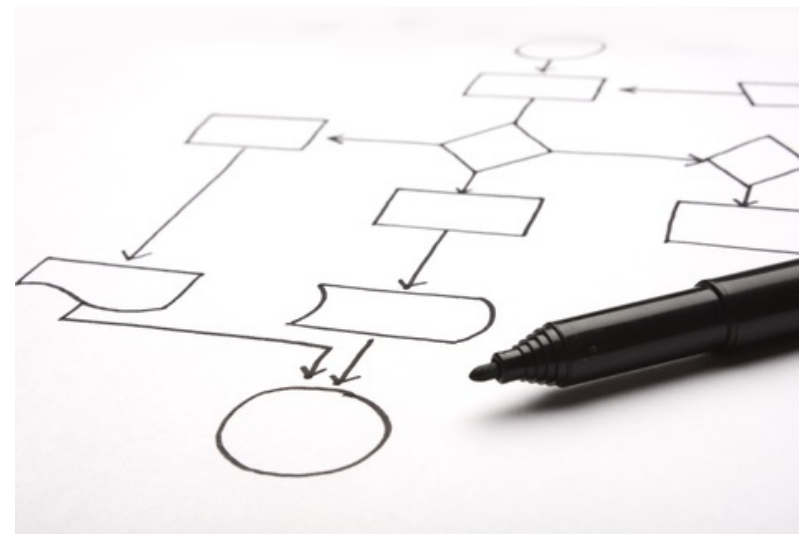
### Cons:

- Some important decision making deferred to PIP and SA procedures
- Questionable if it enables better PIP procedures
- Communication regarding timelines should be clearer



## Summary observations from the pilot phase

- Very limited number of requests were in scope.
- Feedback from applicants was generally positive if interaction occurred.
- Need for early interactions remains but scope and operations need to be fine-tuned to meet expectations of all parties.





# Thank you for your attention

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