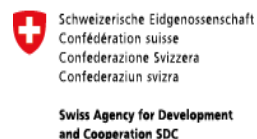


Improving access to HIV medicines in EECA through Medicines Patent Pool (MPP)

November 2024

Mila Maistat
Senior Manager
Policy, Strategy and Market Access

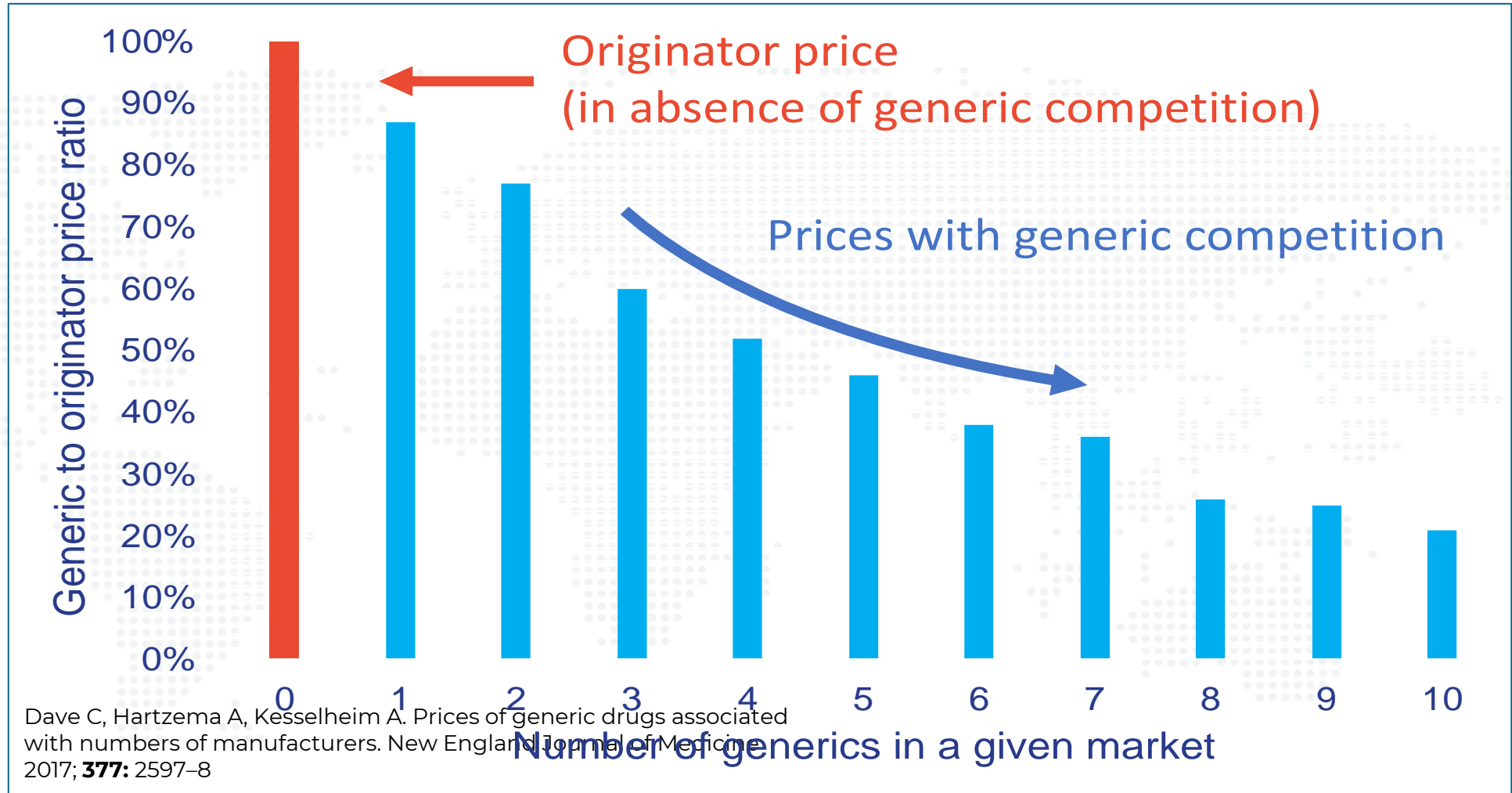


Patent status of important medicines for HIV and other infectious diseases

Medicine	Patent Expiry Date
Bedaquiline	2023-27
Cabotegravir Long-acting	2031
Dolutegravir (and TLD)	2026
Lenacapavir	2034-38
Molnupiravir	2035-38
Nirmatrelvir/r (Paxlovid ®)	2041

