

Innovative HIV medicines, long-acting therapies and emerging trends

IAS Educational Fund – Armenia and Georgia

20 May 2026

MPP negotiates with pharmaceutical companies to accelerate access to new, essential health products for the people who need them



Conflict of Interest Disclosure

- I have no relevant financial relationships with pharmaceutical companies to disclose.

Thanks to the entire MPP team!



Acknowledgment

- The work of the Medicines Patent Pool in HIV and TB is made possible by the financial support of Unitaid.
- We thank them, as well as our other current public and philanthropic funders.

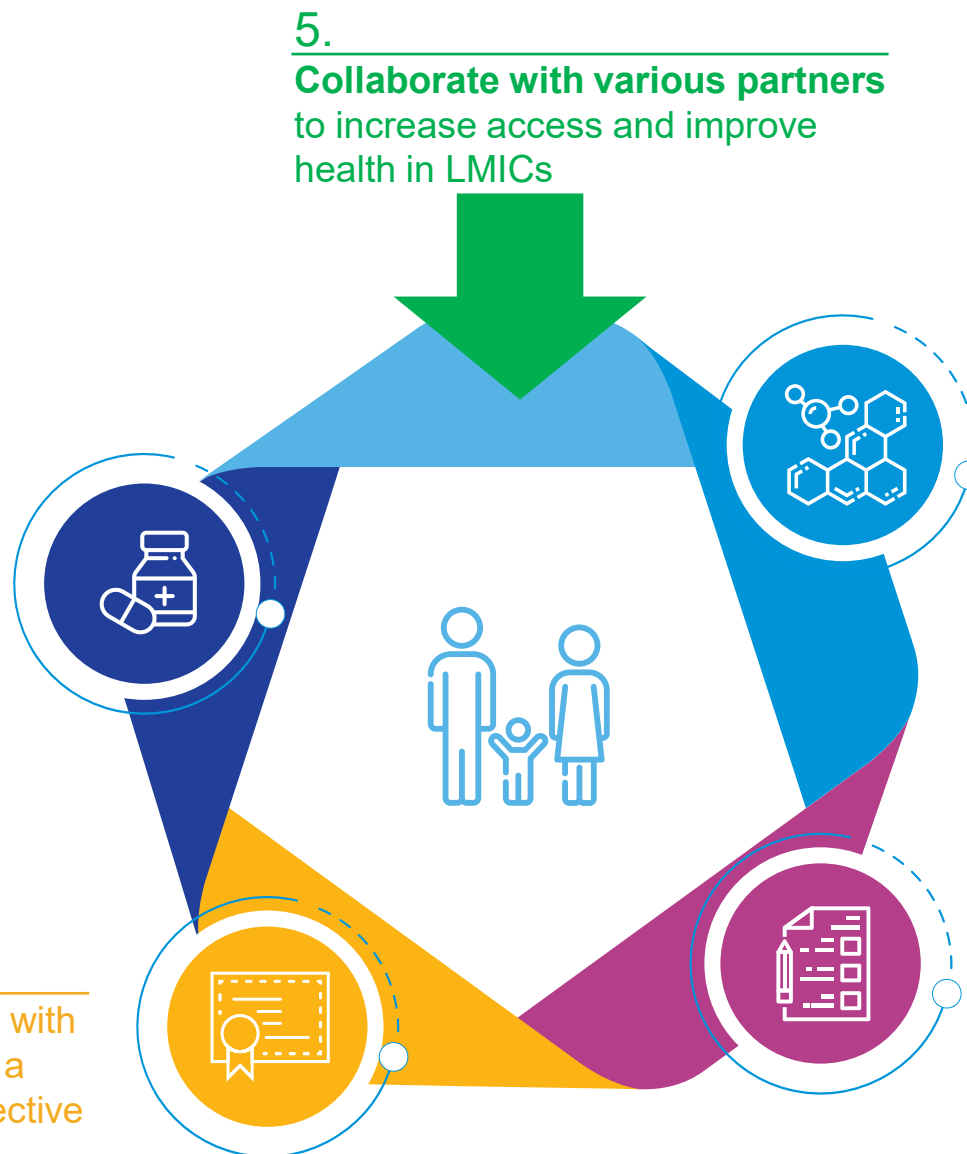


MPP Model in practice



1.
Identify medicines needed in low- and middle-income countries where licensing can improve access

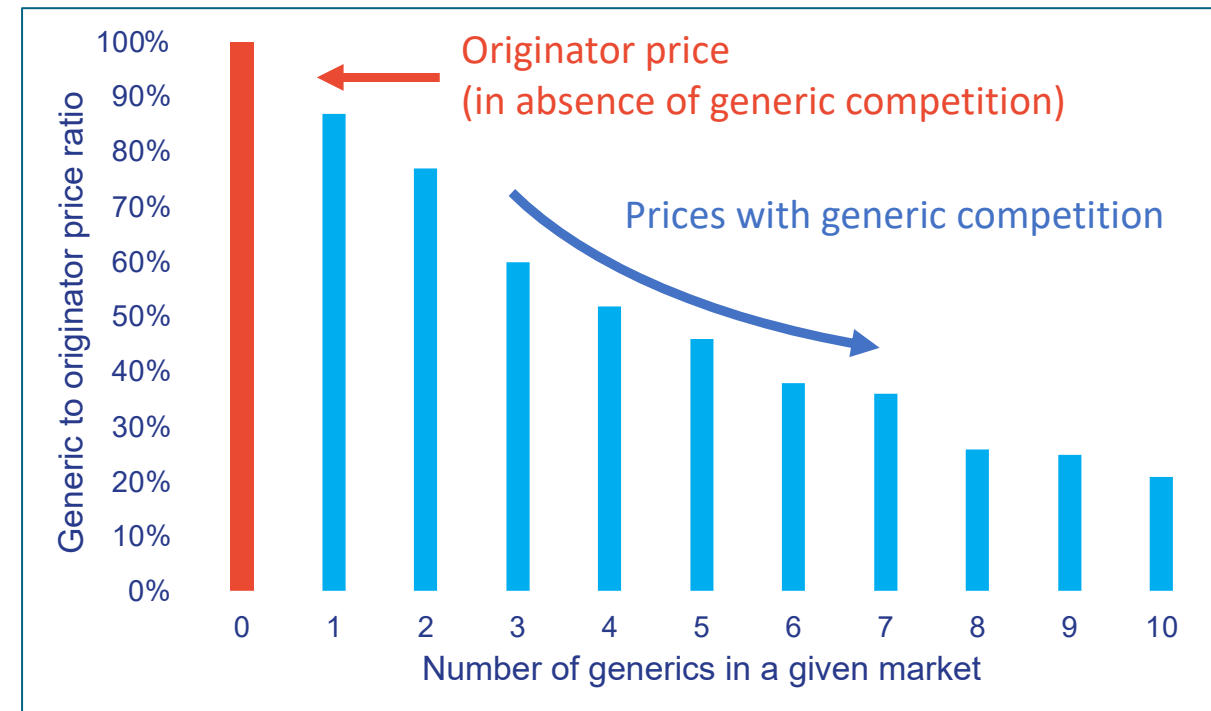
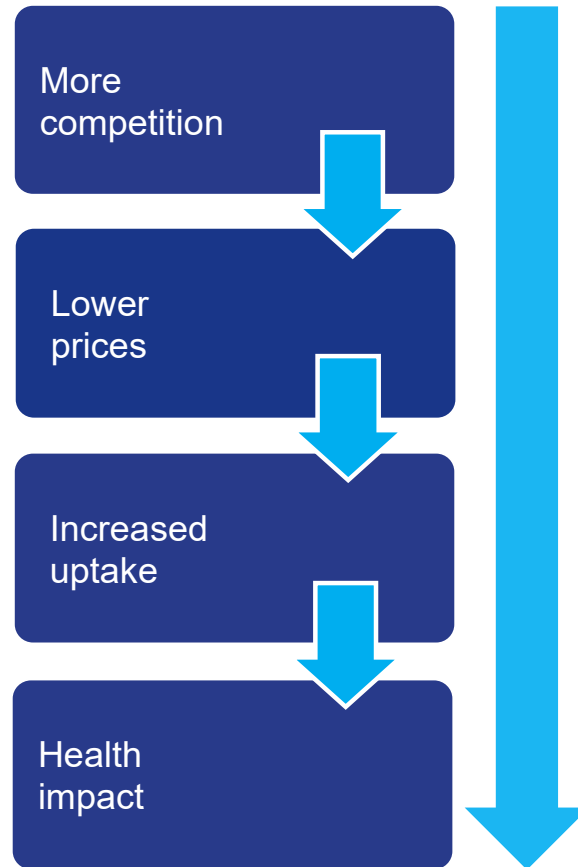
2.
Negotiate licences with patent holders from a public health perspective



Accelerated access and price reductions

Overview of MPP's voluntary licensing model

- Driving prices down through generic competition
- Accelerating timelines for generic product availability



