

HIV MID-YEAR MARKET MEMO, 2020

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



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Introducing the fourth 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 2019.



Questions about the HIV Mid-Year Market Memo?

Please feel free to reach out to [Vineet Prabhu](mailto:vprabhu@clintonhealthaccess.org) (vprabhu@clintonhealthaccess.org)

COVID-19

New and rapidly evolving challenges presented by the COVID-19 pandemic have affected many ongoing projects and developments in the HIV space. These impacts, as well as key recommendations to ensure continuity of HIV services in these challenging times, are highlighted throughout the memo. Additional COVID-19 resources for national HIV programs can be found at <https://www.newhivdrugs.org/covid-19>.

Test Smart



At ≤ \$1/test, PEPFAR would support facility-based HIVST to increase testing uptake among priority populations while reducing burden on health care workers

HIV Self-Testing (HIVST)

Current Price (USD)
\$2.00 - \$3.10



4 HIVSTs are WHO Prequalified (PQ), with more expected in 2020



Updated WHO Guidelines on HIV Testing

Recommend transition to **3 consecutive reactive tests** for HIV-positive diagnosis in all settings
– Previously only 2 tests were recommended where national HTS positivity was ≥ 5%



Strong recommendation for syphilis testing in antenatal care. Countries should consider use of **HIV/syphilis dual test**

(Updated Nov 2019)

Expanded use of HIVST could reduce client and HCW contact while maintaining essential HIV testing in the COVID-19 era

Treat Right

By Addressing Advanced HIV Disease (AHD)

PEPFAR and the Global Fund support and encourage the purchase and use of a number of AHD commodities.

Through Unitaid-driven agreements, there have been a number of AHD-related price reductions and new product developments.



	PEPFAR	Global Fund
CD4 Testing	✓ where AHD prevalence >15%	✓ no minimum AHD prevalence rate
CrAg Screening	✓ under 200 CD4 cells/μL Including preemptive therapy and CM treatment	✓ under 200 CD4 cells/μL
TPT	✓ required	✓ required where high TB/HIV co-infection

Pricing Updates	Product	Price (USD)	Suppliers
	SFC (500 mg) - 100	\$75/pack (prev. \$110)	Mylan, Strides
	RPT/INH (300/300 mg) - 36	\$15/pack	Macleods
	RPT (150 mg) - 24	\$5/pack (prev. \$15: press release)	Sanofi
	VISITECT AHD RDT	\$3.98/test (new: press release)	Omega

Focal AHD commodities are now monitored by the APWG and included in quarterly APWG forecasts.

For tools to support the introduction of AHD products, see the AHD toolkit at <http://www.differentiatedcare.org/Resources/Resource-Library/Global-Advanced-HIV-DiseaseToolkit>

With Optimal ARVs for Adult Patients

TLD Market Overview

120M +

30-pack equivalents of TLD ordered between 2017-2019

3M +

patients on TLD (Dec '19)

120 + countries

have included TLD in national guidelines

7 suppliers

have US FDA approval or WHO PQ for TLD



Including South Africa where TLD rollout began in Dec 2019.

Weight Gain

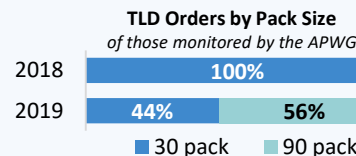
Results from the ADVANCE study show higher incidence of weight gain with DTG, especially in those on a regimen also containing TAF.

Supported by Unitaid, CHAI and AfroCAB convened a community forum in Feb 2020 to discuss this issue. The community concluded:

"We believe that people should be fully informed about the benefits and possible side effects of DTG. As the beneficiaries, we believe in our ability to make informed decisions and we demand a choice in our treatment options"

Multi-Month Dispensing (MMD)

There have been significant increases in orders of larger pack sizes of TLD as countries move toward MMD.



Source: 2020 APWG KPI Analysis

PEPFAR now requires that MMD must be part of annual quantifications and will **no longer procure 30-pill bottles** beginning in 2020.

MMD is also an opportunity to decongest health facilities and limit exposure of PLHIV to COVID-19

Adult and pediatric **LPV/r** global patent rights will no longer be enforced by AbbVie, increasing generic access in MICs

However, due to anticipated shortages of LPV/r (200/50 mg) tablets, programs should consider WHO-recommended 2L alternatives: **DTG** and **ATV/r**

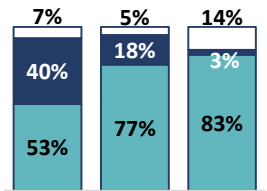
Treat Right

With Optimal ARVs for Pediatric Patients

Pediatric Optimization

There has been a continued shift toward procurement of optimal pediatric products (according to data from the APWG).

