High-Level Dialogue to Assess Progress on and Intensify Commitment to
Scaling Up Diagnosis and Treatment of Paediatric HIV
Pontifical Academy of Sciences, Vatican City
6-7 December 2018

Introduction

On 6-7 December 2018, leaders of major pharmaceutical and medical technology companies, multilateral organizations, donors, governments, organizations providing or supporting services for children living with HIV, and other key stakeholders participated in a High-Level Dialogue to Assess Progress on and Intensify Commitment to Scaling Up Diagnosis and Treatment of Paediatric HIV. The meeting was convened by His Eminence Peter Kodwo Appiah Cardinal Turkson, Prefect of the Dicastery for the Promotion of Integral Human Development, and organized by the World Health Organization (WHO) and Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) (as co-chairs of the AIDS Free Working Group of the Start Free Stay Free AIDS Free framework), together with PEPFAR, UNAIDS, the World Council of Churches – Ecumenical Advocacy Alliance, and global partner organizations. The High-Level Dialogue provided an opportunity for stakeholders to build on previous dialogues on ending paediatric HIV and assess progress on the commitments made as part of the November 2017 Pediatric HIV Rome Action Plan.

The goal of this High-Level Dialogue was to determine the most effective ways to improve access to both HIV diagnostics and optimal antiretroviral drugs (ARVs) for children living with HIV, with the ultimate objective of reducing morbidity and mortality among this highly vulnerable group. Participants put forward a variety of steps they have taken or could take to expand access to early infant diagnosis (EID) and viral load testing, as well as to identify more HIV-exposed children and quickly link them to testing and treatment services. They also presented further steps that needed to be taken to accelerate the development and roll-out of priority paediatric formulations of antiretroviral drugs (ARVs), including streamlining regulatory processes, improving financing for the whole spectrum of paediatric formulations development and introduction, and ensuring wide availability and uptake of such optimal formulations.

These action points were translated into a set of commitments made by all groups of stakeholders present as well as by individual organizations. The commitments complement those made during the 2017 High-Level Meeting, most of which are still being implemented and remain valid. The ensemble of action points will be referred to collectively as the Rome Action Plan on Paediatric HIV, with each set applying only to the actors present at the relevant meeting. The co-chairs of the AIDS Free Working Group offered to continue to take responsibility for monitoring progress on the Action Plan and to promote full and timely implementation of the action points, including tracking progress towards milestones, and communicating regularly with participants about progress on their commitments and overall implementation of the Plan.

2018 Action Points

DIAGNOSTICS

National governments, with support from implementing partners, commit to:

1. Scale up appropriate, timely, high quality, cost-effective early infant diagnosis, using comprehensive laboratory mapping and optimized use of all available diagnostic resources, recognizing the patient benefits of Point of Care (POC) Early Infant Diagnosis (EID) for timely diagnosis and ART initiation.
2. Prioritize effective, evidence-based case-finding strategies to increase demand for testing of children of all ages and improve patient identification, including testing all children attending

nutrition, TB, and inpatient wards, testing of mother-infant pairs in immunization clinics, scaling up index testing, etc.
3. Develop strategies to optimize the use of new technologies and interventions in countries.
4. Work with national regulatory authorities to streamline procedures and strengthen the use of WHO prequalification listing when considering national regulatory approval.
5. Develop more accurate, transparent, and consolidated forecasts to support manufacturing and reagent availability.
6. Support multiplexing of available diagnostic technologies across programs for more optimal utilization of available platforms and wider access to testing.
7. Work towards eliminating user fees from diagnostic and health services in the public sector.

Ministries of Health and other partners commit to work with National regulatory authorities to:

8. Prioritize fast track national regulatory approval of EID and viral load (VL) products that have stringent international regulatory approval and/or WHO prequalification listing.
9. Accept WHO guidance suggesting countries should refrain from requiring national evaluation studies that would be duplicative, but instead adopt a rapid and streamlined registration and national approval process for EID and viral load products.
10. Prioritize the development and operationalization of collaborative regional registration schemes and take part in the collaborative registration procedure for diagnostics, to be developed by the WHO.
11. Develop and implement post market surveillance of diagnostic products.