In countries where these products are patented, generics would typically only enter the market after patent expiry, **unless licences are issued.**

The Role of Generic Manufacturers in price reductions for Essential Medicines



MPP is a UN-backed public health organization established by Unitaid in 2010 to improve **access to new HIV medicines** (initially) in LMICs

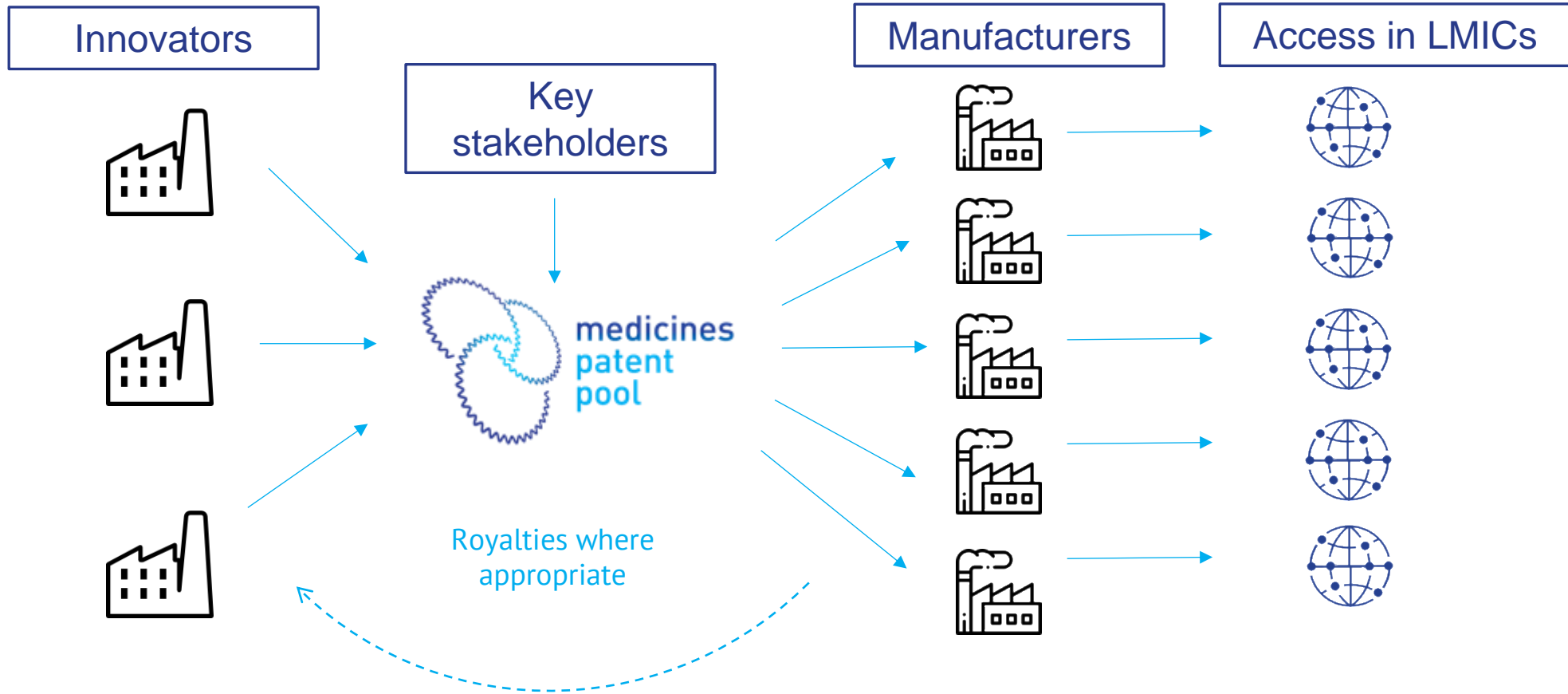
...and to facilitate the **development of new formulations needed in developing countries** (fixed-dose combinations, pediatrics)

Operates through public health-oriented **voluntary licensing** to facilitate **early entry of generics** in low- and middle-income countries (LMICs)

