Outcomes of the Paediatric ARV Drug Optimization 4 (PADO 4) and Paediatric Hepatitis C Drug Optimization meetings

Webinar

19 December 2018, 14:00-15:00 CET
The GAP-f formalizes collaboration across sectors to ensure accelerated development and uptake of the most needed drugs and formulations for children.
GLOBAL ACCELERATOR FOR PAEDIATRIC FORMULATIONS – GAP-f

Accelerating the delivery of better paediatric products to reduce child mortality

Opportunities well-vetted against clinical knowledge and treatment impact
- Creates a high-value portfolio of better and pediatric-friendly products

Opportunities integrated into a prioritized, broadly-endorsed product portfolio
- Aligns with partners, collaborators, donors, and people living with HIV

Coordinated with innovators and regulators
- Eliminates substantial delays

Optimized work streams
- Reduces the time and cost to delivery

Work streams coordinated in timing and funding
- Fills gaps and delivers better treatment regimens much sooner

Proactive
- Focused
- Purposeful
- Efficient
- Coordinated
- Accountable
Key publications available at www.gap-f.org

Articles in The Lancet HIV and JIAS

Supplements in JAIDS and JIAS
GLOBAL ACCELERATOR FOR PAEDIATRIC FORMULATIONS – GAP-f

AIDS 2018 satellite on “Accelerating the development and uptake of the most needed drug formulations for children”

See slide sets and watch the recording at http://programme.aids2018.org/Programme/Session/1484
GAP-f is accelerating existing work:

2018 Optimal Formulary and Limited-Use List for Paediatric ARVs

Read the policy brief here
GAP-f is accelerating existing work:

Transitioning to an optimal paediatric ARV formulary: implementation considerations

Read the policy brief here
GAP-f is already delivering:

**Draft FDA guidance for industry on pediatric HIV infection: Drug development for treatment**

See the draft guidance [here](#)
GAP-f is already delivering:

**Toolkit for research and development of paediatric antiretroviral drugs and formulations**

Access the toolkit [here](#)

Access an online version with slide sets [here](#)
GAP-f partners are also contributing:

**ILF policy brief**

**Advance procurement: A pragmatic approach to incentivize the development of priority paediatric ARV formulations**

By 2017, 80% of pregnant women living with HIV were receiving antiretroviral therapy (ART) to prevent the transmission of the virus to their children, overtaking 1.1 million new infections since 2010 [1]. In spite of this, there are still an estimated 1.8 million children (age 0-14 years) living with HIV worldwide, and only 52% of them are receiving ART [2]. Without treatment, 50% of these born with the virus will die before their second birthday [3].

The UNAIDS 90-90-90 and Start Free, Stay Free, AIDS Free Framework for Ending AIDS Among Children, Adolescents and Young Women targets will not be met unless efforts to increase children’s access to lifesaving treatment are intensified [4,5]. Effectively increasing treatment coverage for children presents a number of significant challenges. In particular, the development of oral ART formulations adapted to the specific needs of children lag far behind that for adults by 8 to 10 years. Consequently, of those children who are on treatment, many are receiving suboptimal and age-inappropriate drug formulations, leading to high rates of virological failure and HIV drug resistance in these children [6]. New and better-formulated paediatric treatment options are therefore urgently needed.

The many challenges of developing drugs appropriately formulated for children are compounded by a series of market factors that make these efforts costly and complex, discouraging drug manufacturers – especially generic drug manufacturers – from prioritizing investments in new paediatric treatment options. This brief explores the concept of advance procurement as a method for reducing uncertainty within the paediatric ART market and spurring investment in adapted child-friendly drug formulations.

Large antiretroviral (ARV) buyers – most notably national governments (particularly the Government of South Africa), the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) – are uniquely positioned to assert tremendous influence on the global paediatric HIV treatment market. In light of the slow progress in developing and increasing access to new and better-formulated drugs for children, there is significant potential for these actors to reduce market uncertainty and catalyse investment in research and development (R&D) through advance purchase commitments of priority paediatric ARVs. Used in conjunction with other market-shaping approaches (such as those implemented by other stakeholders like Unitaid), and together with other proven methods for reducing the cost of development and increasing access to essential medicines, advance procurement has the potential to help close the persistent gap between adult and paediatric treatment coverage.
### Today’s agenda

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<th>Time</th>
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<td>14:00 CET</td>
<td>Welcome and introduction</td>
<td>Sébastien Morin (IAS, Switzerland)</td>
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<td>14:05 CET</td>
<td>HIV – Paediatric ARV Drug Optimization 4 (PADO 4)</td>
<td>Martina Penazzato (WHO, Switzerland)</td>
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<td>14:30 CET</td>
<td>HCV – Paediatric Hepatitis C Drug Optimization</td>
<td>Philippa Easterbrook (WHO, Switzerland)</td>
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<td>14:45 CET</td>
<td>Q&amp;A</td>
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<td>14:55 CET</td>
<td>Closing remarks</td>
<td>Sébastien Morin (IAS, Switzerland)</td>
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Key considerations: Compliance with competition rules

What to avoid

• **Do not** discuss with other participants competitively sensitive information on anything relating to topics such as prices, discounts, margins, price-related contractual terms or territorial protection.
• **Do not** exchange information on costs, capacity, business plans or commercial strategy. The only exception is for industry data that are publicly available via data services, such as interest rates.
• **Do not** exchange individualized information on output plans.
• **Do not** engage in conduct that could have the effect of restricting competition by excluding actual or potential competitors from the market or preventing them from competing effectively.
• **Do not** discuss matters relating to your company’s marketing plans, design, production or distribution.
• **Do not** share with other participants any other competitively sensitive or confidential information.

What to do

• **Do** report to the IAS any discussion or conduct that you suspect might violate these guidelines, and keep a copy of such correspondence.
• **Do** leave any discussion that you feel might infringe these guidelines, and ask for your leaving to be recorded in the minutes.
• **Do** refuse any commercially sensitive or confidential information you might be offered. If you receive such information, return them immediately, emphasizing that you do not want to have access to them. Keep a copy of such correspondence.
• **Do** remember that you are responsible for your own compliance with these guidelines.

Read more at [http://www.iasociety.org/Web/WebContent/File/ILF__Compliance_with_competition_rules.pdf](http://www.iasociety.org/Web/WebContent/File/ILF__Compliance_with_competition_rules.pdf)