Donors (Global Fund, PEPFAR, Unitaid) commit to:

12. Discourage and refrain from funding national evaluation studies that would be duplicative of studies done for WHO PQ listing or SRA approval.
13. Fund impactful technologies and interventions quickly.
14. Support in a transparent manner the procurement of commodities and operational costs to maintain and further scale-up POC EID, as well as viral load testing for infants, children, and pregnant and breastfeeding women, as an integral part of optimized and integrated national laboratory networks and in accordance with national EID and VL plans and targets.
15. Support the development of a competitive, healthy, and sustainable market for POC and laboratory technologies.
16. Continue to support WHO PQ to shorten timelines for dossier review and minimize time to national registration.

WHO commits to:

17. Develop and implement a sustainable and affordable collaborative registration procedure for diagnostics in 2019 and support national regulatory bodies to make use of it to streamline their national regulatory procedures.
18. Subject to support from donors (see 16 above), reinforce the capacity of its Prequalification of In Vitro Diagnostics programme, so that additional staffing can help to optimise process efficiencies and support transparent and predictable timelines for the review of HIV diagnostic products (in particular EID and VL products, and in alignment with WHO guidance).
19. In order to facilitate reduction of national evaluation studies (see points 9 and 12 above), provide relevant additional information within the public reports of products achieving prequalification status for increased data sharing to countries.
20. Provide additional guidance and support implementation on post-market surveillance and quality assurance to manufacturers, countries, and national regulatory authorities.
21. Develop guidelines and tools to support multiplexing of diagnostic technologies as well as viral load frequency for pregnant and breastfeeding women and children and consider novel interventions with patient impact evidence for review in next guidance review processes, including upgrading the POC EID recommendation.

Diagnostic manufacturers commit to:

22. Make every effort to stay in the EID market to ensure there is a sufficient testing capacity to reach and maintain accelerated Fast Track targets (95% of HEI tested by 2020 and beyond).
23. Ensure consistent reagent pricing across partners within countries and within regions, and provide a transparent breakdown of pricing for the products and services sold.
24. Consider moving from separate instrument, consumable, and service procurement towards more consolidated, ideally all-inclusive pricing models.
25. Provide service level agreements that clearly spell out key performance indicators POC, near POC, and high-throughput laboratory instruments, including target up-times and failure rate threshold (with consideration for different causes), plus a mitigation plan when the threshold is exceeded.
26. Consider the inclusion of a clinical indeterminate range in test result reports for more accurate diagnosis of infants per WHO guidelines.
27. Rapidly communicate stock shortages with major buyers and work on joint mitigation strategies.

Faith Based Organizations commit to**:**

28. Equip, mobilize, and support faith leaders, FBOs, people in places of worship, and the wider community to create demand for testing of infants and children.
29. Combat stigma and discrimination among faith leaders and within communities of faith.
30. Further collaborate and coordinate community mobilization, education and outreach to find otherwise hard-to-reach children, adolescents, youth and adults for age appropriate prevention education, testing and linkage to treatment and health and social support services and integrate into the national system.
31. Ensure FBO participation in local and national diagnostic product/supplies forecasting.
32. Support and participate in national efforts to improve the use and impact of pediatric diagnostics and develop national strategies to optimize the use of new technologies and interventions.
33. Work to implement new HIVST modalities (such as oral fluid testing) in communities and homes, where national polices and regulations allow for lay implementation with children.

All partners commit to:

34. Tackle the stigma and discrimination in communities, schools, and healthcare settings that prevent children living with HIV from accesing testing and treatment.
35. Promote provider initiated testing and counseling (PITC) of children outside PMTCT settings, testing of children of index HIV cases and siblings of HIV infected children, and pursue innovative avenues to identifying children living with HIV of all ages and ensuring access to testing and treatment.
36. Promote and support virological (rather than serological) testing at the 9 months of age time point for all HIV-exposed infants per WHO 2018 EID algorithm changes.
37. Support rational integration and scale up of point of care virologic platforms within laboratory networks for timely identification and monitoring of infants and children with HIV.
38. Increase literacy about viral load and promote a client-centered approach to support expansion of access to viral load for pregnant and breastfeeding women and children on treatment.
39. Advocate for the elimination of user fees from diagnostic and health services in both the public and private sector.

Caritas commits to:

40. Improve case-finding approaches through religious services.

Catholic Relief Services commits to:

41. Strengthen and expand case-finding through developing nurturing and enabling environments, integrating testing into orphans and vulnerable children (OVC) programs, adapting and localizing case management tools, and promoting social services.

