

July 31, 2018

Update July 2018

Dear colleagues,

During the April webinar, we requested the project management team to prepare an overview of progress on the Rome Action Plan. The assessment showed that the stakeholders who adopted the Rome Action Plan are largely taking their commitments seriously, leading to improvements along the spectrum of paediatric ARV research, development, and uptake. Out of the 52 action points and commitments, significant progress has been observed on 13%, good progress made on 42%, and partial progress has been noted in 25%. In addition, real progress is needed on one item, and there are no updates on 10 items. The most notable developments have been:

- clarifying regulatory requirements to accelerate completion of pediatric plans;
- communicating to research networks, pharma, and SRAs on the need to focus on prioritized ARVs;
- fostering greater attention to children among networks of people living with HIV;
- organizing formal and informal meetings on diagnostics, with a planned high-level meeting in the fall;
- and revising treatment guidelines to enable use of more potent drugs in children.

Good progress has been made in:

- encouraging procurement of optimal drugs and formulations;
- collaborating on planning for country introduction of soon to be available products;
- and ensuring their availability in larger quantities and at access price.

Partial progress has been observed in:

- expediting regulatory review (both SRA and NRA) of priority formulations;
- and on the development of specific drugs.

The slowest progress has been on compressing pharma's R&D timeframes for specific priority pediatric ARVs, many of which are falling behind schedule and one of which is not proceeding in accordance with the spirit of the Action Plan. In several other areas stakeholders have not yet reported on progress. While many of the activities outlined above represent the continuation of previous efforts, the Rome Action Plan has provided an important opportunity to strengthen or expedite action, as well as to spur complementary steps that would not have otherwise been taken.

Please find below the updates on actions taken over the last month:

FOCUS

- Action 4: Experts met in June to update the optimal pediatric formulary
- Action 5: PADO priorities and Rome Action plan communicated to IMPAACT and PENTA members with active collaboration to accelerate completion of DTG plan.
- Action 7: GAP-f members developing proposals to communicate to FDA and EMA on priority review of PADO-related PSPs and PIPs dAction 10: The ARV Procurement Working Group created a website that could facilitate the provision of reliable forecasts and heighten awareness of the continued procurement of less optimal products:

ACCELERATE

- Action 11:
- Action 21: Unitaid is exploring options to facilitate rapid introduction of paediatric DTG in early adopting countries, leveraging the Optimal ARV Project in collaboration with CHAI.
- Action 25: UNICEF, in collaboration with USG (USAID, CDC & PEPFAR), UNAIDS and WHO, is planning multi-country meetings for the WCA & ECA for 3rd and 4th quarter to build capacity in countries for availability and use of age, sex and geographic disaggregated data for planning and programming. Paediatric scale up in WCA is proceeding with a recent large multicountry workshop hosted by UNICEF and partners to promote adoption of family based index case testing policies. This workshop was followed by targeted TA visits to countries to develop SOPs and protocols for rapid rollout of family-based index testing.
- Action 26: All the 10IATT optimal paediatric formulations needed to provide WHO recommended preferred and alternative first- and second- line regimens for all children have been placed on UNICEF's products list of ARV formulations, and UNICEF SD continues to advocate for countries to procure optimal paediatric formulations. UNICEF SD has long-term arrangements with manufacturers for 9 out of the 10 IATT formulations. Raltegravir 100mg chewable tablets is procured through adhoc tenders. UNICEF tenders issued for HIV POC diagnostics in 2018 also seeks to promote the POC pipeline through inclusion in the tender scope of products that are expected to enter the market as well as those that are already available. In April 2018 UNICEF launched a tender which would serve as an instrument for piloting all-inclusive pricing contracts for Nucleic Acid testing services, uniform across assay types (HIV Quant, HIV Qual, HCV, HBV and HPV), in four selected early-adopter countries: Malawi, Tanzania, Uganda, and Zimbabwe.

COLLABORATE

- Action 31: The Pediatric HIV Treatment Initiative (PHTI) met on 7-8 June to discuss collaboration on the registration, introduction, and roll-out of formulations expected to become available in 2019.
- Action 35: UNAIDS worked with the UN Human Rights Council to ensure the language of an upcoming resolution on human rights and HIV included strong language on access to optimal drugs for children.
UNAIDS has provided funding to community-based organizations in a number of countries, including Cameroon, DRC, Mozambique, Uganda to support women during pregnancy and breastfeeding to remain in care and on treatment, and to encourage them to have their infants and other children tested for HIV. Lessons learned from these networks may provide best practices in encouraging families to have their children tested.
UNAIDS is supporting countries on launches of the OAFLA/AU Free to Shine Campaign, including a launch with the First Lady of Mozambique in June.

PEPFAR included pediatric treatment targets in all 2018 COPs. UNAIDS is working with countries on setting pediatric treatment targets within NSPs, including the recently released NSP in Swaziland.

Individual Commitments

- In May, the FDA issued draft guidance entitled which includes “recommendations on when sponsors should initiate pediatric formulation development and begin pediatric studies to evaluate antiretroviral drug products for the treatment of HIV infection.” The draft guidelines closely parallel the commitments made in Rome, so if issued as drafted, they will provide a clear public reinforcement of these commitments.

We count on you to keep the team updated on steps you have been taking to implement the Action Plan. Please send updates to tgabelnick@pedaids.org, Francesca.Merico@wcc-coe.org, or penazzatom@who.int. We also encourage you to visit the online tracker to see whether the status of your actions is up to date and to learn about progress on other items: <https://www.paediatrivactionplan.org/>

Best regards,

Gottfried Hirschall and Chip Lyons, AIDS Free Working Group Co-Chairs