Expanded to work on **hepatitis C, tuberculosis** (2016), other **patented essential medicines** (2018) and **COVID-19** (2020)



MPP operating model



Guiding Principles

- ✓ Public health driven
- ✓ Flexible
- ✓ Bespoke
- ✓ Collaborative

- ✓ Focus on accelerating access
- ✓ Facilitating innovation
- ✓ Complementary to other access mechanisms

- ✓ Non-exclusive
- ✓ Voluntary
- ✓ Transparent

HIV

ABACAVIR – PAEDIATRICS (ABC)
 ATAZANAVIR (ATV)
 BICTEGRAVIR (BIC)
 COBICISTAT (COBI)
 DOLUTEGRAVIR - ADULT (DTG)
 DOLUTEGRAVIR - ADULT (DTG)
 for AZ, BY, KZ and MY
 DOLUTEGRAVIR - PAEDIATRICS
 (DTG)
 ELVITEGRAVIR (EVG)
 EMTRICITABINE (FTC)
 LOPINAVIR, RITONAVIR (LPV/r)
 LOPINAVIR, RITONAVIR (LPV/r)
 PAEDIATRICS
 PATENTS RELATED TO
 DARUNAVIR
 RALTEGRAVIR (RAL)
 PAEDIATRICS
 SOLID DRUG NANOPARTICLE
 TECHNOLOGY
 TENOFOVIR ALAFENAMIDE (TAF)
 TENOFOVIR DISOPROXIL
 FUMARATE (TDF)



COVID

Other

ELISA ANTIBODY
 TECHNOLOGY
 (Diagnostic)
 MOLNUPIRAVIR
 NIRMATRELVIR
 ENSITRELVIR

NIH

A VSV-EBOV-BASED VACCINE (Vaccine
 candidate)
 ACE2 DIMER CONSTRUCT (Research tool
 for drug development)
 DETECTION OF SARS-COV-2 AND OTHER
 RNA VIRUS (Diagnostic)
 HIGH-THROUGHPUT DIAGNOSTIC TEST
 (Diagnostic)
 NEWCASTLE DISEASE VIRUS-LIKE
 PARTICLES DISPLAYING PREFUSION-
 STABILISED SPIKES (Vaccine candidate)
 PARAINFLUENZA VIRUS 3 BASED
 VACCINE (Vaccine candidate)

PREFUSION SPIKE PROTEINS (Vaccine
 development)
 PSEUDOTYPING PLASMID (Research
 tool for vaccine development)
 RNASEH-ASSISTED DETECTION ASSAY
 FOR RNA (Diagnostic)
 STRUCTURE-BASED DESIGN OF SPIKE
 IMMUNOGENS (Research
 tool for vaccine development)
 SYNTHETIC HUMANISED LLAMA
 NANOBODY LIBRARY AND USE
 (Research tool for drug and diagnostic
 development)



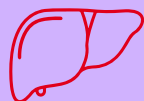
Cancer

NILOTINIB



Viral Hepatitis

DACLATASVIR (DAC)
 GLECAPREVIR/
 PIBRENTASVIR (G/P)
 RAVIDASVIR



Tuberculosis

SUTEZOLID - Johns Hopkins
 University
 SUTEZOLID - Pfizer



Long-Acting Therapeutics

CABOTEGRAVIR LONG-ACTING
 (LA) FOR HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)
 LONG-ACTING INJECTABLE HIV
 DRUG COMBINATION TECHNOLOGY
 LONG-ACTING TECHNOLOGIES FOR HCV,
 TB, AND MALARIA TREATMENT
 LONG-ACTING TECHNOLOGY FOR MALARIA
 VECTOR CONTROL



Health and economic impact of MPP licence agreements

22

patent holders
working
with MPP

43.56
Bn

doses of
treatment
supplied
(2010 - 2023)



USD
1.9 Bn

dollars saved through
procurement of more
affordable treatments in
LMICs (2010 - 2023)



By 2030

170,000

projected
deaths
averted



58

generic
manufacturers
and product
developers

148

countries have
benefited from
access to MPP's
products



118.04
million

patient years of
treatment
through MPP's
generic partners
(2010 - 2023)



By 2030

USD
3.9 Bn

projected
savings



Why licensing through MPP is a WIN-WIN ?

