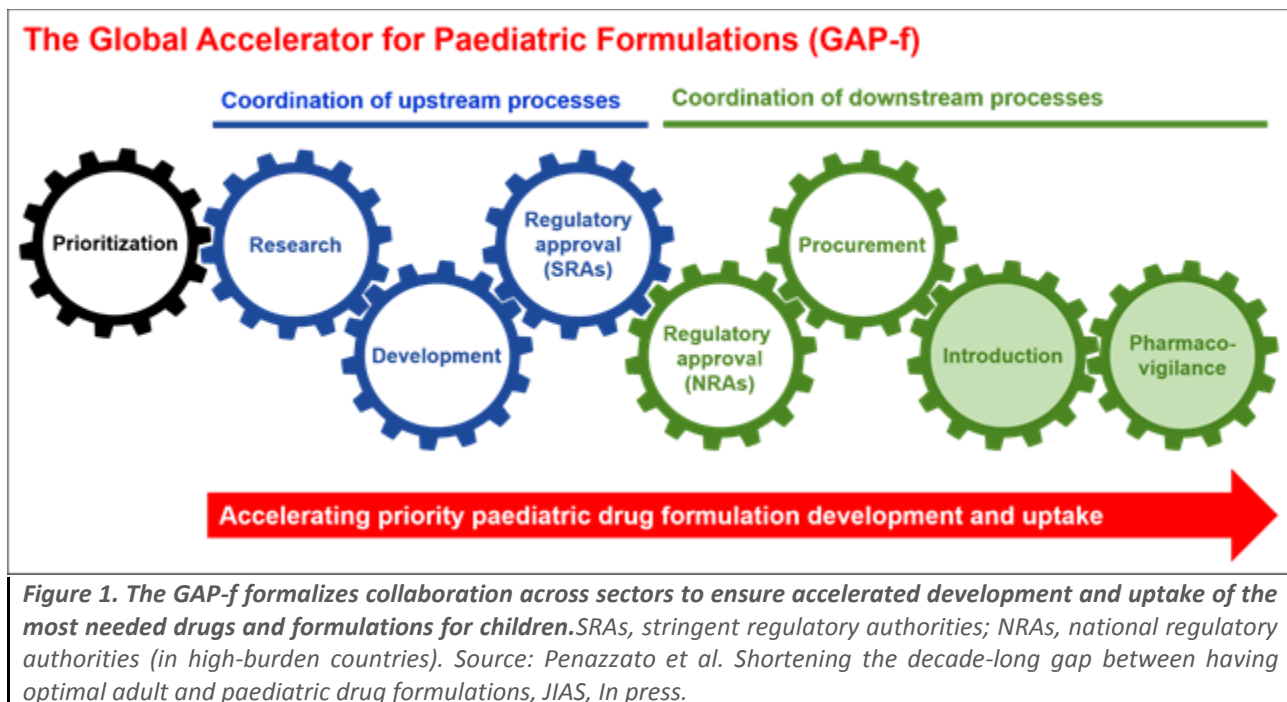


From: Sébastien Morin <sebastien.morin@iasociety.org>
Sent: Monday, January 29, 2018 9:01 AM
Subject: Progress update -- Global Accelerator for Paediatric Formulations
To: Tamar Gabelnick <tgabelnick@pedaids.org>

Dear colleague,

We are glad to share updates on our continued efforts to advance the development of the Global Accelerator for Paediatric Formulations (GAP-f).

Limited treatment options and sub-optimal formulations have contributed to poor adherence and outcomes for children living with HIV. Despite the need for expanded and improved options for paediatric treatment, which are essential for sustained adherence and better treatment outcomes, barriers to incentivizing research and development remain. The GAP-f aims to promote a faster, more efficient and more focused approach to paediatric formulation development. It is a collaborative framework that can help get better paediatric products quicker and cheaper by prioritizing products, streamlining the generation of clinical evidence, incentivizing manufacturers, accelerating product development and introduction, and coordinating procurement. As shown in Figure 1 below, the GAP-f formalizes collaboration across sectors to ensure accelerated development and uptake of the most needed drugs and formulations for children.