Generic competition induced pricing benchmarks: Dave et al. (2017) *NEJM*

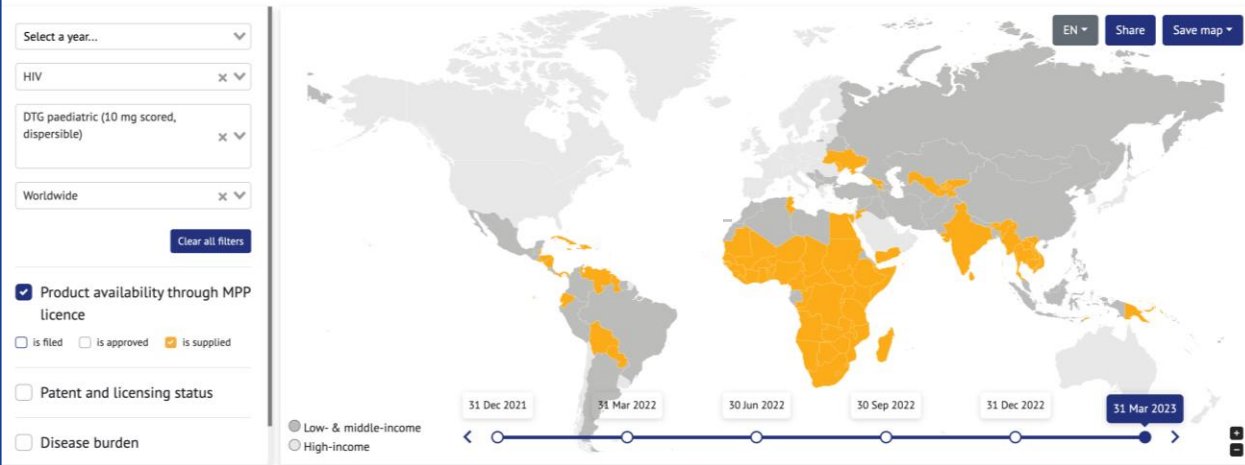
Four tools to support access to medicines



MedsPaL
THE MEDICINES PATENTS AND LICENCES DATABASE

<https://www.medspal.org>

Access to medicines tracker – Interactive map



<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>

Access to medicines tracker – Interactive table

Key: ■ HIV ■ Hepatitis C ■ Tuberculosis

Filter table rows by product: Filter:

PRODUCTS	COMPANIES DEVELOPING THE PRODUCT	PENDING APPROVAL		READY TO SUPPLY			COUNTRIES WHERE		
		WHO-PQ*	USFDA**	WHO-PQ* APPROVED	USFDA** APPROVED	ERP*** APPROVED	PRODUCT IS FILED	PRODUCT IS APPROVED	PRODUCT IS SUPPLIED
DTG 50mg Licensed from ViiV Healthcare 	12			Cipla DESAPIO Emcure HETERO LAURUS-LES Mylan SUN PHARMACEUTICALS 	 Cipla HETERO LAURUS-LES Mylan		Benin, Bolivia (Plurinational State of), Burkina Faso, Burundi, Cameroon, Dominican Rep El Salvador, Gambia	Anguilla, Antigua and Barbuda, Bahamas, Barbados, Botswana, Cambodia, Chile, Congo,	Afghanistan, Albania, Angola, Anguilla, Antigua and Barbuda, Argentina, Armenia, Azerbaijan, Bahamas, Barbados, Benin.

<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>

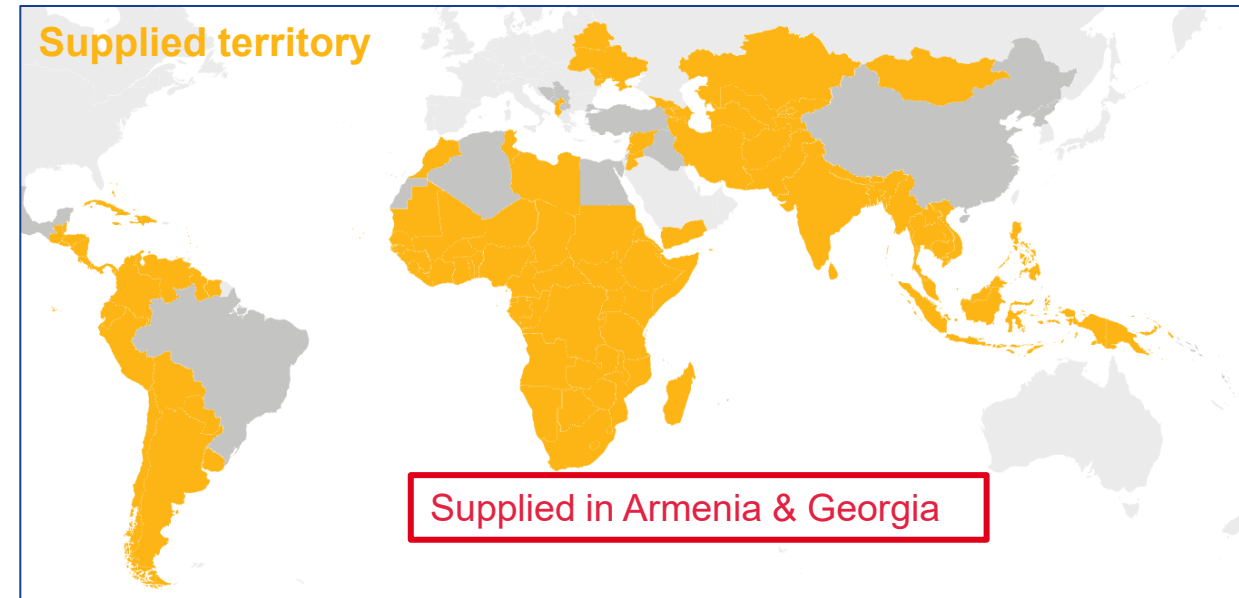
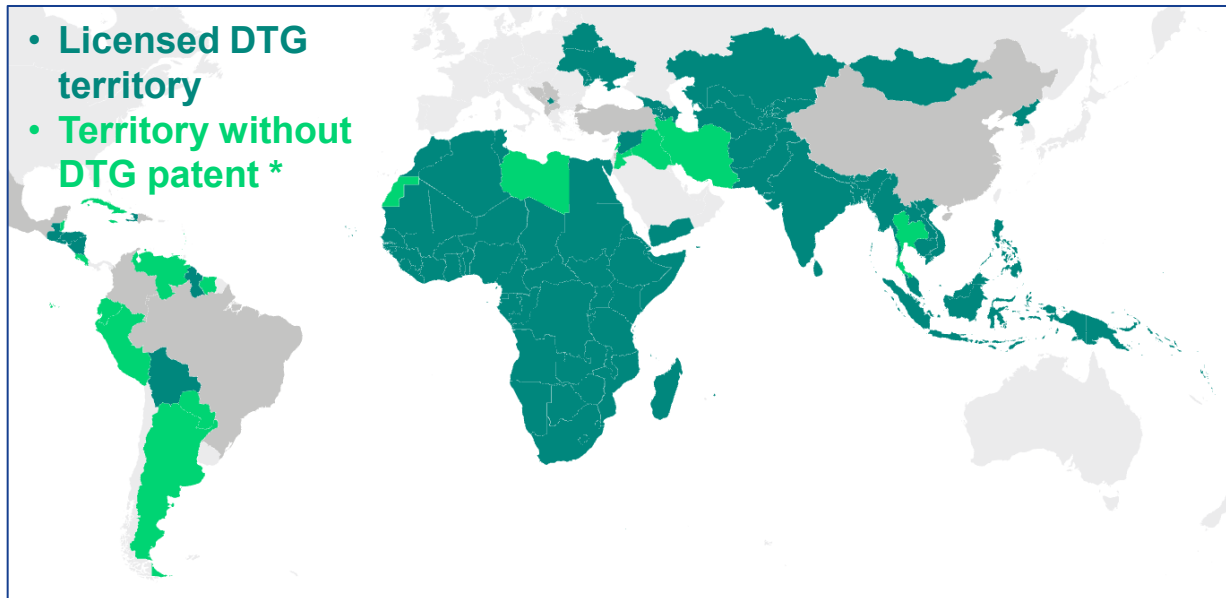
LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