CHAI commits to:

42. Support POC EID as well as case-finding through enhanced testing in inpatient, TB, and nutrition wards through the development of clear policies as well as program and operational guidance, and through implementation support.
43. Promote broader uptake of new sample types for laboratory systems and multiplex testing to improve cost efficiencies.
44. Invest in data management to provide more visibility to optimized laboratory networks for faster corrective actions and better quality testing.
45. Support Country Governments with 1) the latest data on performance and regulatory status of new diagnostics; 2) implementation of global guidance on product approvals and post market surveillance; and 3) once the WHO Collaborative Procedure for IVDs is established, promote rapid adoption, shifting the focus of quality assurance to post-market instead of pre-market.
46. Support the development of programmatic and operational guidance on POC VL for children, adolescents, and pregnant and breastfeeding women including by building evidence to support these policies.

EGPAF commits to:

47. Support POC EID as well as case-finding through enhanced testing in inpatient, TB, and nutrition wards.
48. Support broader uptake of new sample types for laboratory systems and multiplex testing to improve cost efficiencies.
49. Support case-finding through contact tracing and testing, including at the community level.

FIND commits to:

50. Support the near term mapping of diagnostics services in pediatric HIV with a view to optimising their use, alongside TB, HCV and adult HIV services.

GNP+ commits to:

51. Mobilize communities to reduce stigma and create demand for point of care diagnostics in order to improve early infant diagnosis.

UNAIDS commits to:

52. Work with communities, civil society partners, including organizations of people living with HIV and faith partners, to address barriers of stigma and lack of information and increase the uptake of HIV testing among children and families, including advancing family-based testing in West and Central Africa, with linkage to appropriate care and treatment.

UNICEF commits to:

53. Support POC EID as well as case-finding through enhanced testing in inpatient, TB, and nutrition wards.
54. Promote family HIV testing as a strategy for identifying children with HIV.
55. Provide additional investments and support in West and Central Africa through Bridge to Scale POC diagnostics (including optimizing multiplexing) to close the diagnostic and paediatric ART treatment gaps.

Unitaid commits to:

56. Support the expansion of the WHO-led Collaborative Registration Process to diagnostics, and leverage existing projects in diagnostics to support the roll out of the procedure for key diagnostics.
57. Remove duplicative in-country performance evaluations from operational budgets of ongoing investments and grants.
58. Support implementing partners (including CHAI) to address outstanding barriers on diagnostics optimal uptake and scale.

US-Food and Drug Administration intends to:

59. Reclassify HIV diagnostic devices from class III PMA to class II 510(k) to expedite patient access to these tests per the July 19, 2018 Blood Products Advisory Committee recommendation.

Abbott commits to:

60. Move to a new pricing model for the Point of Care (POC) m-PIMA molecular diagnostic system for EID and VL assays that is an all inclusive price (including instrument, data services, connectivity, service and maintenance) of $30 per test, moving down to $15 per test with sufficient aggregate EID and VL volumes.
61. To complement existing HIV, viral hepatitis, TB, haemorrhagic fever and other important infectious disease assays, Abbott will to continue to develop additional assays of strategic importance across the platforms.
62. Commit to coordinate across business divisions to provide the most comprehensive solution of centralized and decentralized molecular platforms for each country.
63. Continue to implement consistent and transparent pricing, communicating openly on volume requirements for pricing levels.

Cepheid commits to:

64. Include a small additional surcharge price (ideally with a maximum of $1.50, but volume dependent) to cover the service level agreement in 2019.
65. Evaluate the potential for further price reductions with increased volumes of all virology molecular assays (HIV, HCV, HBV, HPV) in 2019.
66. Support further decentralization through launch of EDGE technology and HCV testing through finger-prick assay development and submission to regulatory bodies and WHO PQ in 2019.
67. Work with WHO on the potential inclusion of a clinical indeterminate range for the EID assay in 2019.
68. Improve comprehensive connectivity solution.

Diagnostics for the Real World commits to:

69. Submit finger-prick based leuco-depleted HIV viral load and EID assay to WHO PQ.
70. Propose volume-based, bundled pricing for EID and viral load assays and instrument platforms, including service and maintenance costs, in order to reduce cartridge and instrument prices.
71. Launch SAMBA Dash Board for easy data tracking, instrument and assay performance monitoring and stock counts at POC sites.
72. Continue menu expansion of SAMBA I near-POC system and SAMBA II true POC system to include TB, Hepatitis B, Hepatitis C, HPV etc.
73. Work with WHO re consideration and implementation of indeterminate range for SAMBA assays

Hologic commits to:

74. Enter the EID market through application for CE-IVD mark and WHO prequalification of the dual claim assay with whole blood/dried blood spot.
75. Implement the indeterminate range guidance within the EID product insert in Q1 2019.