In November 2017, a *High-Level Dialogue on Scaling Up Early Diagnosis and Treatment of Children and Adolescents* was convened by His Eminence Peter Kodwo Appiah Cardinal Turkson, Prefect of the Dicastery for the Promotion of Integral Human Development, with PEPFAR, UNAIDS and Caritas Internationalis, and in close collaboration with the World Council of Churches-Ecumenical Advocacy Alliance, EGPAF and the WHO. Key principles of the GAP-f set the [basis](#) of discussion, which led to an action plan including an impressive list of commitments from industry, regulators, UN agencies and

other stakeholders. The commitments from the [Rome action plan](#) promote three key principles: **focusing** on priority paediatric drugs and formulations; **accelerating** development, review, and introduction of paediatric formulations; and **collaborating** to expedite the development and introduction of paediatric products. These principles align with the foundations of GAP-f and give further opportunities to address challenges in paediatric drug formulation development, as shown in Figure 2 below.

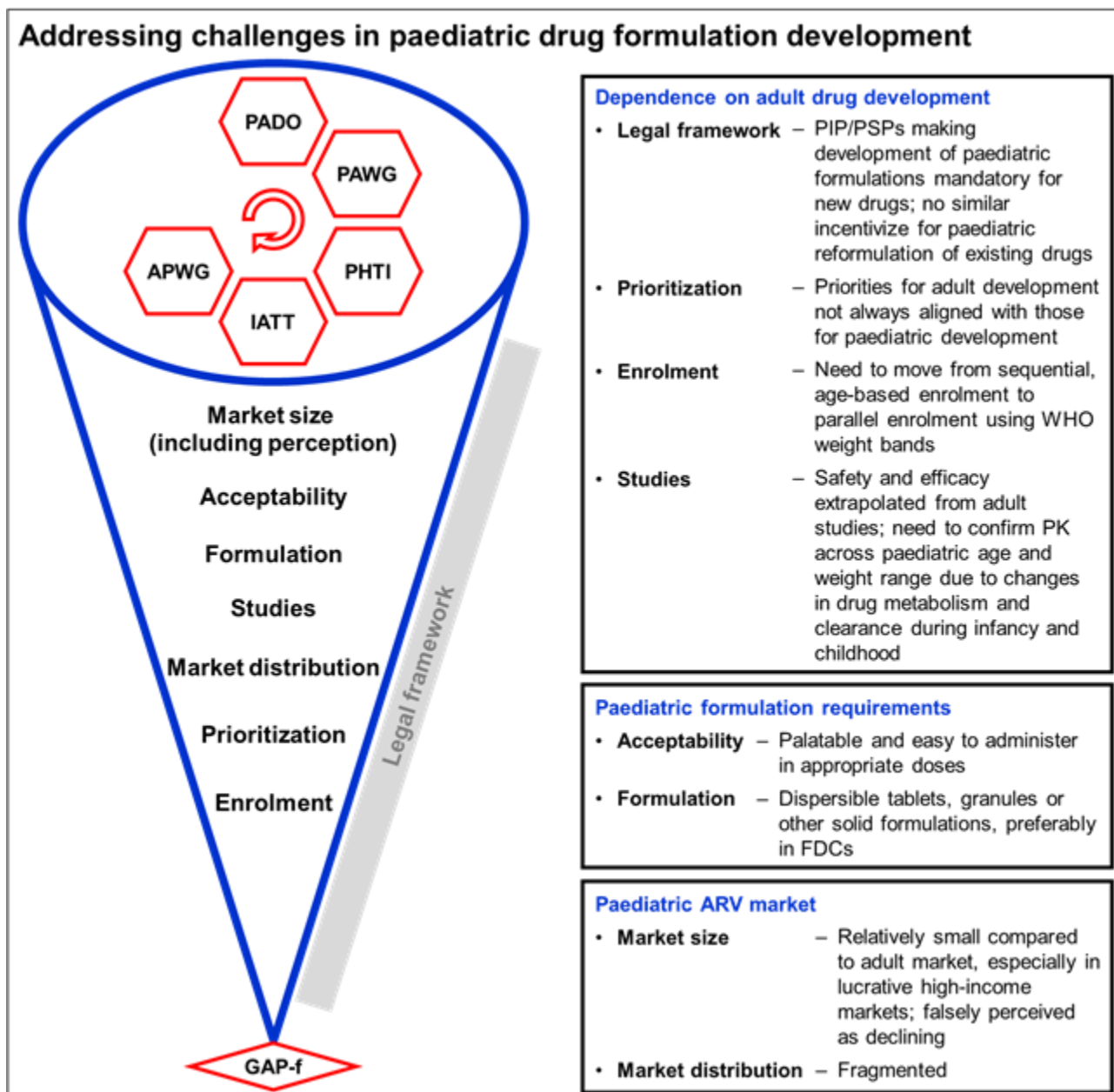


Figure 2. The GAP-f represents an opportunity to address challenges in paediatric drug formulation development. Challenges are grouped around three areas: dependence on adult drug development, paediatric formulation requirements and paediatric ARV market. Progress to date in addressing these challenges is depicted along a funnel originating from precursor mechanisms (the existing initiatives that are unified under the GAP-f) and leading up to the GAP-f collaborative model. Legal framework challenges are placed outside of the funnel because of the limited influence of the GAP-f to directly address these. Source: Penazzato et al. Shortening the decade-long gap between having optimal adult and paediatric drug formulations, JIAS, In press.

As part of GAP-f activities, a Research Toolkit for Paediatric Drug and Formulation Development is being assembled (with launch expected for AIDS 2018) to provide guidance to researchers and manufacturers (both originators and generics) as well as other organisations with an interest in drug development, and facilitate faster, more efficient and focused development of paediatric formulations. The toolkit will comprise 10 modules, each addressing key areas for the development of paediatric drugs:

1. Pharmacokinetic (PK) studies and PK modelling
2. Clinical trial designs
3. Pregnant and breastfeeding women
4. Co-infections
5. Acceptability
6. Community engagement
7. Target product profile
8. Forecasting and programme introduction
