

May 10, 2018

Update May 2018

Dear Colleagues,

We are pleased to share with you the latest update on the implementation of the Rome Action Plan on Pediatric HIV Treatment and Diagnosis. We would also like to take this opportunity to thank the large number of people who actively participated in the first webinar on the Action Plan, held on 24 April. As heard on the webinar and summarized below, it is clear that the positive energy from the Vatican meeting continues to inspire action across the three thematic areas and on individual commitments. We look forward to hearing about additional steps forward in the coming weeks and months.

Below please find a synopsis of some of the actions taken since our last update, including many of the elements reported in the 24 April Rome Action Plan webinar. A more comprehensive overview, including further details on the points below, is available on the tracking website: <https://www.paediatrivactionplan.org/> . Please remember to send regular updates to our project management team (tgabelnick@pedaids.org or Francesca.Merico@wcc-coe.org) so they can properly reflect your efforts and accomplishments.

Best regards,

Gottfried Hirschall and Chip Lyons, AIDS Free Working Group co-chairs

FOCUS

- Action 3: PAWG has provided input to Gilead on the TAF development plan, recommending faster development of the PADO prioritized formulation (F/TAF alone), especially for younger children.
- Action 5: IMPAACT and PENTA have been collaborating (including sharing data and expertise) to accelerate the final dosing plan for pediatric DTG (adolescents down to newborns)
- Action 6 : ViiV has committed additional resources in Pediatrics with the appointment a Head of Pediatric Strategy (Bill Collier) who has convened a cross-functional team to address possible ways to accelerate development of pediatric DTG.

ACCELERATE

- Action 8: PEPFAR is working with the GAP-f and PAWG to determine where support is needed to advance priority pediatric drug development. PEPFAR is looking at opportunities to support practical studies evaluating program experiences with introduction of Raltegravir granules for newborns and young infants. PEPFAR has also been working directly with originator manufacturers (Merck, ViiV, J&J) on their plans to be the direct supplier of optimal pediatric ARV products in PEPFAR-supported HIV programs until those products are available from other sources.
- Action 9: Since 2017, PEPFAR has taken direct action to ensure that PEPFAR funds are not used to purchase ARVs that are no longer standard of care (eg, PEPFAR funds should no longer be used to purchase nevirapine products for treatment in older children and adults). Its COP18 guidance stated, “For children, PEPFAR supports use of currently preferred regimens (e.g. lopinavir/ritonavir-based first-line regimens for children under 3 years old or 30 kg.) in child-friendly formulations and will support rapid introduction of new drugs and formulations for children (e.g.dolutegravir) as they become available and recommendations are updated. “ [page 56, <https://www.pepfar.gov/reports/guidance/c77910.htm>]
- Action 10: The ARV Procurement Working Group (APWG) met on 16 April to discuss pediatric ARV procurement patterns and forecasting.
- Action 11: WHO is finalizing an open letter to EMA and FDA that includes feedback from PAWG on PIPs for EMA. The messages of the letter will be communicated to relevant companies on dedicated calls with PAWG members to facilitate dialogue. PAWG members will remain available to discuss specific products with relevant innovators. PAWG recommendations will be posted on WHO’s website.
- Action 13: ViiV will be further increasing resources in Pediatrics by appointing a Medicine Development Lead to promote pediatric medicines across their R&D portfolio.
- Action 18: ViiV has new data sets for pediatric DTG and will be requesting a meeting with FDA early this summer to review development plans. J&J reported on work with CHAI and University of Liverpool on a pediatric Darunavir FDC, possibly using nanotechnology. See also updates from Cipla and Mylan, below.
- Action 21: PEPFAR provides funds to implementing partners for activities that include, as appropriate, provision of technical assistance and training for introduction of new drug regimens for adults and children. It is working with partners to ensure that plans for TLD roll-out include children down to 30kg.
- Action 24: A first draft of a PAWG toolkit for pediatric drug and formulation development, developed by WHO in collaboration with Unitaid, IMPAACT, PENTA-Id and other partners, has been shared with manufactures and regulators for review, and the final version will be made available in July 2018. GAP-f is working on a pediatric forecasting model, with a prototype due to be launched in July.
- Action 29: GNP+ has had early conversations with ICW about collaborating to mobilize communities of mothers and parents. Currently, GNP+ is trying to add a focus on children into its existing work plans and it is trying to identify some joint resource mobilization activities in order to do more. GNP+ has also conducted a survey of approximately 800 PLHIV from more than 90 countries on ARVs, including pediatric ARVs. The official release of the data will be at AIDS 2018.