<https://www.lapal.ch>

Our success - Access to generic TLD

Generic TDF/3TC/DTG 300/300/50 mg for adults and adolescents

- MPP licence for DTG enables **access in at least 124 countries**
- The product is filed for approval in 12 countries and approved in 76 countries *
- **12 MPP-licensed generics** have regulatory approval for this product
- The product has been **supplied in 123 countries** (286 000 000 packs of 30 in 2025) *
- The Global Fund price is 2.80 USD per pack of 30 (**33.60 USD/year**) **



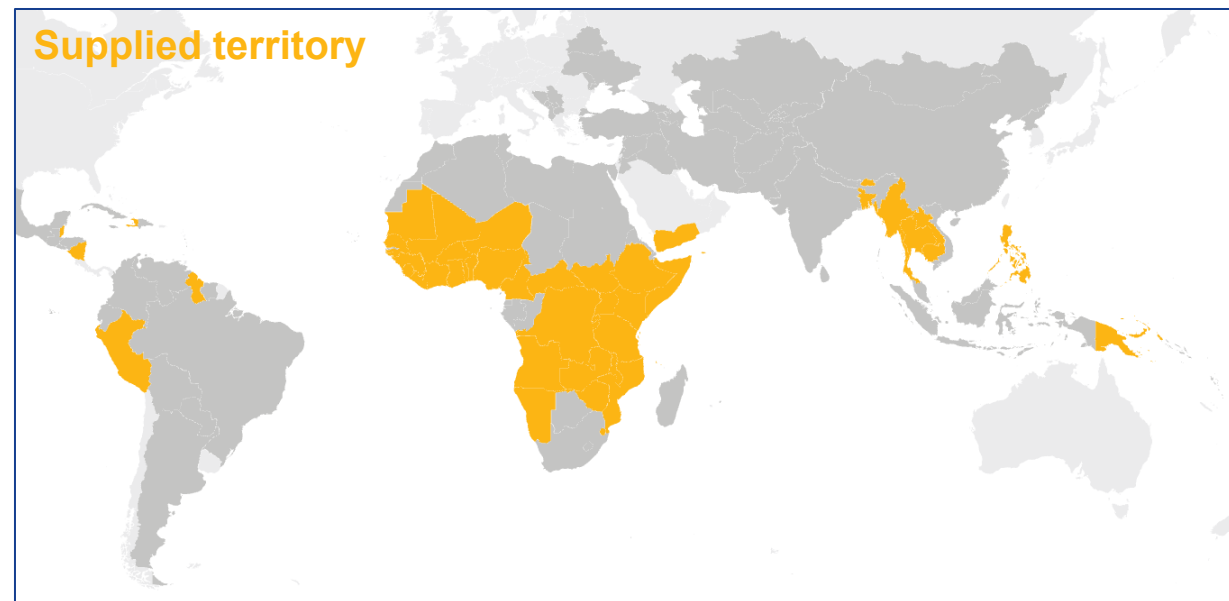
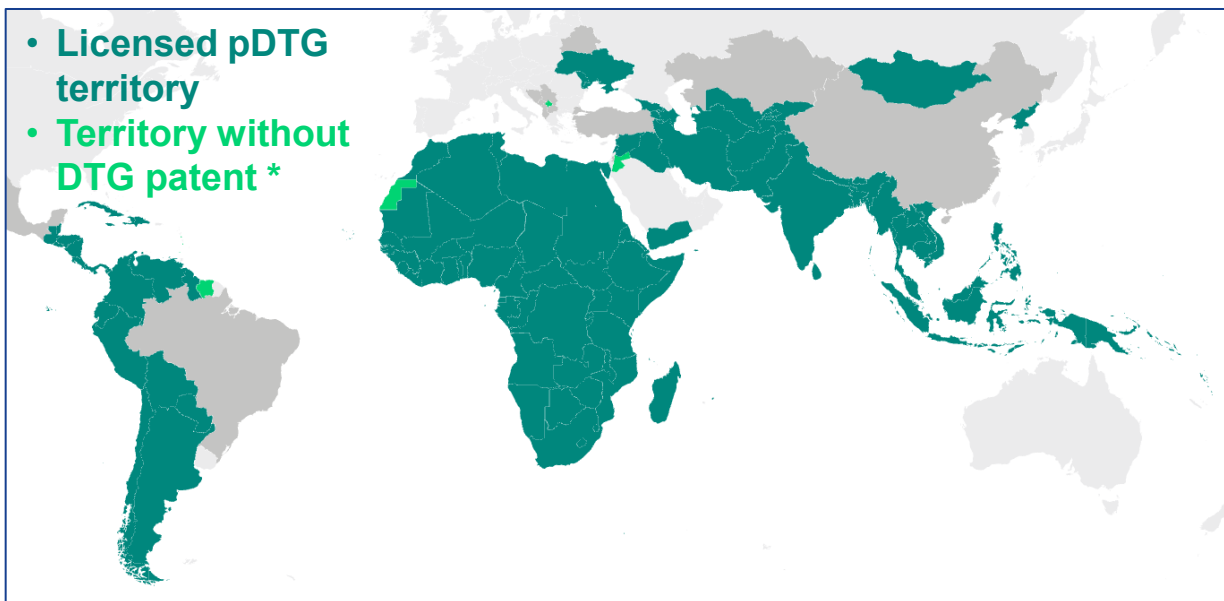
* MPP data (end 2025).

** Global Fund catalogue (March 2026).

Our hope - Access to generic paediatric ALD (pALD)

Generic ABC/3TC/DTG 60/30/5 mg dispersible fixed-dose combination for children

- MPP licence for paediatric DTG enables **access in at least 128 countries**
