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
ILF/CIPHER thematic roundtable series on paediatric ARVs

Since 2013, the IAS’s 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.

November 2013, Geneva

July 2014, Melbourne

March 2015, Geneva

October 2015, Webinar

November 2015, Blog

March 2016, Geneva
ILF/CIPHER thematic roundtable series on paediatric ARVs

Challenges making the most needed paediatric ARVs available

• Technical difficulties developing child-friendly formulations and performing paediatric clinical trials

• Differing definitions and product specifications

• Need for reliable market forecasts

• Difficulty including industry in the development of normative guidance

• Lack of awareness of paediatric initiatives
Today’s conversation

**Brainstorm on a pragmatic and innovative approach to fast track development of the most needed paediatric ARV formulations**
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<tr>
<th>Time</th>
<th>Session Description</th>
<th>Facilitator/Presenter</th>
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<tr>
<td>18:30 – 18:35</td>
<td>Welcome</td>
<td>Sébastien Morin (IAS)</td>
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<td>18:35 – 18:50</td>
<td>Opening remarks</td>
<td>Gottfried Hirnschall (WHO) &amp; Linda-Gail Bekker (IAS)</td>
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<td>18:50 – 19:30</td>
<td>Framing the rationale for a new mechanism to fast track development of the most needed paediatric ARVs formulations</td>
<td>Martina Penazzato (WHO)</td>
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<td>19:30 – 20:00</td>
<td>Roundtable discussion I: Fast tracking the approval of new drugs</td>
<td>Linda Lewis (CHAI)</td>
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<td>20:00 – 21:00</td>
<td>Roundtable discussion II: Fast tracking the development of priority formulations</td>
<td>George Siberry (PEPFAR)</td>
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<td>21:00 – 21:45</td>
<td>Roundtable discussion III: Funding a global accelerator for paediatric formulations</td>
<td>Jennifer Cohn (EGPAF)</td>
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<td>21:45 – 22:00</td>
<td>Summary and closing comments</td>
<td>Greg Perry (MPP) &amp; Marissa Vicari (IAS)</td>
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Meeting participants

A diverse group representing:

- Industry
- Regulators
- Research networks
- NGOs
- UN agencies
- Philanthropies
- Donors
- Other key stakeholders involved in paediatric ARVs
A safe space for discussion

- Active participation
- Constructive feedback
- Collaborative approach
Housekeeping announcements

- Introduce yourself (name, affiliation) before speaking
- Speak through the microphone
- WebEx
  - Mute your microphone when not speaking
  - Use the “raise hand” icon in the participant panel to request permission to speak; we will call you when it is your turn
  - Alternatively, use the “chat” to send any questions or comments
  - Switch off your camera
- Please note that the meeting is recorded for reporting purposes only (no recording will be shared)
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Opening remarks

Gottfried Hirnschall
Director, HIV/AIDS Department
WHO

Linda-Gail Bekker
President-Elect
IAS