

# HIV MID-YEAR MARKET MEMO, 2018

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



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Questions about the HIV Mid-Year Market Memo?  
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## Introduction

Introducing the second edition of CHAI's **HIV Mid-Year Market Memo**, an informational brief that covers the latest trends in the HIV space in low- and middle-income countries (LMICs) since the publication of CHAI's annual [ARV Market Report](#) in September 2017.

### 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

## Key Mid-Year HIV Market Themes

### Transition to TLD

There's wide excitement about the transition to TLD, and while new preliminary data from Botswana may impact the rate of transition in certain countries, over 10 LMICs continue to plan a full first-line transition to this optimal product

### Oral PrEP Uptake

Oral PrEP continues to be rolled out in LMICs, with over fifteen countries including oral PrEP in their national guidelines, and new access points such as university health clinics being piloted for delivery

### Scale-up of new testing modalities

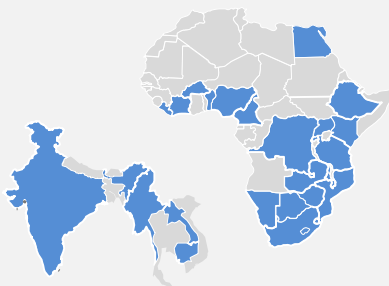
Point-of-care EID testing continues to be scaled up in many LMICs. Additionally, self-testing is generating interest from both countries and suppliers as a way to improve testing rates

## Adult ARV Market

### TDF+3TC+DTG (TLD) Market Overview

#### Demand

**Inclusion of DTG in Tx Guidelines**  
Or confirmed plans



Not pictured: Armenia, Belarus, Brazil, Cape Verde, Georgia, Guatemala, Haiti, Iran, Jamaica, Kyrgyzstan, Lebanon, Pakistan, Syria, Ukraine, Uzbekistan, Yemen

#### Supply

Currently approved suppliers  
**Aurobindo (FDA\*)**  
**Cipla (GF ERP)**  
**Hetero (GF ERP)**  
**Macleods (GF ERP)**  
**Mylan (FDA\*)**  
**Sun Pharma (GF ERP)**

GF PPM reference price, June 2018  
**US \$6.25 per pack**

Anticipated global TLD capacity by Q4 2018  
**Well over 8M packs per month**

Please find the ARV Procurement Working Group's (APWG) full [recommendations on TLD procurement and supply security here](#)

### 2L ARVs

#### GF PPM 2L ARV Pricing

June 2018, USD, PPPY

\$221      \$179

LPV/r

ATV/r

**US \$42 PPPY**

Estimated annual savings per patient from switching from LPV/r- to ATV/r-based adult second line regimens

Tentative FDA-approved suppliers of ATV/r:

**Cipla**  
**Mylan**  
**Emcure**

### DTG Operational Research

Unitaid & CHAI, 2017-2018

#### Locations

Nigeria Uganda

#### Key Goal

Describe the experience and acceptability of using DTG as part of alternate 1L ART from the patient and provider perspectives

#### Outcomes

Early results very positive in terms of preference for DTG. **Results will be shared on CHAI's [New Product Introduction Toolkit](#)**

### Other TLD News

- 1 Week 24 results from INSPIRING trial show that double-dosed DTG is safe and effective in HIV patients co-infected with TB
- 2 Preliminary Botswana data suggests potential safety concern for DTG use during conception, but data for other populations remains strong, and [PEPFAR](#) and other partners continue to encourage TLD rollout in a responsible manner
- 3 WHO to disseminate new HIV guidelines, including use of DTG, at AIDS 2018 in Amsterdam in July

### TAF/FTC/DTG (25/200/50 mg)

- Mylan received tentative FDA approval in Q1 2018
- Likely sole supplier until 2019
- Not currently in WHO guidelines due to questions on use in TB and pregnancy

