USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

PROCUREMENT AND SUPPLY MANAGEMENT

THE DOLUTEGRAVIR OPPORTUNITY

Frequently asked questions

Q. What are dolutegravir and TLD?

A. 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. TLD is a fixed-dose combination (FDC) of tenofovir 300mg /lamivudine 300mg /dolutegravir 50mg (TLD) and is considered a desirable FDC to be used as a first-line regimen in people living with HIV.

Q. Why are HIV/AIDS treatment programs transitioning to TLD?

A. Many clinicians are excited about the introduction of the fixed-dose combination of TLD because the 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 that other ARV drugs."

DTG's high barrier to drug resistance is especially important for countries — of which there are many — where it is not possible to do drug resistance testing, and where there are not very many treatment options.

Q. What is PEPFAR's position on the transition to TLD?

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

Q. Which countries are planning to transition to TLD?

A. Currently five countries — Botswana, Malawi, Nigeria, Tanzania, and Uganda — have firm plans to transition first-line patients to DTG in 2018.

Q. Which manufacturers are producing TLD for developing countries?

A. 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 TLD.

Q. What will be the price for TLD?

A. Under a pricing agreement between key donors and the first two ARV manufacturers to receive FDA tentative approval for TLD (Aurobindo and Mylan), the price of DTG-containing regimens is approximately US$75 per person/per year for orders delivered after April 1, 2018. For current pricing through GHSC-PSM, see our catalog at https://www.ghsupplychain.org/for-suppliers/products

Q. What are typical lead times for ordering TLD?

A. Lead times can vary greatly from country to country, depending on product registration, waiver requirements, and customs clearance. To determine exact lead times, those placing orders should discuss with their procurement agent, including GHSC-PSM.

Q. What are the supply chain risks in transitioning?

A. 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.

Q. What is GHSC-PSM doing to help countries manage the transition?

A. 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 are using a TLD transition forecasting tool, the first of several tools currently in development.

Q. What other tools are available to help countries manage the transition?

A. GHSC-PSM provides a forecasting tool to help plan the transition between TLE, currently the most commonly used first-line ARV, and TLD. Anyone can request the tool by emailing TLDinfo@ghsc-psm.org The Clinton Health Access Initiative also provides a number of tools at https://www.newhivdrugs.org/

Q. Where can I get more information about TLD?

A. The GHSC-PSM website has a comprehensive list of additional resources — including basic information, tools, and journal articles — available from the project and others sources. To access them visit https://www.ghsupplychain.org/node/373.