

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 most appropriate 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).

A new generic ARV, DTG, is now available in low- and middle-income countries. It is an integrase inhibitor. By blocking integrase, the inhibitor prevents 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 of DTG as a single tablet (via innovator form) 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 has limited significant uptake.

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

The drug combination provides many clinical benefits, according to the World Health Organization (WHO), including “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 has instructed programs that it supports a quick transition to TLD “as the first and second line anti-retroviral (ARV) treatment for adolescents (10 years old and older with body weight of 30 kg or more) and adults.”

PRICE WILL IMPACT THE TRANSITION

In September 2017, UNAIDS and other donors announced “a breakthrough ceiling pricing agreement” with Aurobindo and Mylan. Under the agreement, in which PEPFAR participated, the price of triple-fixed dose TLD will be around US\$75 per person/per year, lower than the price for other regimens.

PEPFAR is encouraging countries to transition to TLD 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:
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The price ceiling comes into effect for TLD orders to be delivered after April 2018. This agreement is open to all partners regardless of order volume. Global fund, and governments can also participate.

This pricing agreement could also accelerate countries' plans to optimize the ARV formulations provided to patients, and transition patients to TLD from tenofovir/lamivudine/efavirenz (TLE) and other ARV formulations.

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 a new regimen is incorporated into supply plans and is adequately funded.

Based on past experience with other new ARV introductions, the transition to TLD brings potential risks, such as global demand outpacing manufacturing capacity. GHSC-PSM is working with its field offices, suppliers, USAID, and global and local partners to manage a smooth transition and reduce risks. GHSC-PSM country offices have access to a TLD forecasting tool, to help stakeholders in country quantify the TLD needed to begin a transition to the new ARV.

TWO TLD SUPPLIERS ARE AVAILABLE, WITH MORE TO COME

As noted above, two ARV suppliers have received FDA approval for TLD. Several other suppliers have and are expected to file for approval in the near term. All current and potential 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 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/TLD>

For more information:

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