Paediatric HIV Treatment Initiative

CLOSING THE TREATMENT GAP
THROUGH INNOVATION

UNITAID

medicines patent pool

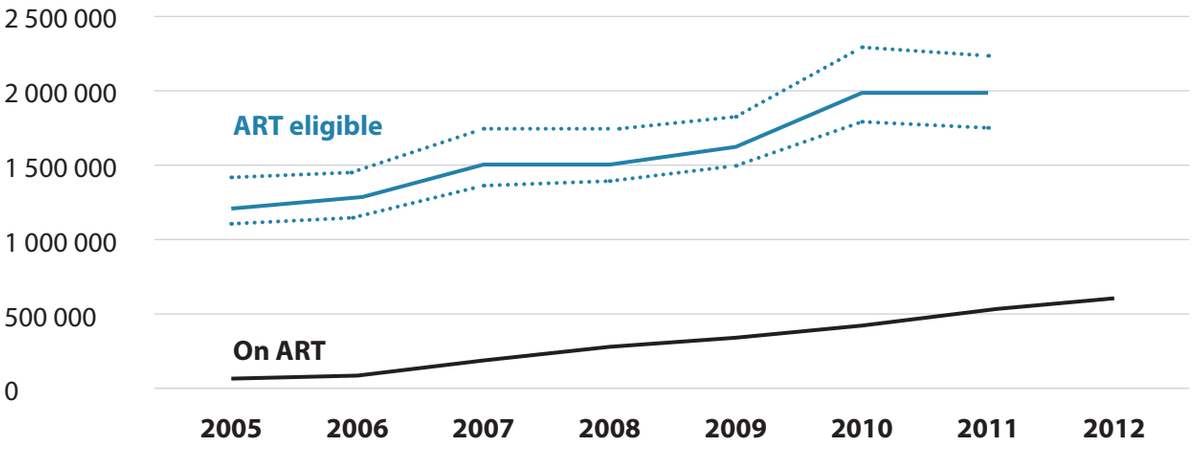
DNDi
Drugs for Neglected Diseases *initiative*

THE CHALLENGE

While the international community has made significant strides over the past 15 years to scale-up antiretroviral therapy (ART) in low- and middle-income countries for adults, progress in reaching children living with HIV/AIDS has significantly lagged behind. Of the 3.4 million children with HIV/AIDS, only 647,000 children receive ART. Despite efforts to reach the goal of eliminating new paediatric HIV infections by 2015, each day 700 children are newly infected and 500 children die of HIV/AIDS-related causes. Moreover, appropriate and affordable formulations, specifically as fixed-dose combinations (FDCs), are urgently needed to implement new treatment guidelines and to simplify treatment in a way that contributes to treating more children living with HIV. While the WHO has clearly identified key missing formulations and appropriate dosing schedules, intensified coordination among actors is needed to expedite their development and ensure rapid delivery and market uptake.

Figure 1. Treatment Gap between Children Eligible and Children Receiving ART

(Source: 2013 UNAIDS Report on the Global AIDS Epidemic)



THE RESPONSE - PHTI

UNITAID, the Drugs for Neglected Diseases *initiative* (DNDi) and the Medicines Patent Pool (MPP), therefore propose the Paediatric HIV Treatment Initiative (PHTI) to meet this need. In coordination with the WHO, the PHTI will strive to identify and overcome potential barriers to developing, producing, and making available priority medicines, with a particular focus on intellectual property (IP), research and development, and market shaping.

The key objective of the PHTI is therefore to catalyse development of, and accelerate access to, *new, better-adapted* paediatric ARVs and formulations to improve treatment for all children living with HIV.

The initiative is in line with UNITAID's Strategic Objective of increasing "access to affordable, adapted paediatric medicines to treat HIV/AIDS", with MPP's approach of expanding access to HIV medicines through voluntary licensing agreements, and with DNDi's partnership model aimed at developing and delivering new treatments for paediatric HIV. The PHTI will build upon and complement past and current initiatives.