- The product is filed for approval in 13 countries and approved in 21 countries *
- **5 MPP-licensed generics** have regulatory approval for this product
- The product has been **supplied in 47 countries** (2 670 000 packs of 180 in 2025) *
- The Global Fund price is 13.00 USD per pack of 180 (**104.00 USD/year**) **



* MPP data (end 2025). ** Global Fund catalogue (March 2026). *** For a child of 10-14 kg.

1. TAF based treatments as an alternative to TDF

Tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) + lamivudine (3TC) or emtricitabine (FTC) is the preferred nucleoside reverse transcriptase inhibitor (NRTI) backbone for initial and subsequent ART in adults, adolescents and children > 30 kg.

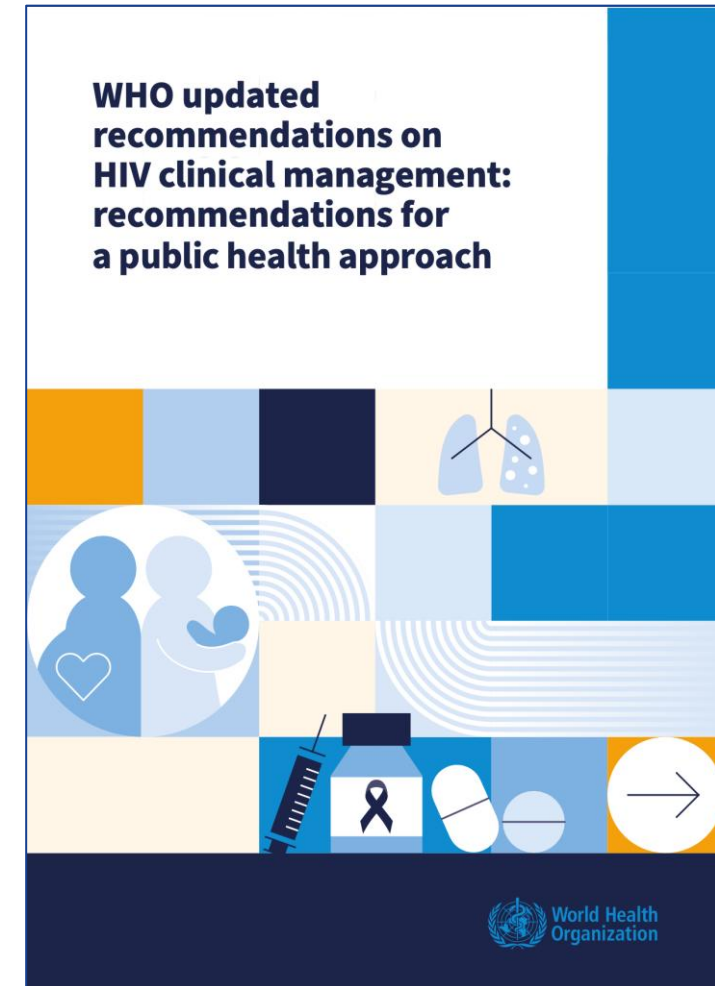
This includes individuals previously treated with or exposed to tenofovir.