76. Maintain the multiplex availability on the Panther system with continued support for the HCV, HBV, and HPV assays.
77. Maintain the all-inclusive, transparent price of $12 across molecular assays (HIV EID and VL, HCV, HBV, HPV assays).
78. Jointly develop and implement KPIs with our partners in country including instrument uptime and mean time to respond/repair.

OraSure commits to:

79. Complete the actions necessary to expand the product claim originally submitted to and listed by WHO PQ for the use of the professional use product to allow caregivers to test children 24 months and older by end Q1 2019.
80. Develop and execute a study by end Q2 2019 to verify usability in adult caregivers testing children with OraQuick HIV Self-Test.
81. Work with partners to develop and execute a more comprehensive study to assess social consequences of the use of the OraQuick HIV Self-test in testing children by parents or caregivers for consideration by WHO in self-testing guidelines

Roche commits to:

82. Support development of optimized laboratory networks and introduction of new, innovative solutions to the marketplace.
83. Develop additional assays for current laboratory technologies, including TB, hepatitis, and HPV to support multiplex testing.
84. Closer collaboration with countries, partners, and donors for better forecasting.
85. Include the EID indeterminate range into new systems.
86. Provide pricing transparency through Global Fund collaboration.
87. Support development of key performance indicators.

For all stakeholders' considerations

Interventions for long-term consideration and prioritization include:

- Expore the development of a device-free POC EID.
- Consideration of the Inclusion of HIV-2 for EID and viral load for conventional and POC testing in new technology development.
- Development of connectivity solutions that can easily offer interoperability with national laboratory health information and quality systems.
- Development of, in collaboration with governments and other stakeholders, sustainable waste management solutions that are incorporated into existing national biosafety systems for the appropriate disposal of toxic laboratory products. Ensure that new products in the pipeline are environmentally friendly.

TREATMENT

REGULATORY

Pharmaceutical companies, SRAs, WHO Prequalification Programme (PQ) and NRAs commit to:

1. Accelerate the national drug registration process to enable registration of any ARV listed by WHO EOI in around 40 participating countries within 1 year by ensuring that:

   FOR PRODUCTS WITH PQ APPROVAL:

   - Company submits for registration in countries requesting use of the CRP (based on PQ approval) and process completed within around 4-5 months (country decisions within 3 months, plus submission processing time)

   FOR PRODUCTS THAT HAVE NOT YET RECEIVED PQ APPROVAL:

   - Company submits with USFDA for full approval or tentative approval and process completed within 6 months;
   - USFDA approval or tentative approval review shared with WHO for Collaborative Registration Procedure-lite (CRP-lite), a pilot program at first allowing FDA to share up to 5 minimally redacted reviews.
   - Company submits for registration in countries requesting use of the CRP (based on WHO PQ, FDA (CRP-lite) or other SRA review) and process completed in around 4-5 months (country decisions within 3 months, plus submission processing time)

The European Medicines Agency commits to:

2. Release an official communication to reflect that the review of Paediatric Investigation Plans (PIP)s, while maintaining that each PIP is evaluated on a scientifically justified case-by-case basis, will continue to ensure that the following points are always considered:
   - Paediatric formulation development must be integrated from the beginning in the planning and implementation of the overall paediatric drug development starting at least by the time of completion of phase 1 studies in adults taking into account paediatric dose finding and clinical studies;
   - Adolescents should be included in initial pivotal efficacy and safety trials in adults, or adolescent trials should be conducted in parallel with adults unless otherwise scientifically justified;
   - When scientifically appropriate studies of drugs across the paediatric spectrum of ages/weights (at least down to the age of 4 weeks) should be conducted in parallel rather than in series (unless a particular product has a specific safety or drug disposition factor that warrants a different approach).
   - Drug development studies in children should be based on weight rather than age and should align with the WHO weight bands.
3. Work on measures to improve the handling of PIP applications including to facilitate the modification process as agreed in the EMA-EC action plan published in October 2018.
4. Continue to discuss with USFDA prior to and during the review of PSPs and PIPs in order to align on content as much as possible, specifically also for ARV products identified as priority products by PADO.