COLLABORATE

- Action 35: UNAIDS continues to work with the AU Free to Shine initiative to highlight the work on pediatric treatment.
- Action 37: Webinar: On 24 April, the AIDS Free Working Group co-chairs hosted a webinar among Vatican meeting participants and other key stakeholders to provide an update on their efforts to monitor implementation of the Rome Action Plan and to allow those who make commitments to provide brief updates directly to the group. The webinar was well-attended and showed that activities are ongoing on the majority of action points. As suggested during the call, an overall assessment of implementation status across the Action Plan will be done in the coming weeks to identify any significant gaps. A recording of the webinar is available upon request (send requests to tgabelnick@pedaids.org).
- Action 38: Milestones have been developed for most action points, all available online at <https://www.paediatricivactionplan.org/>
- Action 40: The Global Accelerator for Pediatric formulations (GAP-f) launched a new website where a variety of resources related to pediatric drug and formulation optimization can be found, as well as information on the activities of the GAP-f and its partners: www.gap-f.org . GAP-f partners published a peer-reviewed commentary in JIAS on “Shortening the decade-long gap between adult and paediatric drug formulations: a new framework based on the HIV experience in low- and middle-income countries” is now published ([here](#)).
- Action 41: On March 29, 2018, PEPFAR convened diagnostics companies, donors, and select implementing partners for a one-day Consultation meeting in New York City on strategies to improve access to HIV (and TB) diagnostics for infants and children in lower middle income countries (LMICs). Ambassador Birx provided opening remarks and participated in side meeting discussions with key attendees. The meeting ended up with concrete action items for diagnostic manufacturers to address to ensure cost efficient and uninterrupted diagnosis services for children and adolescents. On 19-20 April, on the margins of the UNAIDS/WHO Annual Consultation with Pharmaceutical Companies, Partner Organizations and Stakeholders meeting in Geneva, AFWG members met bilaterally with diagnostics companies to discuss challenges and opportunities for expanding access to pediatric diagnostics. As noted in the previous update, these consultations and others planned this summer are intended to culminate in a high-level meeting on pediatric diagnosis with a set of commitments across key stakeholders, which is likely to be held at the Vatican in early fall 2018.

Individual Commitments:

- PEPFAR included pediatric treatment targets in its country plans to maintain pressure for expanded access to ARVs. It has developed a website that makes program data available for review and analysis: <https://data.pepfar.net/>. PEPFAR and FDA have been working on mechanisms that would enable making FDA review documents available to WHO and/or national drug regulatory authorities for tentatively approved products to facilitate more timely regulatory approval of those products for use in PEPFAR-supported HIV programs. PEPFAR has also been working with WHO in

advance of the upcoming WHO Guidelines meeting to advance optimal ARV regimens for children.

- ViiV: See actions 6, 13, and 18, above
- Cipla reported that in January, it filed with FDA for approval of a new process for its 2-in-1 pellets (LPV/r) that would multiply by 5 its current production capacity. Regarding the 4-in-1 (ABC/3TC/LPV/r) granules, clinical trials are beginning in Uganda in May and BE study underway. If BE data is deemed sufficient by regulators, the filing can be done in August, but if clinical data is needed, it will be filed in January 2019.
- Mylan reported that it filed for approval of 2-in-1 (LPV/r) granules with WHO PQ in December 2017 and with FDA in February 2018.
- Merck is working with PEPFAR and WHO to increase availability of Raltegravir for infants and to further simplify formulations for young children.
- Additional commitment: MPP The Medicines Patent Pool (MPP) committed to facilitating access to the best available medicines for children. Specifically, the MPP will continue to work with patent holders to in-license paediatric drugs as prioritized by the WHO/PADO, and to sublicense to generic manufacturers to ensure that appropriate formulations are rapidly developed, registered and made available in as many developing countries as possible