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## **ILF/CIPHER Thematic Roundtable on Paediatric ARVs: Stimulating development of the most needed formulations**

Monday, 7 March 2016, 13:00 – 16:30 CET  
Room St. Moritz, Starling Hotel, Geneva, Switzerland

### **CONCEPT**

The IAS's Industry Liaison Forum (ILF) and Collaborative Initiative for Paediatric HIV Education and Research (CIPHER, the IAS Paediatric HIV Programme), in collaboration with the Paediatric ARV Drug Optimization (PADO) group, are pleased to invite you to attend the next thematic roundtable on paediatric ARVs which will discuss approaches to stimulate development of the most needed paediatric ARV formulations.

The global community has identified priorities for future R&D for paediatric ARV formulations through the Paediatric ARV Drug Optimization (PADO) meetings; however, there are many challenges to making these formulations available. Although coordinated procurement efforts have been successful in reducing market fragmentation, the paediatric market is small compared with adults, and manufacturers do not have incentives to develop these priority paediatric formulations. Existing regulatory frameworks promote development of paediatric formulations, but implementation of those frameworks may have resulted in inefficient allocation of resources for paediatric R&D. In addition, the success in preventing mother-to-child transmission has reduced the number of new HIV infections, making it increasingly challenging to conduct robust clinical trial to assess efficacy, safety and acceptability of new paediatric drugs and fixed dose combinations across the age spectrum.

For these reasons, alternative financing mechanisms which build upon existing regulatory processes, optimize the investment in paediatric ARVs, and enable a more sustainable development of prioritized products need to be explored to ensure availability of the best treatment for infants and children living with HIV in the future. This requires promoting an open dialogue between manufacturers and key stakeholders such as policy makers, research networks and regulatory agencies.

The main objectives for this discussion are therefore to:

- Inform attendees from different backgrounds about the gaps between available and most needed paediatric ARV formulations
- Share information on some existing innovative funding mechanisms and partnerships to support collaborative research and development between the public and private sectors
- Brainstorm on pragmatic approaches to address challenges for the rapid development of the most needed paediatric ARV formulations.

Thank you for your interest.

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### **About the ILF/CIPHER thematic roundtable series on paediatric ARVs**

Since 2013, the ILF and CIPHER have catalysed multi-stakeholder dialogues to raise awareness of and brainstorm on approaches to address some of the key challenges around paediatric ARVs. This aligns with the mission of the IAS to lead collective action on every front of the global HIV response through its membership base, scientific authority, and convening power. Past ILF/CIPHER publications on paediatric ARVs are listed below:

- [Paediatric ARVs: Giving industry a seat at the table](#) (blog post published on 2015-11)
- [ILF/CIPHER Thematic Roundtable on Paediatric ARVs: Aligning, coordinating and accelerating actions to provide better ARVs for children](#) (meeting held on 2015-03)
- [ILF/CIPHER Thematic Roundtable on Paediatric HIV: Removing barriers and seizing opportunities in paediatric HIV](#) (meeting held on 2014-07)
- [ILF Industry Roundtable on Paediatric ARVs](#) (meeting held on 2013-11).

### **About the Collaborative Initiative for Paediatric HIV Education and Research**

[CIPHER](#) is aimed at optimizing clinical management and delivery of services to infants, children and adolescents affected by HIV in resource-limited settings through advocacy and research promotion. The content and structure of CIPHER is guided by paediatric experts in paediatric HIV convened by the IAS.

*CIPHER is supported by founding sponsor ViiV Healthcare and Janssen.*

### **About the Industry Liaison Forum**

The [ILF](#) highlights the perspective of the HIV biomedical industry and catalyses multi-stakeholder dialogue and engagement as well as reflections and actions to address barriers along the HIV – prevention, diagnostics and treatment – cascade. Challenges around cross-cutting issues affecting industry's contribution to the HIV response are also of central importance. The ILF performs this role by bringing together stakeholders (e.g., through roundtable discussions) and by highlighting key data and points of view (e.g., with publications). The work of the ILF is guided by a strong, multi-stakeholder advisory group, which is composed of industry and non-industry representatives.

*The ILF is grateful for the unrestricted support received from its Gold Partners (Gilead Sciences, MSD and ViiV Healthcare), its Silver Partners (AbbVie, Alere and Janssen) and its Bronze Partners (Abbott, bioLytical Laboratories, Cepheid, Cipla, Female Health Company, Omega Diagnostics, Roche Molecular Systems and Sysmex Corporation). This discussion is sponsored by ILF Gold and Silver Partners.*

### **About the Paediatric ARV Drug Optimization Group**

The Paediatric ARV drug optimization group is convened and lead by the HIV Department at the World Health Organisation and puts together a number of key stakeholders who are committed to advance the drug optimisation agenda and ensure access to paediatric ARVs in the optimal formulations. The group advises the WHO in how to optimise sequencing and preferred regimens, and most importantly identifies priority products to be rapidly developed to ensure children have access to the most optimal formulations suitable for where the highest burden of the diseases is. Meeting reports for PADO 1 (2013) and PADO 2 (2014) are available on the WHO website ([PADO 1](#), [PADO 2](#)).