The US Food and Drug Administration (USFDA) commits to:

5. Continue to meet with EMA prior to and during the review of PSPs and PIPs to try to align on content.
6. For PIPs/PSPs on ARVs identified as priority products by PADO, strive to ensure alignment with EMA on study requirements and approach to dossier review.

7. Initiate implementation of the agreement with WHO to facilitate the CRP-lite pilot program of products with USFDA full approval or tentative approval by Q1 2019.
8. Consider requests for the further deferral of pediatric assessments in PSPs of paediatric ARVs that are not identified as priority products by PADO.

WHO Prequalification Programme commits to:

9. For ARVs identified as priority products by PADO and included in WHO EOI, strive to ensure alignment with USFDA on study requirements and approach to dossier review.
10. Increase support for harmonization, convergence, and work-sharing through regional regulatory networks and reactivate the Paediatric Regulatory Network by Q2 2019.
11. Initiate implementation of the agreement with USFDA to facilitate the CRP-lite pilot program of products with USFDA full approval or tentative approval by Q1 2019.
12. Encourage wider use of Collaborative Registration Procedures, in particular by the 21 AIDS Free WG priority countries.

Pharmaceutical companies commit to:

13. Share their methodological approaches to acceptability studies (including palatability and ease of administration) and contribute to a repository held by GAP-f partners to guide future investigation of acceptability for paediatric products.
14. Consider the use of the CRP for national registration of pediatric ARV products on PADO, Optimal formulary and Limited use lists.
15. Ensure all drug registration dossiers meet minimum requirements at the time of filing and that responses to specific queries are complete and provided in a timely manner

FINANCING

GAP-f partners commit to:

16. Seek and direct funding to support the additional clinical research required to inform development and use of PADO priority products.
17. Identify and facilitate the most suitable financial incentive for a given product included in PADO list, possibly including one or more of the following:
    - Support to development upon timely achievement of key milestones
    - Catalytic procurement
    - Advance market commitments.
18. Promote donor coordination to cover the full spectrum of activities required to ensure accelerated research, development, registration, commercialization, roll-out, and appropriate monitoring of PADO priority products.
19. With the support of Unitaid, partner with Janssen and generic manufacturers to develop and register DRV/r 120/20 mg by Q4 2020.

Pharmaceutical companies commit to:

20. Manufacture new PADO priority pediatric ARV products “at risk” such that the new product is available for supply at time of approval/tentative approval/prequalification, including validation of manufacturing process during regulatory review.

Donors commit to:

21. Support catalytic procurement of all or part of initial validation batches from manufacturers such that product availability is not delayed once approval or tentative approval is achieved.
22. Incentivize commercialization of new pediatric ARV products “at risk” to accelerate introduction and scale up of new paediatric ARV product such that product is available at time of approval/tentative approval/prequalification.

INTRODUCTION, UPTAKE AND PROCUREMENT

Manufacturers of heat-stable LPV/r formulations and all relevant stakeholders involved (ARV Procurement Working Group, Unitaid, Ministries of Health, GAP-f partners) commit to:

23. Jointly agree upon and execute next steps to optimize the availability and delivery of these formulations in 2019 including:
    - Timely and regular information sharing (including orders placed and timelines for deliveries)
    - Providing best possible demand forecasts
    - Collaborate on the optimization of limited supply within and among countries and joint prioritization among orders to ensure sustainable supplies to children once initiated
    - Support product uptake at country level
    - Regulatory filings as needed to support scale-up, timely responses to queries raised during the review, and implementation (re-validation as required) of post approval changes at risk during the review period.
24. Mylan commits to double its manufacturing capacity of LPV/r granules by Q4 2019 (to 5-6 million sachets/month)
25. DNDi commits to continue supporting efforts to improve sustainable in-country access to 2-in-1 LPV/r by providing technical support on use of LPV/r pellets and granules through collaboration with Unitaid, APWG, other GAP-f partners, PEPFAR, MoHs, and HIV stakeholders in country.
26. DNDi, ICAP, and EGPAF commit to collaborate on product uptake for solid oral dosage forms of LPV/r (2-in-1's and 4-in-1), including:
    - Development of healthcare workers' training tools based on implementation research data generated by DNDi; and
    - Acceleration of product uptake in selected countries with engagement of all stakeholders including MOH, civil society, FBOs, and communities of people living with HIV, and to share the training toolkit and experience by disseminating information globally.
27. UNICEF commits to collaborate with GAP-f partners to develop, test, and disseminate training tools for treatment initiation with LPV/r and other optimal pediatric formulations

PEPFAR, MSD, and EGPAF commit to:

28. Partner on the assisted introduction of RAL granules for neonates, starting with the MoH of Eswatini, followed by other countries beginning early 2019, donating sufficient supplies at the outset of the project and then selling at no profit in low income and sub-Saharan African countries to ensure sustainability of the initiative.

