Access to quality affordable HIV treatment regimens in LMICs: Mapping the landscape of MPP-licensed products
[abstract TUPEF635]

S. Morin[1], **L. Gaayeb**[1], **M. Levy**[1], **M. Piccolis**[1], **S. Warerkar Pai**[2], **A. Das**[2], **A. Larbi**[1], **E. Burrone**[1]
[1] Medicines Patent Pool, Geneva, Switzerland [2] Medicines Patent Pool, Mumbai, India

Background

The 2025 WHO HIV treatment guidelines newly recommend several **non-TLD first-line regimens** to optimize antiretroviral therapy: TAF-based three-drug (**TAF-ED** & **TAF-LD**), dual oral (**DTG+3TC**), and dual long-acting injectable (**CAB-LA + RPV-LA**) options. These may offer clinical and implementation advantages, as well as challenges: dual regimens are not indicated for people living with HIV (PLHIV) with HBV, RPV-LA requires cold chain, TAF-based regimens are currently more expensive. **Rollout has so far been limited,** partly due to low awareness of their affordable-access landscape in low- and middle-income countries (LMICs). This work maps opportunities for expanded access.

Methods

We mapped patents and licences covering non-TLD regimens now recommended by WHO, complementing with data from MPP-licensed generic manufacturers (including one direct bilateral licence between ViiV Healthcare and Aurobindo). This data includes regulatory filings, regulatory approvals, and country supplies of these products until March 2026 (**AccessPaL**, https://accesspal.org). It covers three product groups: (1) TAF replacing TDF in 3-drug daily oral regimens (**TAF-ED** & **TAF-LD**); (2) a dual oral regimen (**DTG+3TC**); and (3) a dual long-acting injectable regimen (**CAB-LA + RPV-LA**).

What's new in 2025 WHO guidelines

TAF-based regimens
TAF or TDF + FTC or 3TC + DTG is the preferred regimen for initial and subsequent ART in adults, adolescents, and children > 30 kg

Dual oral regimen
DTG + 3TC is a treatment simplification option for PLHIV with undetectable HIV viral load on 3-drug ARV regimens and without active hepatitis B infection

Long-acting injectable regimen
Injectable CAB-LA + RPV-LA is a switching option in adults and adolescents who have an undetectable HIV viral load on oral ART and no active hepatitis B infection

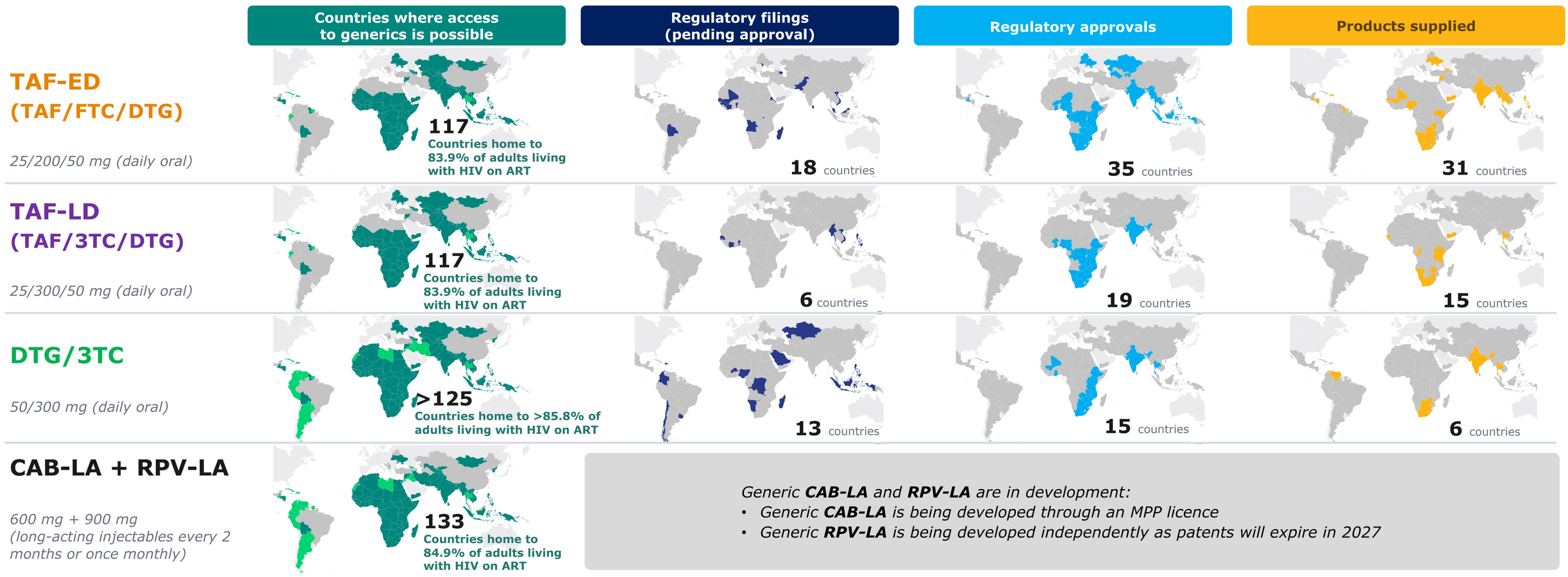
TLD remains WHO's preferred first-line regimen