2. Simplified treatment with two-drug antiretroviral

Dolutegravir (DTG) + lamivudine (3TC) can be used for treatment simplification in persons stable on 3DRs and without active hepatitis B.

3. Long acting injectable ARVs

Long-acting injectable cabotegravir (CAB) + rilpivirine (RPV) can be used as an alternative switching option in adults and adolescents stable on oral ART and without active hepatitis B.

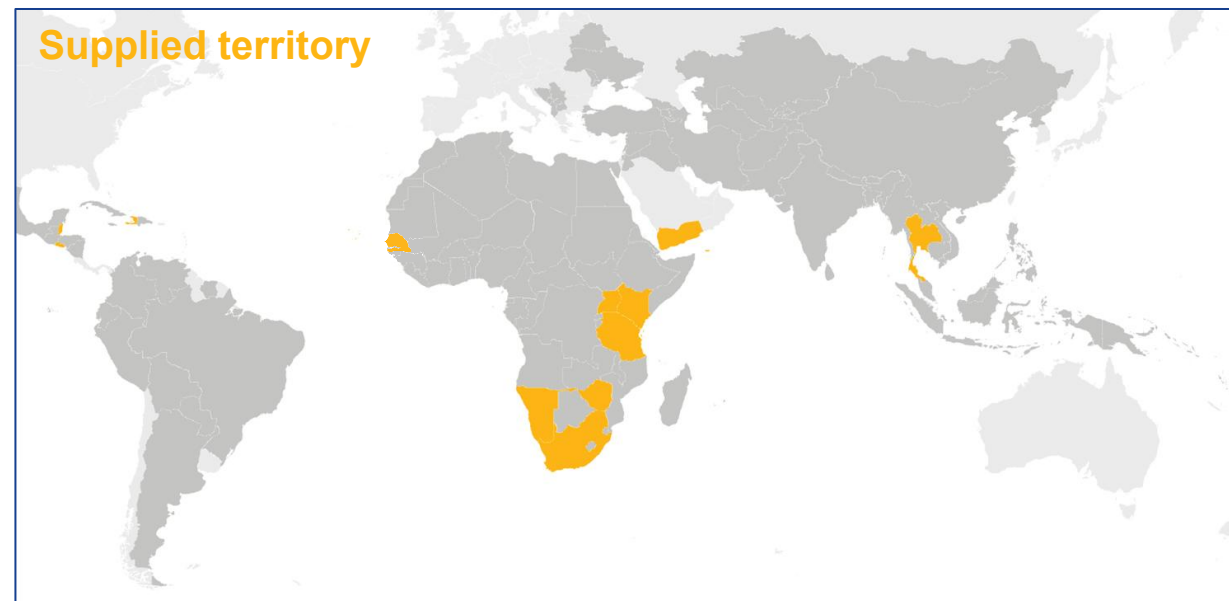


<https://www.who.int/publications/i/item/9789240119468>

New option: Access to generic TAF-LD

Generic TAF/3TC/DTG 25/300/50 mg for adults and adolescents

- MPP licences for TAF and DTG enable **access in 116 countries**
- The product is filed for approval in 6 countries and approved in 18 countries *
- **4 MPP-licensed generics** have regulatory approval for this product
- The product has been **supplied in 14 countries** (2 710 000 packs of 30 in 2025) *
- The Global Fund price is 4.35 USD per pack of 30 (**52.20 USD/year**) **



* MPP data (end 2025).