GAP-f partners

All GAP-f partners commit to:

29. Sustain and strengthen collaboration among relevant stakeholders to ensure the most efficient development and uptake of optimal paediatric ARV formulations, in close consultation with the community of people living with HIV.
30. With the support of Unitaid, provide visibility on the demand for formulations in the pipeline (LPVr solid formulations, DTG 10 mg scored DT, RAL granules and RTV 25 mg).
31. Collaborate with PAWG to offer technical advice to national ERBs to accelerate the process.

CHAI commits to:

32. Collaborate with WHO to house and incubate the GAP-f partnership through its start-up phase.

MPP commits to:

33. Inform all countries in the paediatric license group on the status of paediatric ARV patents.

PENTA and IMPAACT commit to:

34. Rapidly develop and implement research actions (including carrying out specific studies to generate high quality evidence for regulatory submissions and high quality pharmacovigilance studies where needed) in the framework of GAP-f to accelerate access to innovative, high quality, and affordable drugs for children worldwide.
35. Ensure appropriate evidence generation from ongoing DTG studies to enable ViiV regulatory submissions by end 2019.

Pharmaceutical companies

Cipla commits to:

36. Bring RTV 25 mg to the market, producing first batch beginning in June 2019

Gilead commits to:

37. Prioritize development of low dose F/TAF dispersible tablet and complete investigation of low dose paediatric dose for 15-25kg by end of 2019
38. Undertake a bioavailability study for dispersible tablets of F/TAF by mid-2019 and begin enrolment of children under 15kg by end 2019, using parallel enrolment of weight bands where feasible.

Hetero commits to:

39. Submit LPV/r taste-masked pellets before end 2019
40. Begin development of DTG/3TC/ABC when data available to inform dosing and ratio.

Janssen commits to:

41. Ensure availability of DRV paediatric formulations in LMIC countries until DRVr FDC is available, and partner with GAP-f partners to develop transition plans to generic products once the generic FDC is available (expected in Q4 2020).

Macleods and **Mylan** commit to:

42. Submit the dossier for DTG 10mg scored dispersible tablet in Q1 2020[1]

ViiV Healthcare commits to:

43. Continue to work closely with FDA & EMA, IMPAACT and PENTA to strive to meet target submission date of December 2019 for DTG 5mg dispersible tablet and expanded weight band indication for 50mg.

Generic companies commit to:

44. Develop pediatric ARV products at a scale that will meet ultimate market demand as provided by GAP-f partners.

Donors

PEPFAR commits to:

45. Contribute to the funding of the secretariat of the Global accelerator for 2 years, plus additional funding upon achievement of milestones.

Elma commits to:

46. Contribute to the funding of the secretariat of the Global Accelerator and its activities as outlined in the product portfolio of the GAP-f business plan

[1] Subject to FDA acceptance of ViiV's DTG submission by end of 2019 and of the filing strategy that will use ViiV's IND for BE studies.

Unitaid commits to:

47. Provide financial incentives for the development of child-friendly formulations for ARVs, including DTG 10 mg dispersible tablet and LPV/r fixed-dosed combinations
48. Continue to strategically support GAP-f and the relevant participation of Unitaid-partners, and engage with Unitaid Executive Board in 2019 to explore funding new investment cases for paediatric ARV optimization and access.