At **33 USD per person-year** (Global Fund), TLD is available at the lowest price ever reached at scale for a first-line regimen, down from 75 USD per person-year in 2017

Supplied in 123 countries to date

TLD supplies from 12 generic suppliers totaled ~286 million packs (of 30 tablets) in 2025, the equivalent needed to treat 24 million PLHIV for one year

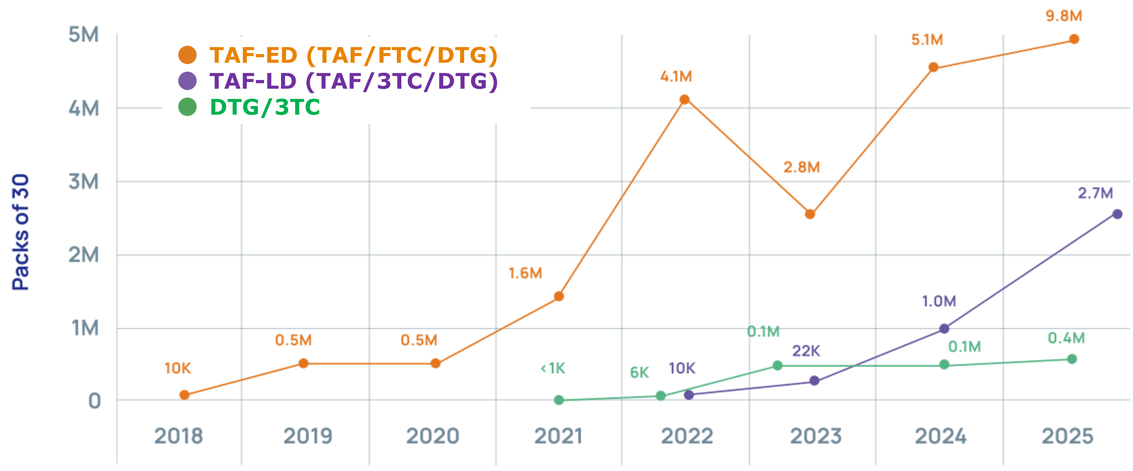
Results - From licence to people: The access landscape for non-TLD first-line generic HIV treatment



*Generic **CAB-LA** and **RPV-LA** are in development:*
- *Generic **CAB-LA** is being developed through an MPP licence*
- *Generic **RPV-LA** is being developed independently as patents will expire in 2027*

*MPP's **AccessPaL** (https://accesspal.org), data as of March 2026.*
% is based on the total number of PLHIV on ART within the licence territory (where published).