BENEFITING ALL STAKEHOLDERS

PATENT HOLDERS

- Effective and impactful way to make **available innovative products** in resource-limited settings
- **licence management**
- reduced **distribution costs**
- **Opening markets** in LMICs through introducing affordable versions of products

GENERIC PRODUCERS

Accelerated approach to development of **affordable** versions of existing **medicines**, creation of **formulations and fixed-dose combinations**

GOVERNMENTS, TREATMENT PROVIDERS

Ability to stretch budgets to **treat more people** with WHO-recommended medicines

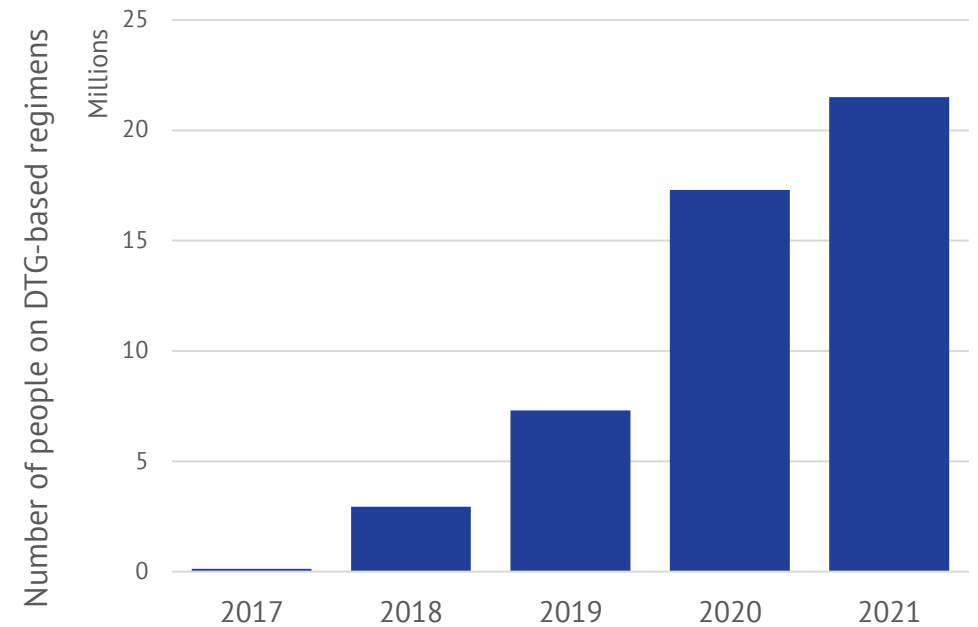
COMMUNITIES

Greater access to quality-assured **affordable therapeutics**

The case of dolutegravir: a 10 year journey

- Dolutegravir (DTG) was approved by USFDA in Aug 2013 for HIV treatment and licensed to MPP shortly afterwards
- 10 years later:
 - Generic DTG-based regimens supplied in **128 countries**¹ (including 34 upper middle-income countries)
 - 1st line DTG-based regimen **costs under USD 45 per person per year**² (the lowest ever for a WHO-recommended regimen)
 - Over **24 million people** are estimated to be on generic DTG-based regimens (over 70% of all people on ART worldwide)
- All this while patents are yet to expire in 2026

Number of people on DTG-based regimens by year



¹ <https://medicinespatentpool.org/news-publications-post/transformation-partnership-between-the-medicines-patent-pool-and-viiv-healthcare-enables-24-million-people-in-low-and-middle-income-countries-to-access-innovative-hiv-treatment>

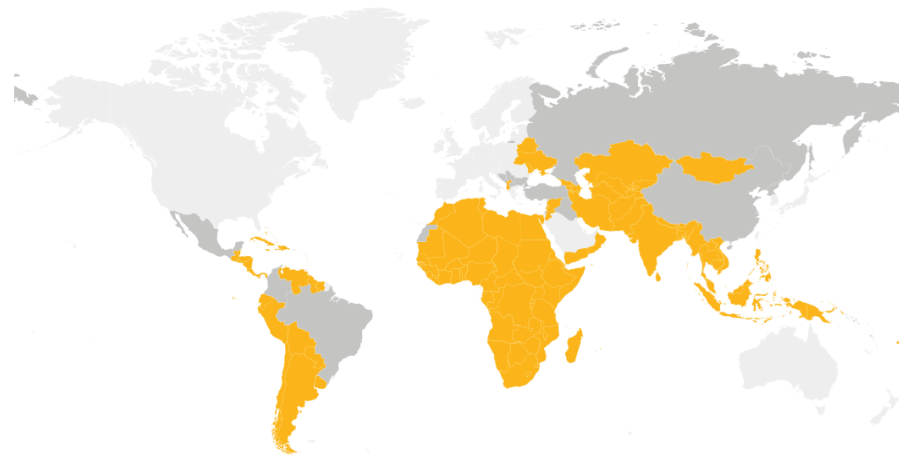
² <https://www.theglobalfund.org/en/news/2023/2023-08-30-global-fund-agreements-substantially-reduce-price-first-line-hiv-treatment-below-usd45-a-year/>