International organizations

UNICEF

49. Support Ministries of Health to expand paediatric care and treatment within broader MCH services

Ministries of Health (Kenya and Zimbabwe) commit to:

50. Accelerate transition to more optimal regimens and formulations as described in WHO Guidelines and 2018 Optimal formulary by:
    - Developing transition plans by Q1 2019
    - Introducing DTG 50 mg for children above 25 kg by Q2 2019
    - Fully phasing out NVP based regimens by Q3 2019 in children older than 3 years and by Q2 2020 in children younger than 3 years.
    - Optimizing the use of LPVr solid formulations by prioritizing infants and children that most need them as well as using LPVr tablets as soon as a child can swallow them
    - Transitioning stable children to optimal regimens as outlined by in the WHO treatment guidelines and in the Optimal Formulary and Limited Use List
51. Increase viral load monitoring of children and ensure linkage of children failing first line drugs to 2nd and 3rd line drugs, working with donors and manufacturers to ensure availability of drugs in line with WHO guidelines.

Civil Society

Faith Based Organizations commit to:

52. Ensure FBO participation in local and national forecasting of optimal paediatric drug formulations.
53. Collaborate with GAP-f partners to develop, test, and disseminate training tools for treatment initiation with LPV/r and other optimal pediatric formulations.
54. Support and increase family treatment initiation and retention for children, adolescents, and families by:
    - Increasing identification and provision of same-day/same-appointment mother/infant pair treatment through FBO clinics;
    - Promoting male/father engagement in EMTCT programmes; and
    - Increasing stigma reduction interventions through mobilized faith leaders and faith communities
    - Providing social work interventions to assist fathers to support treatment and adherence of their partners and children living with HIV.
55. Foster and more actively participate in coordinated and collaborative advocacy to:
    - Increase funding for research & development, introduction and scale-up of priority pediatric drugs and formulations;
    - Accelerate regulatory processes for rapid adoption and uptake of optimal paediatric drugs and formulations; and
    - Ensure sustainable access to optimal testing and treatment for infants and children.

GNP+ commits to:

56. Support treatment preparedness programs, ensure improvement of treatment awareness among caregivers of children of all ages and adolescents, and work jointly with other stakeholders on treatment literacy and demand creation for new pediatric formulations.

All partners commit to:

57. Advocate for and support Ministries of Health to quickly adopt and implement WHO Pediatric HIV Testing and Treatment Guidelines
58. Advocate for and support Ministries of Health to rapidly transition to optimal paediatric formulations as outlined by the WHO guidelines, provide coordinated support for the development and implementation of transition plans, inform clinicians and patients of the value of transitioning to new formulations, and ensure communication of reliable information on the availability of new formulations in-country.
59. Tackle the stigma and discrimination in communities, schools, and healthcare settings that prevent children living with HIV from accessing testing and treatment.
60. Promote awareness of, political and financial support for, and full implementation of the Action Plan among all relevant stakeholders.

Annex 1: Participating Organizations

Faith-based Organizations
African Christian Health Associations Platform (ACHAP) / Christian Health Association of Ghana (CHAG)
CARITAS CONGO ASBL
Caritas Internationalis
Caritas Internationalis Nigeria
Catholic Relief Services
Children of God Relief Institute - Nyumbani
Community of Sant'Egidio DREAM program
World Council of Churches - Ecumenical Advocacy Alliance
Zimbabwe Association of Church Related Hospitals (ZACH)
Countries
Kenya – Permanent Mission to the UN, Geneva
Panama – Permanent Mission to the Holy See
Zimbabwe Ministry of Health and Child Care
Holy See
Caritas in Veritae Foundation
Dicastery for Promoting Integral Human Development
International Catholic Migration Commission
Permanent Observer Mission to the UN, Geneva
Secretary of State
Civil Society, Int'l Organizations & Donors
Clinton Health Access Initiative (CHAI)
Drugs for Neglected Diseases initiative (DNDi)
Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
FIND
GNP+
ICAP at Columbia University
IFPMA
International AIDS Society
International AIDS Society and The University of the West Indies, Kingston, Jamaica
Laudato si Challenge
Medicines Patent Pool
MSF Access Campaign
Ospedale Pediatrico Bambino Gesù/Università degli Studi di Roma Tor Vergata
PEPFAR
The Global Fund
UNAIDS
UNICEF
Unitaid
US Mission to the Holy See
World Health Organization
Pharmaceutical and Diagnostics Companies
Abbott
Becton, Dickinson and Company (BD)
CEPHEID
Cipla
Diagnostics for the Real World
Gilead Sciences, Inc.
Hetero Labs Ltd
Hologic
Johnson & Johnson
Macleods Pharmaceuticals Ltd.
MSD
Mylan
OraSure Technologies Inc
Roche Diagnostics International Ltd
ViiV Health Care
Regulators
European Medicines Agency (EMA)
FDA