Supply, scale up, and affordability



Packs of 28 and 90 tablets have been standardized as monthly packs of 30 tablets for this analysis.

Product	MPP-licensed generic products on the market*	Procurement price** (USD/year)	Volumes supplied in 2025 As packs of 30 tablets (and patient-years)
TLD (reference)	**12**	**32.80 USD/year**	**286,000,000 packs** (24 million patient-years)
TAF-ED	**6**	**55.80 USD/year**	**9,770,000 packs** (800,000 patient-years)
TAF-LD	**4**	**52.20 USD/year**	**2,714,000 packs** (220,000 patient-years)
DTG/3TC	**3**	**28.20 USD/year**	**378,000 packs** (31,000 patient-years)
CAB-LA + RPV-LA	***No product on the market yet***	***No generic price yet***	***No volumes supplied yet***

* *This represents the number of MPP-sublicensed generic manufacturers with a regulatory approved product (additional generics may reach some markets via other routes (e.g., independently in countries without patents, including as local/regional production), particularly for DTG/3TC).*
** *Prices for TLD and TAF-based regimens are from the Global Fund (Mar 2026), while the price for DTG/3TC is from the PAHO Strategic Fund.*

1 — 37 countries have been supplied non-TLD regimens vs 123 countries for TLD

TAF-ED is the most accessed non-TLD regimen with 31 countries reached to date, with an equivalent of 800,000 patient-years supplied in 2026.

2 — TAF regimens cost 1.6× the price of TLD

TAF-ED & **TAF-LD** cost ~52-56 vs 33 USD/year for TLD because of lower volumes and less competition. Two inter-changeable TAF formulations fragment the market, reducing economies of scale. TAF regimens have the potential to be cheaper than TLD if volumes go up.

3 — A dual oral regimen is already cheaper than TLD

DTG/3TC could be an interesting option for countries in Latin America and the Caribbean, where HBV prevalence remains relatively low.

4 — Generic dual oral registration is running ahead of actual access

DTG/3TC is filed or approved in countries home to 85% of PLHIV on ART. Supplies to date have reached countries where approximately 40% of PLHIV on ART reside.

5 — Long-acting CAB-LA and RPV-LA are in development

3 sublicensees are developing **CAB-LA** for treatment; the most advanced has initiated its **CAB-LA** bioequivalence study and is planning for regulatory submission at the earliest in early 2028.

6 — pDTG-to-pALD paediatric regimen transition

pDTG has been supplied in 106 countries to date, many are transitioning to the fixed-dose combination **pALD**, which may be accessed in ≥130 LMICs (with supplies in 47 countries to date (reaching ~320,000 person-years in 2025).

Conclusions

TAF-based and dual oral regimens could be made available to additional PLHIV in LMICs who may benefit, with licences allowing access to generics in more than 100 countries in Africa, Asia, Eastern Europe, and Latin America and the Caribbean, at generic-induced prices that should fall as demand grows. Once developed, CAB-LA + RPV-LA could also be widely accessible.

MPP thanks our founder and funder in HIV: **Unitaid**, our licensors for DTG and TAF: **ViiV Healthcare** and **Gilead Sciences**, and our multiple **generic licensees** for DTG and TAF.

Learn more in MPP's 2025 annual report

Further exploring MPP live country-level uptake data

Detailed information on the registration and rollout of MPP-licensed medicines – including some of the information presented in this poster, is available through MPP's Access Pathways and Lifecycle Tracker database **AccessPaL** (https://accesspal.org). Additional MPP strategic information databases provide data on the patent and licence landscape of essential medicines (**MedsPaL**, https://www.medspal.org) and on technical characteristics, patents, clinical trials, and regulatory filings and approvals of long-acting therapeutics (**LAPaL**, https://www.lapal.ch).

AccessPaL — ACCESS PATHWAYS AND LIFECYCLE TRACKER
MedsPaL — THE MEDICINES PATENTS AND LICENCES DATABASE
LAPaL — THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

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