** Global Fund catalogue (March 2026).

Access to generic TAF-ED

Generic TAF/FTC/DTG 25/200/50 mg for adults and adolescents

- MPP licences for TAF and DTG enable **access in 117 countries**
- The product is filed for approval in 19 countries and approved in 34 countries *
- **6 MPP-licensed generics** have regulatory approval for this product
- The product has been **supplied in 30 countries** (9 770 000 packs of 30 in 2025) *
- The Global Fund price is 4.65 USD per pack of 30 (**55.80 USD/year**) **



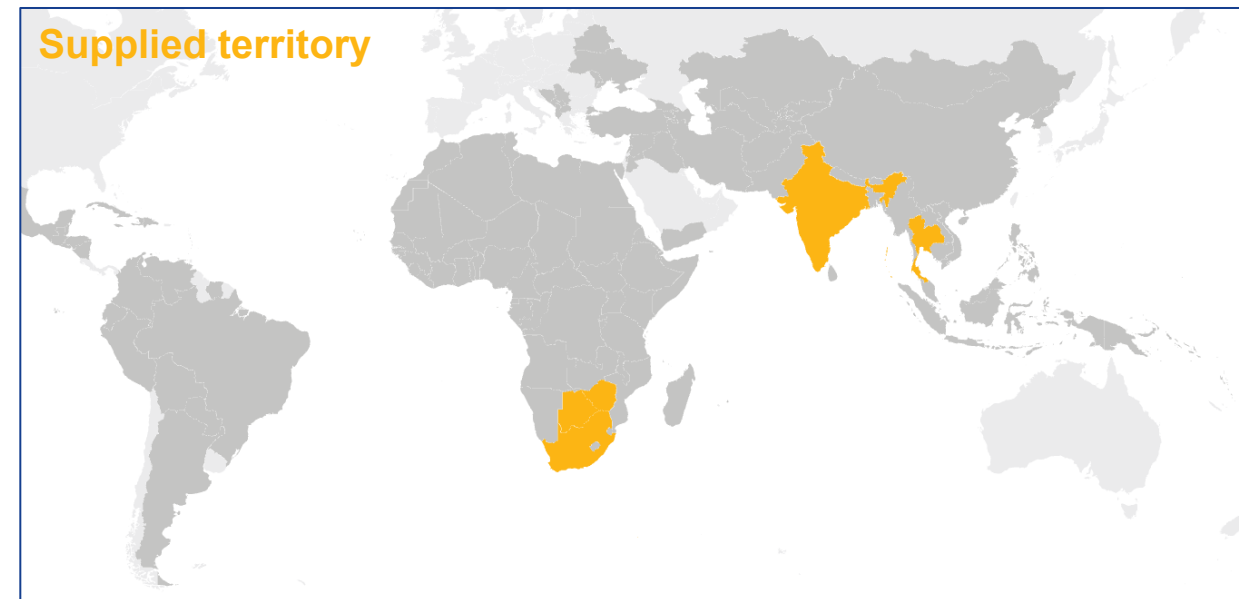
* MPP data (end 2025).

** Global Fund catalogue (March 2026).

Access to generic DTG/3TC

Generic DTG/3TC 50/300 mg for adults and adolescents

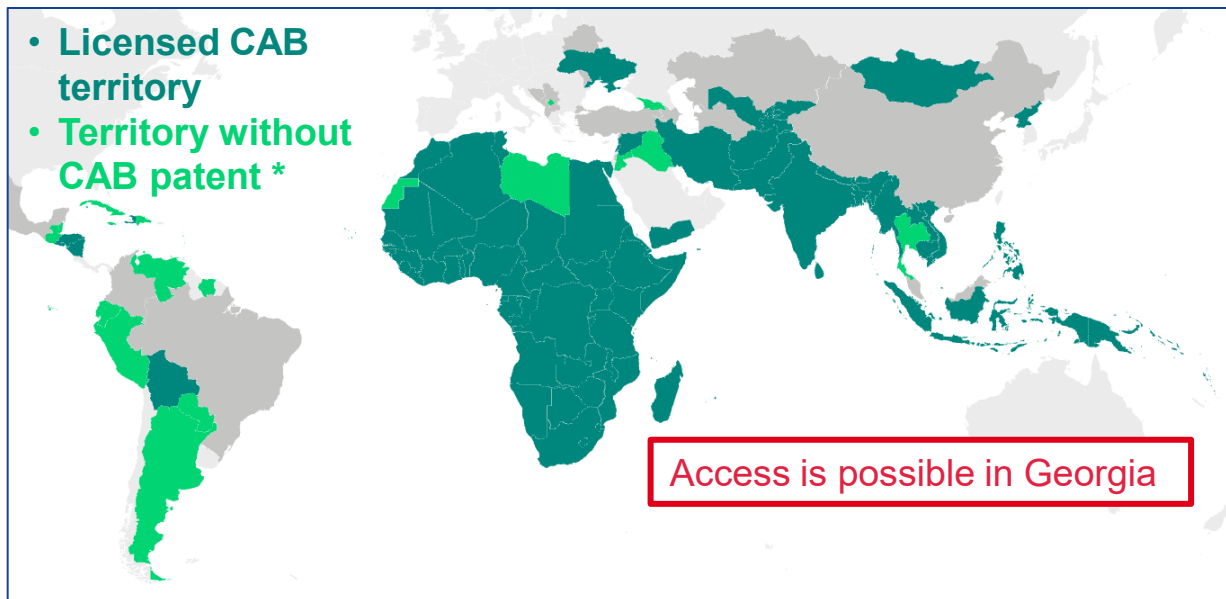
- The MPP licence for DTG enables **access in 125 countries**
- The product is filed for approval in 13 countries and approved in 14 countries *
- **3 MPP-licensed generics** have regulatory approval for this product
- The product has been **supplied in 5 countries** (378 000 packs of 30 in 2025) *
- The lowest reported price is 2.35 USD per pack of 30 (**28.20 USD/year**) *



