

*Introduction to the work of the
PDCO Formulation Working Group:*

*Essentials on the **paediatric needs** with
regard to formulations;
assessing **part D.II** of paediatric
investigation plans;
challenges and difficulties*



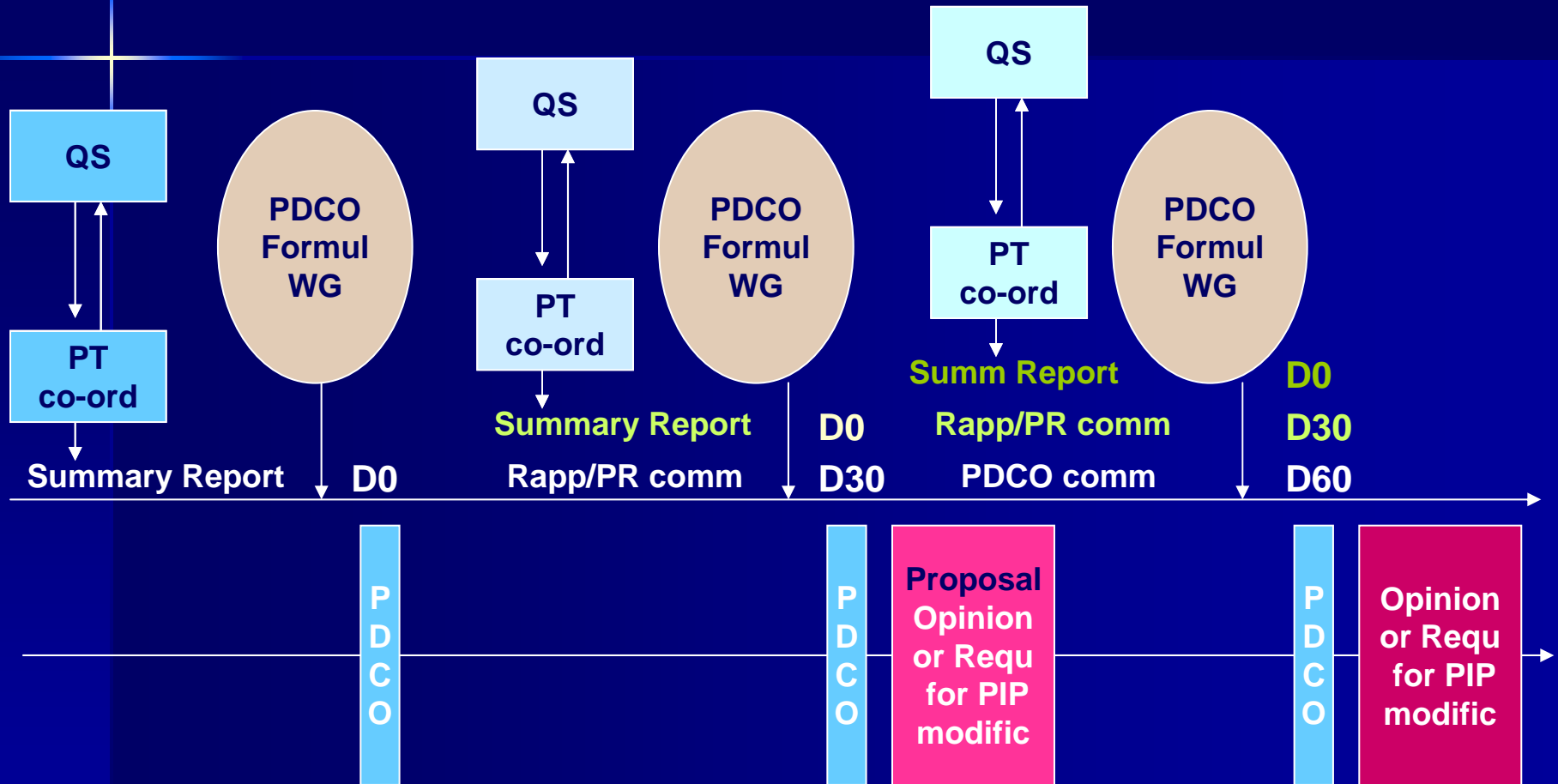
Siri Wang, PDCO FWG chair
Workshop on Paediatric Formulations
31 May 2010, London

PDCO Formulation Working Group (FWG)

- Members / participants
 - PDCO (incl repr)
 - EMA QS
 - QWP
 - External experts (clinical / EuPFI)
 - FDA
- Monthly meetings (Vitero)
- Aim: Facilitate scientifically sound and consistent PDCO positions on formulation issues in PIPs

Assessing formulation issues in PIPs

PDCO process



PIPs nominated by, co-ord, rapp/peer, FWG members

Essentials on the paediatric needs re formulations

- Age appropriateness
 - A formulation the child is able to take
 - Size, taste, volume, ease of administration, dosing regimen, treatment setting
 - With sufficient dosing accuracy
 - Strength, device,
 - Appropriate safety
 - Excipients, device, handling,
- Dose criticality, treatment duration, setting

Part D.II of paediatric investigation plans;

Background info

- Composition (qualitative & quantitative)
- Appearance, taste, size
- Practical handling for administration of the intended dose
- Mixing with food
- Dosing accuracy vs criticality of the dose
- Device – medical device and dosing device

Part D.II of paediatric investigation plans;
Formulation strategy

- Justify strategy
- Justify 'unfeasibility'
- Discuss options
- Discuss and justify 'excipients' in relation to age, treatment duration, severity of disease



Essentials on the paediatric needs re formulations

Challenges during PIP process (1)

■ Early PIPs

- Formulations not fixed
- No experience with formulations
- Plans vague...
- Intentions good...
- PDCO 'follow up'?

