



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PDCO perspectives & proposals

Enpr-EMA coordinating group

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PDCO needs for input from Enpr-EMA/networks

- Paediatric therapeutic needs
 - Urgency of need
 - Indications, age groups → target populations
 - Waivers
- Standard-of-care
- Extrapolation
- Methodological expertise
 - Study designs, outcome parameters, etc.
- Meaningful PIPs relevant for practice → acceptability
- Numbers of patients available
- Feasibility (in the context of above)

- Positioning among several ongoing/upcoming developments
 - Prioritisation
 - Strategic planning for different drugs to address different indications



Ways of interaction

PIP-specific

- Pre-submission meetings with applicant and disease network
- Involvement by PDCO of networks/experts in initial PIP discussions (within day 60)
 - Creation of PDCO contact points within networks to facilitate experts' identification and participation due to strict timelines
- Continuous involvement of networks/experts during PIP life-cycle for necessary modifications
- Early interactions! -- a priori PIP optimisation vs post-hoc PIP rescue



Ways of interaction

Generic issues

- Collaboration in development/update of paediatric inventory of therapeutic needs
- Assistance in PDCO guideline development
- Regular generic discussions on specific therapeutic areas at PDCO meetings (plenary, ORGAM), involving networks, potentially companies (with products of interest)
- Multi-stakeholder workshops on specific therapeutic areas
- Multi-stakeholder platforms



- Feed-back on PDCO proposals
- Please provide networks needs & proposals