

HIV MID-YEAR MARKET MEMO, 2019

Highlighting the latest updates in HIV treatment, prevention, and diagnostics



Published: May 10, 2019

Questions about the HIV Mid-Year Market Memo?

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Introduction

Introducing the third edition of CHAI's **HIV Mid-Year Market Memo**, a brief that covers the latest trends in the HIV space in LMICs since the publication of CHAI's annual [HIV Market Report](#) in September 2018.

Data Sources for the Memo:

- 1 CHAI's annual data request to 25+ LMICs
- 2 Articles from journals and news outlets
- 3 Supplier and partner market intelligence
- 4 Major conferences and meetings

Acronyms Used

3HP: 12-week isoniazid-rifampentine
3TC: Lamivudine
ABC: Abacavir
APWG: ARV Procurement Working Group
ART: Antiretroviral therapy
ARV: Antiretroviral
CrAg: Cryptococcal antigen
DRV/r: Darunavir/ritonavir
DTG: Dolutegravir
EID: Early Infant Diagnosis

FTC: Emtricitabine
INSTI: Integrase inhibitor
LMIC: Low- and middle-income country
LPV/r: Lopinavir/ritonavir
NNRTI: Non-nucleoside reverse transcriptase inhibitor
PrEP: Pre-exposure prophylaxis
RFP: Request for proposal

SRA: Stringent regulatory authority
TAF: Tenofovir alafenamide fumarate
TB: Tuberculosis
TDF: Tenofovir disoproxil fumarate
VL: Viral load
WHO: World Health Organization
WHO PQ: WHO Prequalification

Adult ARV Market

TDF + 3TC + DTG (TLD) Market Overview

TLD orders in 2018 exceeded

35M packs

TLD is included in the guidelines of

60+ countries

The FDA has tentatively approved

5 suppliers



Informed Choice

WHO Guidelines were updated in December 2018 to emphasize a **woman-centered approach** to healthcare, and highlight the importance of **informed choice for use of DTG** by women.



TLD Research Developments

- 1 WHO guidelines expected to be released in July 2019 based on data from Tsepamo cohort and other data sources on risk of neural tube defects
- 2 [DTG used with 3HP](#) found to prevent TB effectively without necessary DTG dose adjustment or any serious adverse events
- 3 Data presented at CROI 2019 suggest modest weight gain with DTG use (Abs. [669](#), [670](#))
- 4 The FDA [approved](#) ViiV's Dovato (DTG/3TC) dual therapy for treatment-naïve patients

NVP Phase-Out

- Adult nevirapine (NVP) is no longer listed as first-line preferred or alternate by the WHO
- PEPFAR aims to phase out adult NVP use and has ceased procurement
- In 2017, NVP accounted for ~15% of the adult NNRTI/INSTI market

South Africa Tender

The results of the South African tender were released in Feb. 2019.

Price Highlights (USD)*

TLD	\$6.03
TDF+FTC+EFV (TEE)	\$6.39
LPV/r (200/50 mg)	\$14.61

*Average prices weighted by volumes across suppliers, on delivered basis, inclusive of 15% VAT, converted to USD from ZAR using the forex exchange rate of 14.35 ZAR (Dec. 31st, 2018).

Advanced HIV Disease (AHD)



WHO Definition of AHD

Adults and Children (Ages 5+)

CD4 < 200 or
WHO stage 3 or 4

Children (Ages <5)

All children under 5
living with HIV



~33% of people initiating ART in Sub-Saharan Africa have AHD

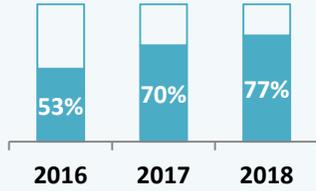
Unitaid and CHAI are collaborating to improve access to AHD commodities to reduce morbidity and mortality

Pediatric ARV Market

Pediatric Optimization

% of Peds Product Procurements Considered "Optimal"

of those monitored by the APWG



Source: 2019 APWG KPI Analysis



DTG (50 mg)

The WHO has updated their treatment guidelines and now recommends the adult dose and formulation of DTG (50 mg) for children $\geq 20\text{kg}$



LPV/r (40/10 mg)

Cipla and Mylan are planning on increasing production of pellets/granules, such that there should be **significantly more supply available by early 2020**



Pediatric NVP

PEPFAR and the Global Fund are **phasing out peds NVP procurement** (for treatment) given high rates of pre-treatment drug resistance and lower efficacy than other ARVs

2018 PADO 4 Priority Products

DTG (10 mg) Disp. Scored

ABC/3TC/DTG (60/30/5 mg) Disp.

DRV/r (120/20 mg)

TAF/3TC (or FTC)

TAF/(3TC or FTC)/DTG

- Generic development supported by a financial incentive award from Unitaid via CHAI, as well as the technical expertise of ViiV Healthcare
- For use by children 3-19.9kg (50 mg adult tablet can be used for those $\geq 20\text{kg}$)
- ViiV expected to file 5mg disp. tablet by Dec. 2019
- Commitments from generics as part of the incentive program to file in Q1 2020
- Would provide WHO-recommended treatment as a convenient FDC
- Efforts underway to accelerate rapid development and commercial availability

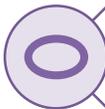
Prevention



The Phase III Discover trial demonstrated that TAF/FTC is non-inferior to TDF/FTC for daily oral PrEP amongst men who have sex with men; Gilead submitted an application for FDA approval in April 2019



In Q3 2018, the Biomedical Prevention Implementation Collaborative (BioPIC) was launched, bringing together 80+ organizations to develop a comprehensive, coordinated product introduction agenda and access strategy for long-acting cabotegravir for prevention



The dapivirine vaginal ring is currently under review by the European Medicines Agency; The International Partnership for Microbicides is working to develop a rollout strategy pending approval

Increase in Oral PrEP Initiations



~200%

South Africa
(Dec. 2017 – Dec. 2018)



>145%

Zimbabwe
(Dec. 2017 – Oct. 2018)



>92%

Kenya
(Mar. 2018 – Oct. 2018)

Diagnostics



Point of Care (POC)

Abbott's m-PIMA received **WHO PQ for POC VL testing** in Apr. 2019, making it the first true POC VL offering in the market

PEPFAR's COP2019 guidance supports the use of **POC VL testing for pregnant and breastfeeding mothers**

Integrated TB & HIV VL/EID testing on the GeneXpert platform has been found to be feasible and to not negatively impact TB services



Pricing

All-inclusive pricing continues to move forward, with PEPFAR launching a global RFP for HIV VL and EID requiring suppliers to make all-inclusive bids, and Abbott announcing an all-inclusive price for m-PIMA at the Vatican in Dec. 2018

Cepheid's surcharge (rather than the usual warranty) has been offered to the market with **countries beginning to opt in**



PEPFAR's **COP2019 guidance** supports **CrAg and TB urine LAM testing** for advanced HIV disease monitoring



BioLytical's INSTI HIV self-test received WHO PQ approval in Nov. 2018, becoming the **second self-test** with this designation

This memo was made possible through the generous support of Unitaid, with complementary support from the UK Department for International Development and the Bill & Melinda Gates Foundation

