

Rome Action Plan – Status Report May 2018

Summary: The adoption of the Rome Action Plan has made possible some solid progress in the area of paediatric HIV. 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:

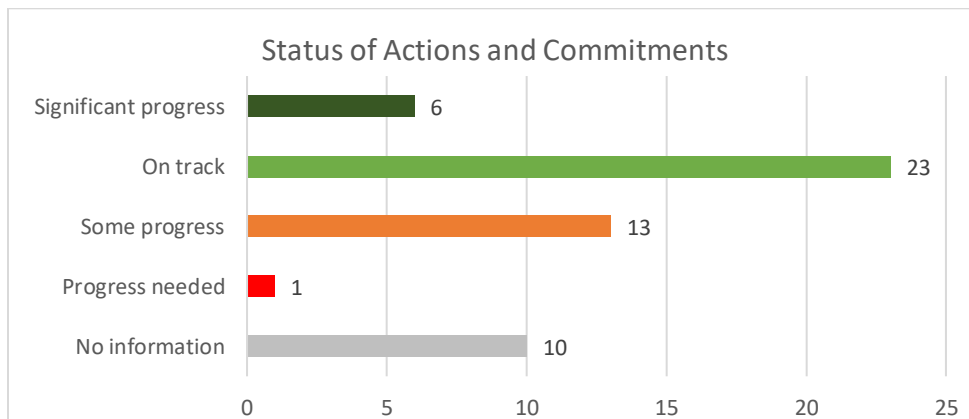
- encouraging procurement of optimal drugs and formulations;
- collaborating on planning for country introduction of soon to be available products;
- and ensuring their availability in larger quantities and at access price.

Moderate 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. In other areas stakeholders have not yet reported on progress. Therefore, additional outreach is needed to move forward on several action points.

While many of the activities outlined below 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. The AIDS FREE co-chairs will continue to hold actors to account for the Rome Action Plan commitments and communicate widely on its progress/challenges.



Significant progress (due to Action Plan)

- **SRAs – Action 20/FDA commitment:** FDA reiterated its acceptance of accelerated steps when evaluating paediatric development plans and reviewing drug applications in a [letter to PEPFAR](#) in January 2018. In May, the FDA issued draft guidance for industry elaborating the same points. EMA endorsed a similar set of principles at a meeting in late May and will put them in a public note for the record.
- **GNP+ commitment:** GNP+ adding focus on children into its existing work plans and is seeking resources to do more; conducted a survey of approximately 800 PLHIV from more than 90 countries on ARVs, including on pediatric ARVs

- **WHO** – Actions 1-2: PADO implementation considerations shared with industry in Feb. 2018. Revised treatment guidelines have just been updated to reflect PADO priorities and will be released in July.
- **Research networks** – Action 5: PADO priorities and Rome Action plan communicated to IMPAACT and PENTA members with active collaboration to accelerate completion of DTG plan.
- **AFWG Co-chairs – Action 41** – Plans are underway for fall 2018 high-level diagnostics meeting. Several group and bilateral meetings have already taken place)

On track / Ongoing

- **WHO** – Actions 3-4: Work within PADO, PAWG, and ARV formulary proceeding normally.
- **Research networks** – Action 19: P1093 and ODYSSEY using weight bands-based dosing and concurrent age groups
- **Donors** – Action 9: PEPFAR COP guidance emphasized no funding for non-optimal ARVs, such no NVP for older children. GF/APWG continues to monitor and encourage procurement of optimal formulations
- **Donors** – Action 21: PEPFAR provides funds to implementing partners to support introduction of new drug regimens. UNITAID exploring options to facilitate rapid introduction of paediatric DTG in early adopting countries, leveraging the Optimal ARV Project in collaboration with CHAI.
- **IPs and FBOs** – Action 22: EGPAF and CHAI beginning preparations for introduction of DTG (CHAI and EGPAF), Mylan granules (EGPAF), RAL (EGPAF)
- **PLHIV, IPs, FBOs** – Action 28: Ongoing awareness raising on pediatric ARVs in various fora
- **PLHIV, IPs, FBOs** – Action 29: Ongoing efforts on ARV distribution in hard to reach places and situation of conflict/crisis
- **GAP-f** – Action 24: Toolkit to support accelerated R&D and introduction of priority formulations to be issued in July 2018
- **All** – Action 31: EGPAF, CHAI, PEPFAR, WHO, DNDi and others are working on rapid registration and uptake of drugs in the pipeline (LPV/r, 4-in-1, DTG, RAL)
- **UNAIDS & PEPFAR** – Actions 35&36: Ongoing work to provide political leadership and advocacy, convene stakeholders at high levels. PEPFAR included pediatric treatment targets in all 2018 COPs. UNAIDS is working with countries on setting pediatric treatment targets within NSPs .
- **AFWG Co-chairs** – Actions 37-38: Regular monitoring of Action Plan implementation with milestones set
- **AFWG Co-chairs** – Action 39: GAP-f partners are working on plans to roll-out 2-3 drugs (LPV/r, 4-in-1, DTG, RAL). Further coordinated among all actors and engagement with communities and national authorities are needed.
- **AFWG Co-chairs/GAP-f Partners** – Action 40: GAP-f partners finalizing new business plan for launch at IAS; website launched
- **CHAI** – Finalized suppliers selection for development of DTG 10 mg scored
- **Merck**: Confirmed to PEPFAR it will make RAL available at access price
- **ViiV**: Confirmed to PEPFAR it will make DTG available at access price.
- **Cipla** – Request filed for larger production method of LPV/r in February 2018. 4 in 1 granules: expect to file dossier with FDA in with BE data in Q3 and clinical data in December 2018.
- **Catholic church**: Ongoing work to mobilize its networks to distribute paediatric medicines in hard to reach places and in situations of conflict and crisis
- **MPP**: Ongoing work within PHTI to bring RAL and ALE to market

