



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PDCO perspectives & proposals

Enpr-EMA coordinating group

Angeliki Siapkara, Marek Migdat

June 2018



An agency of the European Union





PDCO needs for input from Enpr-EMA / networks

GENERAL ISSUES

- Changing/emerging paediatric therapeutic needs
- Positioning among several ongoing/upcoming developments
 - Prioritisation
 - Strategic planning for similar drugs to address different indications
- Methodological expertise
 - Study designs, outcome parameters, novel approaches, scientific basis of extrapolation.
- National restrictions/requirements : CTAs / ETs
- Feasibility (in the context of above)
- Input on Regulatory Guidelines

Meaningful PIPs → relevance + acceptability

Examples of interaction

- Rheumatology : Old vs. new -> networks input needed?
 - change of SoC since many biols now approved in children.
 - New emerging class(es) (for example JAKs)
 - Still withdrawal trial design – is use of placebo possible?
 - extrapolation could be an option but when ?

- PDCO appreciates dialogue with networks (currently one network at PDCO every other month)

Ways of interaction

- **Increase network capacities : invite regulators for training with the aim of better understanding of licensing requirements.**
- **Streamline PDCO feedback for specific products within strict PIP timelines**
 - consolidated “independent” network feedback within timely manner
 - If network identifies serious issues with a PIP trial -> encourage sponsor/PIP applicant to feedback to PDCO promptly, including network perspective on solutions.
- **More information and transparency on Networks’ conflict of interests.**



Ways of interaction

- **International research collaborative approach.**
 - Strategic collaboration of PDCO with on going network initiatives
 - Networks working collaboratively with other networks: e.g. infectious disease network PENTAI with existing neonatology networks for antibiotic studies in neonates
- **Therapeutic areas where Enpr-EMA networks are still missing (for example CV)**