9. Regulatory filing
10. Pharmacovigilance.

Manufacturers will soon be invited to review the content covered in the research toolkit. Representatives of regulatory authorities will also have the opportunity to provide feedback and ensure alignment with existing regulatory framework and guidance.

Finally, the Paediatric ARV Drug Optimization (PADO) group recently reviewed its [list of priority paediatric ARV formulations](#). The review focused on implementation considerations, accounted for key outcomes of the Conference on Drug Optimization (CADO) 3 meeting, and enabled preliminary discussion to inform the upcoming WHO ART guidelines revision (planned for Q2 2018). In collaboration with the WHO and CHAI, we invite you to attend a webinar to report on the PADO 3 review. This interactive session primarily aimed at industry will cover the latest discussions around the list of priority paediatric ARV formulations and will take place on Monday, 5 February 2018. The agenda is available [here](#). Please register in advance to one of two options.

- Option 1: 05:30-06:30 EST / 11:30-12:30 CET / 16:00-17:00 IST – Register [here](#)
- Option 2: 11:00-12:00 EST / 17:00-18:00 CET / 21:30-22:30 IST – Register [here](#).

Efforts to further develop the GAP-f concept and explore synergies are ongoing, and we welcome any input. Please do not hesitate to be in touch with any question or comment you may have.

Please circulate this message to interested colleagues, and let us know if we should include them in our mailing list. Please also do let us know if you prefer not to receive updates on the GAP-f.


On behalf of GAP-f partners,

Sébastien


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About the GAP-f

The GAP-f is an evolving collaboration between a number of partner organizations, including:

- *Clinton Health Access Initiative (CHAI)*
- *Drugs for Neglected Diseases initiative (DNDi)*
- *Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)*
- *Global Fund to Fight AIDS, Tuberculosis and Malaria*
- *ICAP at Columbia University's Mailman School of Public Health*
- *International AIDS Society (IAS, through its Collaborative Initiative for Paediatric HIV Education and Research – CIPHER - and Industry Liaison Forum – ILF)*
- *International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT)*
- *Medicines Patent Pool (MPP)*
- *Paediatric European Network for treatment of AIDS (PENTA)*
- *United Nations Children's Fund (UNICEF)*
- *Unitaid*
- *U.S. President's Emergency Plan for Aids Relief (PEPFAR)*
- *World Health Organization (WHO).*

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