**CHAI-Unitaid RfP to accelerate [DRV/r \(400/50\) affordability](#)**

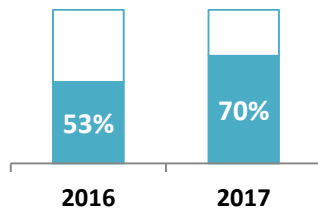
In December 2017, CHAI and Unitaid released an RfP to accelerate affordability of a generic fixed-dose combination of DRV/r (400/50), widely considered the most effective protease inhibitor

\*Tentative FDA approval

# Pediatric ARV Market

## Pediatric Optimization

**% Peds Product Procurements Considered "Optimal" by IATT**  
*Of those monitored by the APWG*



### EFV (200 mg) Scored

Micro Labs joins Strides as the second tentative FDA-approved supplier of EFV (200 mg) scored tablets, the only EFV-based formulation listed as optimal on the IATT Formulary

For more information on product optimization, see the below memos:

- [Optimizing Pediatric Treatment](#)
- [Optimizing ARV Formularies](#)

## Pediatric Product Pipeline Information

### LPV/r (40/10 mg) "Granules"

Another solid formulation alternative to cold chain-dependent oral solution. First generic approval expected **late 2018**

### ABC/3TC/LPV/r "4-in-1"

Provides WHO-preferred regimen for patients less than 3 years old in one formulation (granules). First generic approval expected **mid-2019**

### ABC/3TC/EFV "ALE"

Provides WHO-preferred regimen for patients 3-10 years old in one dispersible pill. First generic approval expected **late 2019**

### DTG (10 mg)

#### Dispersible and Scored



In Nov. 2017, CHAI and Unitaid released an RFP to accelerate development of and access to generic pediatric dolutegravir.

The project involves a close collaboration with ViiV, which will also contribute to the reduction of the generic development timeline by 2-5 years since we will have access to a significant body of technical evidence earlier and in more detail than is typical in a generic development program.

Awards to two generic manufacturers will be announced this year.

In adults, DTG has been shown to be more tolerable, efficacious, and have a higher genetic barrier to resistance than EFV- or LPV/r-based treatments.

Results from IMPAACT P1093 and ODYSSEY trials will inform both pediatric dosing levels and tolerability/efficacy of dolutegravir in smaller weightbands.

## Prevention

### Oral PrEP Updates

15+

LMICs have included oral PrEP guidance in national treatment guidelines



In an innovative effort to reach young people, South Africa has started rolling out oral PrEP in university health clinics



The Prevention Market Manager (PMM) has developed a [Global PrEP tracker](#) to consolidate country-level oral PrEP information in one place



### VMMC

~15M

Circumcisions done between 2007-2016 in 15 countries in sub-Saharan Africa, to avert > 500K infections through 2030

>3.6M

Additional circumcisions have been done between 2017 and Q1 2018

### Long-acting Injectables (LAIs)

HPTN 084, a phase III trial testing the efficacy of LAI cabotegravir in ~3,200 sexually active women in sub-Saharan Africa, officially launched in November 2017 and joins HPTN 083 (focused on MSM and transgender women) in testing the efficacy of cabotegravir-based LAIs for prevention.

HPTN 084's estimated primary completion date is May 2022, while HPTN 083 has an estimated primary completion date of late 2021. These completion dates are estimates as they are endpoint-driven.

## Diagnostics

### Viral Load

25% increase

In viral load testing in global LMICs between 2016 and 2017



Malawi, DRC, and Zimbabwe are piloting POC viral load testing

50% reduction

In price of HIV and HCV GeneXpert tests in India at IPAQT consortium labs

### Self-Testing

The WHO released its first-ever [Essential Diagnostics List](#), and included an HIV self-test on the list



25+

LMICs will have rolled out or piloted HIVST by the end of 2018 to improve testing among hard-to-reach populations

### POC EID Testing

12+ LMICs are piloting or scaling up POC EID in an effort to improve linkage to treatment by reducing turnaround time for children to be informed of their HIV status

### Roche Plasma Separation Card

Roche has developed a Plasma Separation Card that allows for the stable storage and transport of plasma under typically unsuitable conditions