CTA/ILF/CIPHER Thematic Roundtable on Paediatric ARVs:

Fast tracking development of priority formulations

The Royal Hotel, Prince Alfred Suites

267 Anton Lembede Street, Durban, South Africa

Saturday, 16 July 2016, 18:00 – 22:00

Roundtable discussion I:
Fast tracking the approval of new drugs

- SRAs emphasize that early consultations with research networks would be important. How do we ensure industry receives feedback from groups like PADO or PAWG that is consistent and swift?

- How can regulators and companies work together to develop, review, and approve PIP/PSP in a more flexible and rapid way (e.g., how can PADO recommended TPP characteristics be useful)?

- Can ongoing review of regulatory frameworks include innovative elements that support faster product development for paediatrics? And promote a focused development of what is needed?

- How to better coordinate and share information with ERBs to enroll adolescents in studies?

- How to ensure in-country registration and harmonization of country regulators with global paediatric regulators?

Roundtable discussion II:
Fast tracking the development of priority formulations

- Avoid duplication by strengthening existing efforts like PHTI, and encouraging research networks to collaborate on study design and implementation

- Are PADO recommendations taken seriously? Do they need any more formal endorsement?

- Can SRAs strategically use deferrals of paediatric plans or waivers to advance PADO priorities? Could they waive application registration fees for those aligned with PADO priorities?

- Early exchange with regulators on how to properly design bioequivalence protocols and speed up studies

- Sharing of study information and technology transfers as a way to accelerate formulation development

Roundtable discussion III:
Funding a global accelerator for paediatric formulations

- How sustainable do we need this funding to be? Especially considering we may favour using this mechanism to fund formulations for other paediatric diseases?

- What type of monetary (or mix of monetary and non-monetary) incentives may be most attractive, effective and sustainable? What are the pros and cons of grants vs prizes (milestones vs endpoints), etc.?

- What would a fund need to cover (what percentage of development funding and/or de-risking, what regulatory costs)?

- What are the most promising sources of funding? Could a mix work?

  Philanthropies; Matching or challenge funds; Generics – royalties for beneficiaries of fund who bring a product to market; Originators – voluntary deals where any royalties from other products used primarily for paediatrics or in LMICs go to the fund, etc.

- How would the costs and benefits be shared among multiple companies?

- Where could such a fund be housed?