

# USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

## Procurement and Supply Management

# THE DOLUTEGRAVIR OPPORTUNITY

## Managing supply chain risk for the introduction of a new antiretroviral (ARV) medicine

**Optimization of ARV regimens aims to ensure that people living with HIV receive the best medicines available in the most efficient and cost-effective way. The newest movement to optimize the preferred first-line ARV treatment involves the introduction of dolutegravir (DTG).**

DTG is a relatively new ARV available in generic form in low- and middle-income countries. It is an integrase inhibitor that blocks an HIV enzyme (a protein that starts or increases the speed of a chemical reaction) called integrase. By blocking integrase, integrase inhibitors prevent HIV from multiplying and can reduce the amount of HIV in the body. As a single dose, in conjunction with other drugs to form a regimen, 50mg DTG single has been on the market in developing countries for a couple of years. However, its relatively high price and unavailability in a triple fixed-dose form limited significant uptake. Botswana, however, was an early adopter of the DTG single through a special initiative of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

In August 2017, the US Food and Drug Administration (FDA) provided tentative approval for two Indian generic ARV suppliers – Aurobindo Pharma and Mylan Laboratories Limited – for the fixed-dose combination of tenofovir 300mg /lamivudine 300mg /dolutegravir 50mg (TLD), reducing one barrier for adoption in developing countries.

Many clinicians are excited about the introduction of TLD because the drug combination provides many clinical benefits, including, according to the World Health Organization (WHO), “improved tolerability, higher antiretroviral efficacy, lower rates of treatment discontinuation, a higher genetic barrier to resistance, and fewer drug interactions than other ARV drugs,” such as efavirenz or atazanavir. PEPFAR recently instructed programs that it supports a quick transition to TLD.

### PRICE WILL IMPACT THE TRANSITION

In September 2017, UNAIDS and other donors announced “a breakthrough pricing agreement” with Aurobindo and Mylan. Under the agreement, in which PEPFAR and USAID participated, the price of DTG-containing regimens will be around US\$75 per person/per year, considerably lower than the \$80 to \$90 price for other regimens, in exchange for a commitment for donors for a minimum volume of orders. Cost savings from TLD can then be used to put even more patients on treatment.

This pricing agreement could also accelerate countries' plans to transition to TLD from tenofovir/lamivudine/efavirenz (TLE), the most commonly prescribed first-line regimen, and other regimens. This may be especially true in April, when the price guarantee will be in place for ARVs delivered after April 1.

**PEPFAR** highly approves of TLD and encourages countries to adopt this ARV regimen soon.

HIV/AIDS programs can place orders for TLD now.

Orders delivered after April 1, 2018, will benefit from the global price agreement.

GHSC-PSM has developed a forecasting tool to help HIV/AIDS programs manage a smooth transition from TLE and other ARVs to TLD.

**For more information:**  
**GHSC-PSM's TLD Team**

[TLDinfo@ghsc-psm.org](mailto:TLDinfo@ghsc-psm.org)  
[www.ghsupplychain.org](http://www.ghsupplychain.org)



## OPPORTUNITY BRINGS SUPPLY CHAIN RISKS

Introducing a new drug regimen requires changes at multiple levels of the supply chain. For example, quantification and forecasting exercises that engage all partners and donors are essential to ensure the new regimen is incorporated into supply plans and is adequately funded.

Based on past experience with other new ARV introductions, transition to TLD also brings potential risks, such as global demand outpacing manufacturing capacity and stockout or overstock of TLD, TLE, and other ARV regimens at all levels of the supply chain. GHSC-PSM is working with its field offices, suppliers, USAID, and global and local partners to manage a smooth transition and reduce these risks. GHSC-PSM country offices are using a TLD transition forecasting tool, the first of several tools currently in development.

## A GROWING NUMBER OF COUNTRIES ANTICIPATE TRANSITIONING TO TLD IN 2018

GHSC-PSM has surveyed countries in a variety of ways over the past few months. Based on the data collected and other sources of information, currently five countries – Botswana, Malawi, Nigeria, Tanzania, and Uganda – have firm plans to transition first-line patients to DTG in 2018:

- **Botswana** is utilizing DTG single-dose but has no plans to transition to the fixed-dosed TLD
- **Malawi** plans to transition all new and existing patients to TLD by the end of 2018.
- **Nigeria** will prescribe TLD to new patients and to efavirenz-intolerant patients and has placed its first order with GHSC-PSM for deliveries in April and May, 2018.
- **Tanzania** has indicated plans to place orders for DTG and TLD with GHSC-PSM and the Global Fund in 2018.
- **Uganda** will prescribe TLD to new patients as a first-line ARV, and will conduct a pilot study transitioning 450 patients currently on other ARV regimens.

Many other countries are in the process of reviewing their standard treatment guidelines and considering the inclusion of TLD. In July, 2017, the World Health Organization released a policy brief reiterating the organization's recommendation of DTG as an alternative ARV option. The recent guidance from PEPFAR and release of the pricing agreement might very well accelerate transition plans in some countries.

Countries with updated transition plans or processes should reach out to PSM at [TLDinfo@ghsc-psm.org](mailto:TLDinfo@ghsc-psm.org).

## TWO TLD SUPPLIERS ARE AVAILABLE, WITH MORE TO COME

As noted above, two ARV suppliers have received FDA approval for TLD. Several other suppliers are expected to file for approval by early 2018. As no orders have yet been received for TLD, Aurobindo and Mylan are not yet estimating manufacturing capacity. However, once orders are received, these suppliers are prepared to scale up production, having either acquired or built facilities to augment their manufacturing capacities to prepare for TLD production while maintaining their TLE production capabilities. Based on information received to date, supply is anticipated to meet demand in 2018.

\* Based on 2018 PEPFAR Country Operating Plans

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This document will be updated frequently. For the latest version and for more information and links to TLD resources, go to

<https://www.ghsupplychain.org/global-health-area/hiv/aids>

### For more information:

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