Access to CAB+RPV long-acting injectables

Generic CAB-LA 600 mg + RPV-LA 900 mg for adults and adolescents

- **Patents for RPV will expire in 2027**, in time for the availability of generics
- The MPP licence for CAB allows **access in at least 133 countries**
- The product is currently in development by **3 MPP-licensed generic manufacturers**
- The most advanced manufacturer will soon begin its bioequivalence study (48 weeks)
- The most recent estimate anticipates **regulatory submission by the end of 2027**

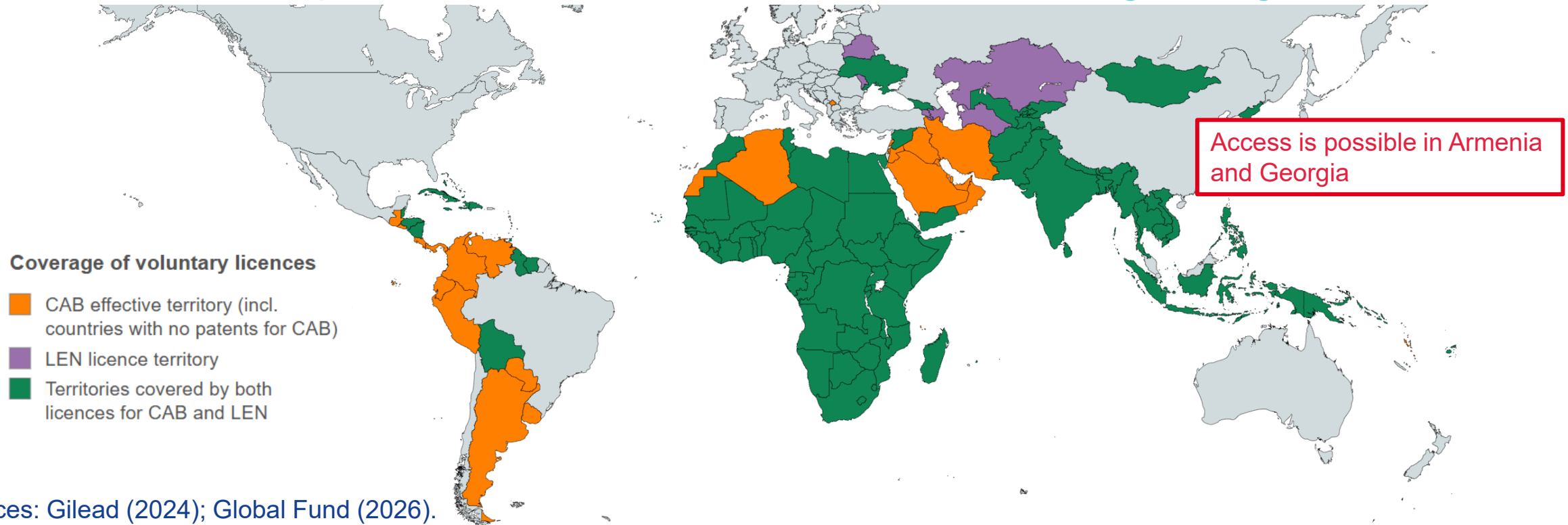


Generic versions for this regimen are not yet available

Access to lenacapavir for HIV PrEP

Lenacapavir – a twice-yearly dosing for HIV prevention

- Gilead voluntary licence covers **120 countries, including Armenia and Georgia**
- Generic versions are being developed by **6 licensed manufacturers**
- FDA-approved (June 2025); under EMA review
- Generic rollout expected **from 2027; Global Fund supporting Georgia from 2026**



With the contribution of various partners, public-health voluntary licensing and technology transfer provide an accountable, inclusive, transparent process that typically results in:

- **Accelerated timeline for development to rollout at scale**
- **More affordable and sustainable access to quality innovative medicines**
- **Better coordinated and broader in-country registration**
- **Rollout at scale more rapidly and in more countries**
- **Life-saving access for more people who need medicines**

WHO now recommends new treatment options

1. TAF based treatment



2. Dual ARV treatment



2. Long-acting injectable treatment

Some options are already available in generic versions

1. Possible in 117 countries at relatively high price

2. Possible in >125 countries at better price than TLD

× Opportunity for the future, but unquantified demand disincentives manufacturers

Possible savings in a tight financing context

× A few countries only have benefited from these new regimens

× Two TAF-based formulations fragment the market, preventing economies of scale

Thank you for your attention !

Please contact me for any question at mlevy@mppf.org