■ Late PIPs

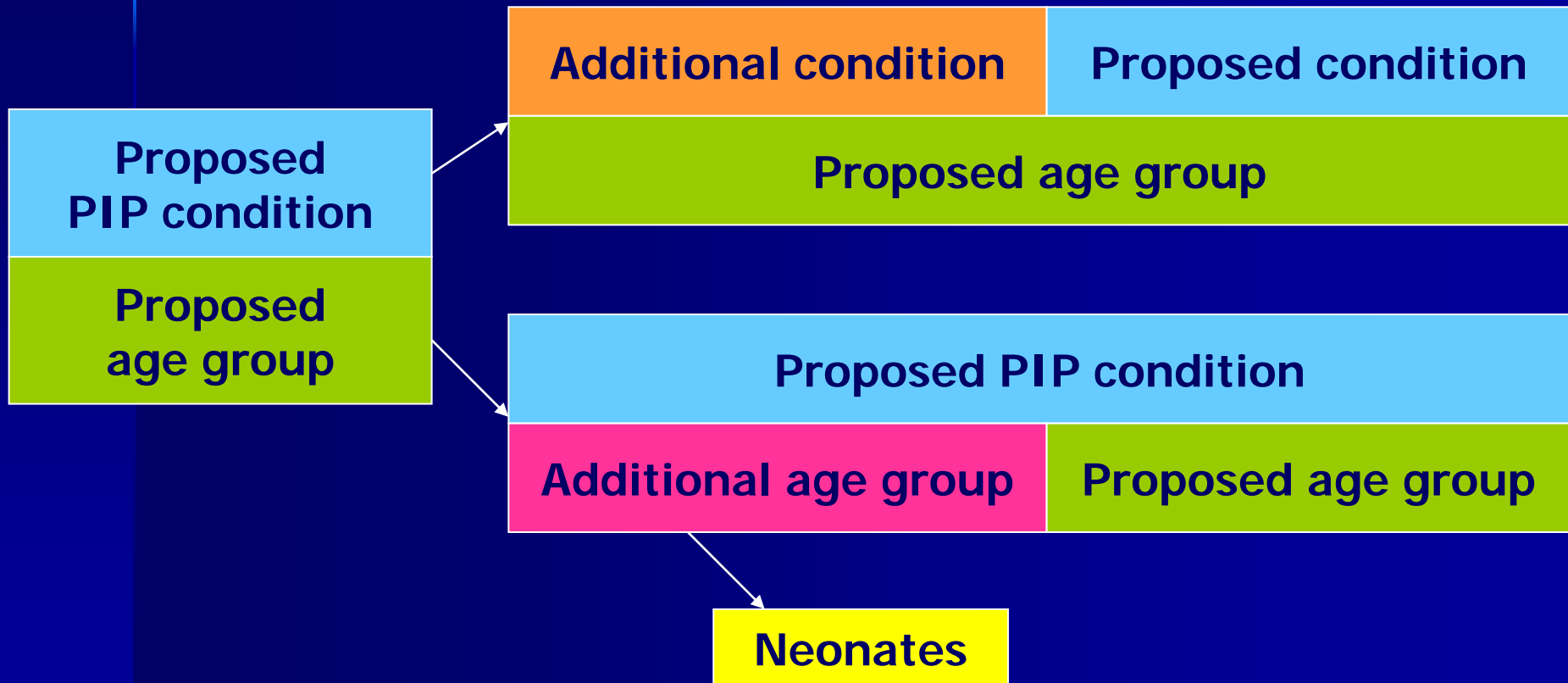
- Formulations often +/- fixed
- Substance well known (company)
- Reluctancy re further formulation development

Essentials on the paediatric needs re formulations Challenges during PIP process (2)

- **Art 8 PIPs** (authorised products)
 - Existing formulations well known
 - Unmet medical need in children known
 - Significant experience on off label use in children
 - Reluctancy re further formulation development

Essentials on the paediatric needs re formulations

Challenges during PIP process (3)



Essentials on the paediatric needs re formulations

Challenges due to **missing data**

- Safety of excipients in the paediatric population??
- Acceptability of different dosage forms in the paediatric population??



Essentials on the paediatric needs re formulations

Challenges due to **missing data**

- Safety of excipients in the paediatric population??
- Acceptability of different dosage forms in the paediatric population??



Essentials on the paediatric needs re formulations

Conclusion

- Focus on the need for **appropriate formulation** for all relevant age groups
- **Reasonable** requests
- **Product specific** decisions
- **Consistent** approach