Some progress

- **SRAs** – Action 7: GAP-f members developing proposals to communicate to FDA and EMA on priority review of PADO-related PSPs and PIPs

- **Donors** – Action 8: PEPFAR considering support for implementation research on RAL in neonates and other studies
- **IPs** – Action 10: APWG continues to promote reliable forecasts and consolidation of orders, but no information from IPs on revision of national procurement plans
- **WHO** – Action 11: WHO sent letter to EMA and FDA on technical opinions on PSPs/PIPs, but no info on timely delivery of dosing and ration recommendations to generics on new FDCs
- **WHO** – Action 12: Working with EMP on facilitation of national registration and in-country registration of specific products.
- **GAP-f** – Action 23: Work with national regulatory authorities via WHO collaborative procedure, but no information on direct advocacy on expedited national/sub-regional processes
- **PLHIV, IPs, FBOs** – Action 27: See GNP+ for their activities; no info on others on demand generation and expanding access
- **All** - Action 32: CHAI is working on alternative incentives for R&D under a Unitaid grant
- **All** – Action 33: GAP-f, APWG continue to support use of currently available pediatric drugs
- **Pharma** - Action 18: Take all possible measures to complete development of drugs and formulations in the pipeline. ViiV meeting with FDA on DTG in June. Cipla and Mylan took steps on LPV/r. Delayed progress on Mylan's 4-in-1 and very slow progress on F/TAF
- **Mylan** – Submitted LPV/r granules for approval early 2018; 4-in-1 timeline not yet known. ABC/3TC/DTG not expected until 2020/21 (late). Waiting for DTG dosing guidance by the end of 2018.
- **ViiV** – Added high level staff and resources devoted to pediatric R&D, but delays with data on DTG. Will meet with FDA in June to discuss next steps.
- **PEPFAR**: No info on efforts to develop a system of shared data and rotating locations for implementation studies or to develop a proposal for further expediting the regulatory approval process. Clear communication on policy to fund procurement only of optimate pediatric ARVs in 2018 COPs.

Progress needed

- **Gilead**: Pursuing its commitment to have clinical data ready for a low-dose TAF based regimen for children 2-12 years by late 2018/early 2019, but not on the PADO-recommended regimen, despite outreach from PAWG and other stakeholders.

No Information

- **Pharma** – Actions 6, 13-17: Prioritize PADO products and compress pediatric timeframes in R&D plans (no info apart from Gilead, see above)
- **Pharma** – Action 30: No work yet on tech transfer and knowledge-sharing
- **IP** – Action 34: Sharing info on roll-out of new formulations
- **UNICEF** - Actions 25-26: No updates provided

Next steps

- Follow up with specific manufacturers on urgent issues (ie. DTG, TAF, 4 in 1)
- Develop detailed work plan on collaboration to quickly roll-out 2-3 priority formulations (RAL, Cipla 4-in-1, Mylan LPV/r granules, ped DTG singles)
- National registration
 - Seek agreement from FDA to provide data for Collaborative Registration Procedure
 - Continue work with EMP on mapping pathways for upcoming priority products to guide regulators and innovators when applying through CRP and to identify actions to actively engage high-burden priority countries that are not included in current EMP. Make them public.