% of Procured Peds Products Considered "Optimal" of those monitored by the APWG



2016 2018 2019
 ■ Optimal ■ ZLN □ Other
 Source: 2020 APWG KPI Analysis

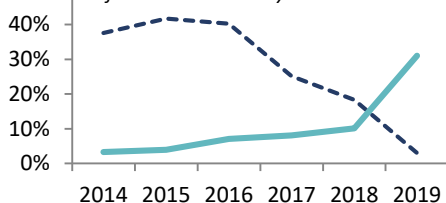
--- ZLN Disp Triple FDC
 — Pediatric LPV/r Formulations
 - LPV/r (100 mg/25 mg) Tablet
 - LPV/r (40 mg/10 mg) Oral Pellet/Granule
 - LPV/r (80 mg + 20 mg/ml) Oral Solution



Pediatric ZLN has been drastically phased out.

LPV/r-based products were among the top procured by volume in 2019.

% of Total Pediatric Volumes Ordered of those monitored by the APWG



Source: 2020 APWG KPI Analysis

LPV/r 2-in-1 Granules & Pellets

- Supply constraints easing after an extended period of challenge
- The APWG maintains a [LPV/r dashboard](#) to assist procurers with supply availability of key pediatric LPV/r-based products

Pediatric DTG

- ViiV Healthcare filed DTG 5 mg disp. tablets with the US FDA and the EMA in Dec 2019
 - US FDA target action (i.e., PDUFA) date in June 2020
- Mylan expected to file **10 mg disp. scored tablets** with the US FDA in Q2 2020
 - Anticipated tentative **approval in late Q4 2020**
- Macleods to file **10 mg disp. scored tablets** with the US FDA at a later date due to impact of COVID-19

ABC + 3TC + LPV/r 4-in-1 Granules

- Cipla filed with US FDA in Oct 2019 but approval has not yet been granted as of publication (PDUFA date was April 15, 2020)

Regulatory filings and review timelines may be impacted by COVID-19

Stay Negative

CAB-LA

Bi-monthly injections of long-acting cabotegravir are highly effective for the prevention of HIV infection in cisgender men and transgender women who have sex with men, according to interim data from the large-scale efficacy trial [HPTN 083](#).

Data is still being collected on use by cisgender women in the companion HPTN 084 study.

Oral PrEP

Oral PrEP Initiations

Selected Highlights, as of April 2020

Kenya	56,000
South Africa	44,500
Zambia	23,500
Uganda	21,500

~ 260,000

Oral PrEP initiations in LMICs as of Q1 2020

Source: [PrePWatch](#), acc. May 2020

Descovy: TAF/FTC (25/200 mg)

was approved by the US FDA in Oct 2019 for use as oral PrEP excluding individuals at risk from receptive vaginal sex.



Gilead is required to conduct a clinical trial for cisgender women and adolescent girls by 2024.

Until such data are available, this product may **have limited reach** for LMIC settings where women are a priority population for oral PrEP.



Uhambo (HVTN 702)

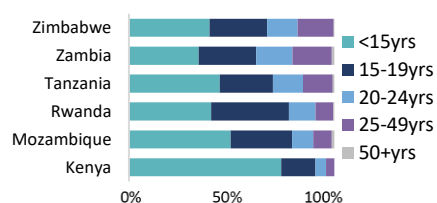
HIV vaccine trial was stopped after results showed the vaccine was ineffective in preventing HIV transmission.

A number of other ongoing HVTN and HPTN trials have been paused or have stopped recruitment as a result of COVID-19

Voluntary Medical Male Circumcision (VMMC)

Based on analysis of adverse events and impact on immediate incidence, circumcision of males under the age of 15 (including EIMC) **will no longer be funded by PEPFAR***

Age Distribution of VMMCs in 2018



This could have a significant impact in countries that have historically circumcised large numbers in the <15 age group.

Source: [Global AIDS Monitoring Database](#)

*Some exceptions are being considered.

Data Sources:

- 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
- 5 PEPFAR and Global Fund technical guidance

5FC: Flucytosine
3TC: Lamivudine
ABC: Abacavir
AHD: Advanced HIV disease
APWG: ARV Procurement Working Group
ARV: Antiretroviral
ATV/r: Atazanavir/ritonavir
CrAg: Cryptococcal antigen
CM: Cryptococcal meningitis
DTG: Dolutegravir
EIMC: Early infant male circumcision
EMA: European Medicines Agency
FTC: Emtricitabine

Acronyms Used

HCW: Healthcare worker
HIVST: HIV self-testing
HPTN: HIV Prevention Trials Network
HTS: HIV testing services
HVTN: HIV Vaccine Trials Network
INH: Isoniazid
LMIC: Low- and middle-income country
LPV/r: Lopinavir/ritonavir
MIC: Middle-income country
MMD: Multi-month dispensing
PDUFA: Prescription Drug User Fee Act (established US FDA target action dates)

PrEP: Pre-exposure prophylaxis
RDT: Rapid diagnostic test
RPT: Rifapentine
TAF: Tenofovir alafenamide fumarate
TB: Tuberculosis
TDF: Tenofovir disoproxil fumarate
TLD: TDF/3TC/DTG
TPT: TB preventative therapy
VMMC: Voluntary medical male circumcision
WHO: World Health Organization
WHO PQ: WHO Prequalification
ZLN: AZT/3TC/NVP

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