

# Recommendations on Country Procurement during the Transition to TLD

## *ARV Procurement Working Group Memo*

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### Introduction

The generic antiretroviral (ARV) market will be in a state of transition in 2018 with the introduction of a new fixed-dose combination (FDC) to serve as an alternative first-line treatment for adults. The product, known as 'TLD', is a single pill comprised of tenofovir disoproxil fumarate (TDF), lamivudine (3TC), and dolutegravir (DTG). Demand for TLD is expected to be significant; the ARV Procurement Working Group (APWG), in coordination with various procurement agents, donors, and other partners, has compiled key recommendations for procurement of TLD to help country programs prepare adequately for this transition. Ultimately, the goal is to ensure all patients, both new and existing, have access to a sustainable supply of ARVs before, during, and after the transition to TLD, while attempting to limit the amount of wasted legacy ARV stock.

### Supply Overview

As of February 2018, Aurobindo and Mylan are the two approved manufacturers of TLD. Commercial manufacturing of TLD is expected to ramp-up significantly in Q1 2018 with at-scale production for the two suppliers likely being reached around mid-2018. Starting in Q4 2018, with the expected addition of more approved suppliers of TLD and approval of additional manufacturing sites for Aurobindo and Mylan, the anticipated global TLD capacity is expected to be well over eight million packs per month. The APWG will have monthly calls with TLD generic manufacturers to map known demand against supply and to provide the opportunity to mitigate any potential issues in a coordinated, rapid fashion.

### Demand Outlook and Recommendations

Because several high-volume countries such as Kenya, Nigeria, South Africa, Uganda, and Zambia have indicated plans to move to TLD in 2018, the APWG anticipates high demand for the product in the year ahead. To ensure supply security during the transition to TLD, the APWG recommends country programs:

- **Plan orders with as much advance notice as possible to procurement agents and suppliers.** Lead times may be slightly longer during the first stage of transition, but are expected to decrease as steady-state production is reached. Preferably notify procurement agents 6-12 months in advance.
- **Stagger large TLD orders into smaller deliveries to avoid overburdening the system.** To avoid overburdening suppliers with one single order representing a very significant volume, the APWG recommends orders be staggered across many smaller deliveries.
- **Share 12-18 month procurement plans for TLD with the APWG and partners.** Country-level procurement plans, that include the TLD transition and beyond, will help the APWG put together a global overview of TLD demand to map against existing supply capacity.
- **Ensure sufficient buffer stock throughout the transition and beyond.** TLD roll-out should begin once there is sufficient buffer stock built-out nationally. Countries should additionally try to phase-in TLD at rates that will minimize wastage of legacy first-line adult products.

### For further information or assistance please contact:

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*Additional resources to support the transition to TLD are available through USAID as well as the [HIV New Product Introduction Toolkit](#).*