

# Briefing Note

## Accelerating the introduction of pALD to simplify treatment for children living with HIV

Date published: 24 January 2023

### Purpose

This Briefing Note describes key considerations for the introduction of pALD, a new product simplifying treatment for children living with HIV, in national HIV programs.

### Background

The World Health Organization (WHO) recommends dolutegravir (DTG)-containing HIV treatment regimens for children living with HIV who weigh at least 3 kilograms (kg).<sup>1</sup> Since 2021, ministries of health across low- and middle-income countries have introduced pediatric dolutegravir 10mg dispersible, scored tablets (pDTG) alongside abacavir/lamivudine 120/60mg dispersible and scored tablets (pABC/3TC) for young children.

ABC/3TC/DTG 60/30/5mg, known as pALD, is a new pediatric product which combines abacavir, lamivudine and dolutegravir into one dispersible tablet. Children at least 3 months of age and between 6 and 25 kg are eligible for this product. The combined product simplifies caregiver administration (i.e., no splitting of tablets, administration from one rather than two bottles) and minimizes the likelihood of monotherapy (whether accidentally or because of stock-outs). The product also simplifies supply chains.

**The Global Fund encourages national HIV programs to transition to pALD.**

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<sup>1</sup> "Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach," Guidance, World Health Organization, last updated July 16, 2021, <https://www.who.int/publications/i/item/9789240031593>.

## Key Considerations

Countries should identify the most efficient and effective approaches for product inclusion in national treatment guidelines, forecasting and quantification exercises, and supply chain processes and documents. Key considerations for national HIV programs planning to support the introduction of pALD include:

- **Partnership support.** Partners have developed resources to support pALD adoption and implementation. These include the Global Accelerator for Pediatric Formulations (GAP-f) brief (available in English, French, Spanish, Portuguese, and Swahili)<sup>2</sup> and CHAI-Unitaid pALD FAQs<sup>3</sup> and product profile.<sup>4</sup> PEPFAR-supported programs<sup>5</sup> are required to transition to pALD.
- **Supply updates.** Generic supply is available and no supply constraints are expected. To date, three generic manufacturers ([Aurobindo](#), [Cipla](#), [Mylan](#)) have stringent regulatory authority (SRA) approval or WHO prequalification for pALD.
- **Generic access.** All Global Fund-supported programs have access to low-costing generics of pALD except for Bulgaria, Romania and Russia. More details on the respective Medicines Patent Pool and ViiV Healthcare licensing agreements can be found on the Medicines Patent Pool website.<sup>6</sup>
- **Pricing.** pALD has been added to wambo.org with a reference price of US\$15 per pack of 180 tablets and US\$7.50 per pack of 90 tablets. These prices are reflected in the list of [Pooled Procurement Mechanism Reference Pricing for antiretrovirals \(ARVs\)](#), available on the Global Fund website. As demand for the product increases, the Global Fund expects the price to come down as seen for other ARVs.
- **Budgeting.** Global Fund resources can be used to support pALD adoption, introduction, and scale-up for both programmatic activities and funding product procurement. pALD will be included in the drop down menus of the next version of the Health Product Management Template (HPMT) (link forthcoming). Until the updated HPMT becomes available, Principal Recipients should select 'Other products' as a placeholder and indicate the product name in the 'Comments' section.
- **Stock Management.** The Global Fund recommends that national programs adhere to procurement best practices and review existing stock levels and order plans for pABC/3TC and pDTG to avoid any overstock, which would delay a transition to pALD, and/or stock-outs.

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<sup>2</sup> "Paediatric Abacavir/Lamivudine/Dolutegravir (pALD) fixed-dose combination. Introduction and rollout planning considerations for national programmes," Technical Document, Global Accelerator for Pediatric formulations, September 26, 2023, [https://www.who.int/publications/m/item/paediatric-abacavir-lamivudine-dolutegravir-\(pald\)-fixed-dose-combination](https://www.who.int/publications/m/item/paediatric-abacavir-lamivudine-dolutegravir-(pald)-fixed-dose-combination).

<sup>3</sup> "pALD Frequently Asked Questions," Clinton Health Access Initiative and Unitaid, last updated September, 2023, <https://www.newhivdrugs.org/post/pediatric-ald-pald-faqs>.

<sup>4</sup> "Product Profile: pALD," Clinton Health Access Initiative and Unitaid, last updated September, 2023, <https://www.newhivdrugs.org/post/pald-product-profile>.

<sup>5</sup> See: "PEPFAR Addendum to Fiscal Year 2024. Technical Considerations," PEPFAR, accessed January 9, 2024, <https://www.state.gov/wp-content/uploads/2023/12/PEPFAR-Addendum-to-Fiscal-Year-2024-Final.pdf>.

<sup>6</sup> See: "Dolutegravir – Paediatrics (DTG)," Medicines Patent Pool, accessed January 9, 2024, <https://medicinespatentpool.org/licence-post/dolutegravir-paediatrics-dtg>.