A THREE-PRONGED APPROACH TO ENSURE APPROPRIATE HIV TREATMENT FOR CHILDREN

The PHTI will focus on 3 key areas:

- **Research & Development (R&D) for New Treatments:** Simpler treatment options, such as FDCs, are required to reduce the gap between children in need of treatment and those who receive ARVs. These options should allow simplified dosing by weight-band; easy implementation in resource poor settings; effective supply chain management; and optimal treatment sequencing.

- **Intellectual Property (IP) – Sharing Patents and Knowledge.** The development of new adapted paediatric formulations requires collaboration of each patent holder to pool IP, data, and know-how. A patent on one or more ARVs in an FDC, or on the FDC itself, can hinder affordability and patient access. IP challenges must be resolved to accompany the R&D and effective use of new ARVs in a timely manner, and incentives are required for companies to play their respective roles in delivering treatments for children.

- **Market shaping: Availability of treatment regimens for children living with HIV/AIDS:** Sustainability of the paediatric HIV market must be assured. To accompany scientific developments and new recommendations, and to ensure that the most relevant paediatric HIV formulations are produced, procured, and available in countries it is vital to stabilize the small and fragile paediatric market.

A SYNERGISTIC PROCESS

The PHTI will operate through a series of synergistic working groups to address these issues. These product specific working groups will, in turn, convene key players in the ARV medicines and paediatrics fields to pool knowledge, talent, resources, and IP for the ultimate goal of developing and delivering better paediatric formulations, and ensuring they are accessible. The initiative will therefore provide a dynamic platform for the exchange of information and contribute to creating the synergies among key partners necessary to accelerate the development and accessibility of specific WHO recommended products.

Pharmaceutical companies with key paediatric ARV products will be invited to join the initiative in order to share appropriate intellectual property rights, know-how, knowledge, and experience for the development of WHO's priority products for children.

Experts, researchers, product development organizations, financing organizations, and communities of people living with HIV will also be invited to join working groups. Financing organizations, for example, would ensure funding is available to conduct clinical trials when needed and to boost market uptake. Funding organizations will also be required to ensure procurement and purchasing of the new formulations.

The PHTI will not duplicate efforts of other organizations and initiatives. It seeks to create synergies among various key partners and support the work of the WHO and the Paediatric ARV Working Group (PAWG) to assess product priorities and clinical needs.

All children living with HIV have the right to appropriate and affordable treatment so as to lead healthy, normal lives. By building a partnership of key actors in the paediatric HIV field, UNITAID, MPP, and DNDi seek through the PHTI to ensure that this objective can become a reality.

JUNE 2013:
WHO Guidelines for HIV paediatric treatment

List of missing formulations compiled by the WHO and the Paediatric Antiretroviral Working Group experts:

Zidovudine (AZT) or abacavir/lamivudine/lopinavir/ritonavir (ABC/3TC/LPV/r): Important combination in 1st and 2nd lines. Currently unavailable in FDC form. LPV/r stand-alone and requires special storage conditions. Demand expected to increase within next five years, even more so if FDC available.

Abacavir/lamivudine/efavirenz (ABC/3TC/EFV): Important combination in 1st line that is recommended as a preferred regimen for children from three to 10 years. Demand expected to increase within the next five years.

Darunavir/ritonavir (DRV/r): Combination needed for 2nd line for children failing on lopinavir/ritonavir LPV/r-based combinations.

Other important products needed

Tenofovir/lamivudine (emtricitabine)/efavirenz (TDF/3TC (or FTC)/EFV): Preferred 1st line regimen for children more than 10 years of age.

Atazanavir/ritonavir (ATV/r): Used as an alternative to LPV/r in children >6 years of age. Its importance in 1st line treatment will increase once approved in <6y.

Raltegravir (RAL): For children who fail on PIs.

DTG-based combinations (e.g. TAF/3TC/DTG and ABC/3TC/DTG)

COBI as an alternative booster to RTV to overcome taste-masking and stability issues.