Impact of MPP-ViiV DTG licence

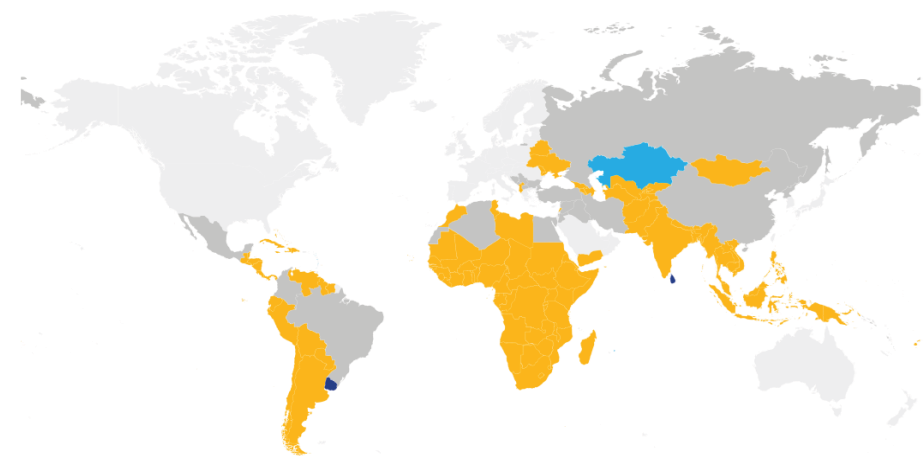
DTG products supplied to 128 low and middle-income countries

DTG (50 mg): 59 mln packs to 126 countries

TLD: 1.05 bln packs to 107 countries



○ High-income countries
● Low- and middle-income countries

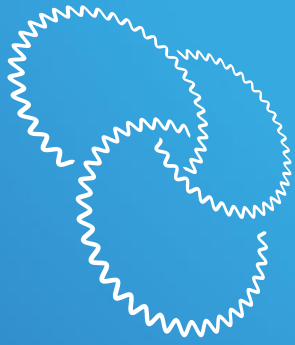


○ High-income countries
● Low- and middle-income countries

Of those:

46 lower-middle income countries and 34 upper-middle income countries (UMICs) have procured generic DTG products from MPP licensees (WB classification 2023-2024)

Over 24 million are estimated to have been taking WHO-preferred treatment regimens over the past 10 years



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Progress with DTG transition in Azerbaijan, Belarus, Kazakhstan and Malaysia

Update as of October 2024

[MEDICINESPATENTPOOL.ORG](https://www.medicinespatentpool.org)

Since 2017, MoH of Malaysia engaged in discussions with MPP to obtain access to affordable DTG

2018-2019, additional requests from the governments of Azerbaijan, Belarus and Kazakhstan were received by both MPP and ViiV (price for DTG from originator: approx. **USD 2,000 per patient per year** in all the four UMICs). Discussions also with **Algeria**, who was a UMIC at the time.

2019, Negotiations between **MPP and ViiV** to include the UMICs started with significant interactions with the 4 governments, including Malaysia.

Meanwhile, *new Interim price from ViiV (USD1,050-1,200 per patient per year)*

November 2020, MPP and ViiV Healthcare announced licence agreement for DTG for the four UMICs

Close collaboration with governments and community groups in the countries played a key role in making it happen

Coverage: Azerbaijan, Belarus, Kazakhstan and Malaysia

Access to WHO-recommended treatments: licence enables access to quality assured DTG and TLD and other DTG-based combinations from generic suppliers in **the public sector**.

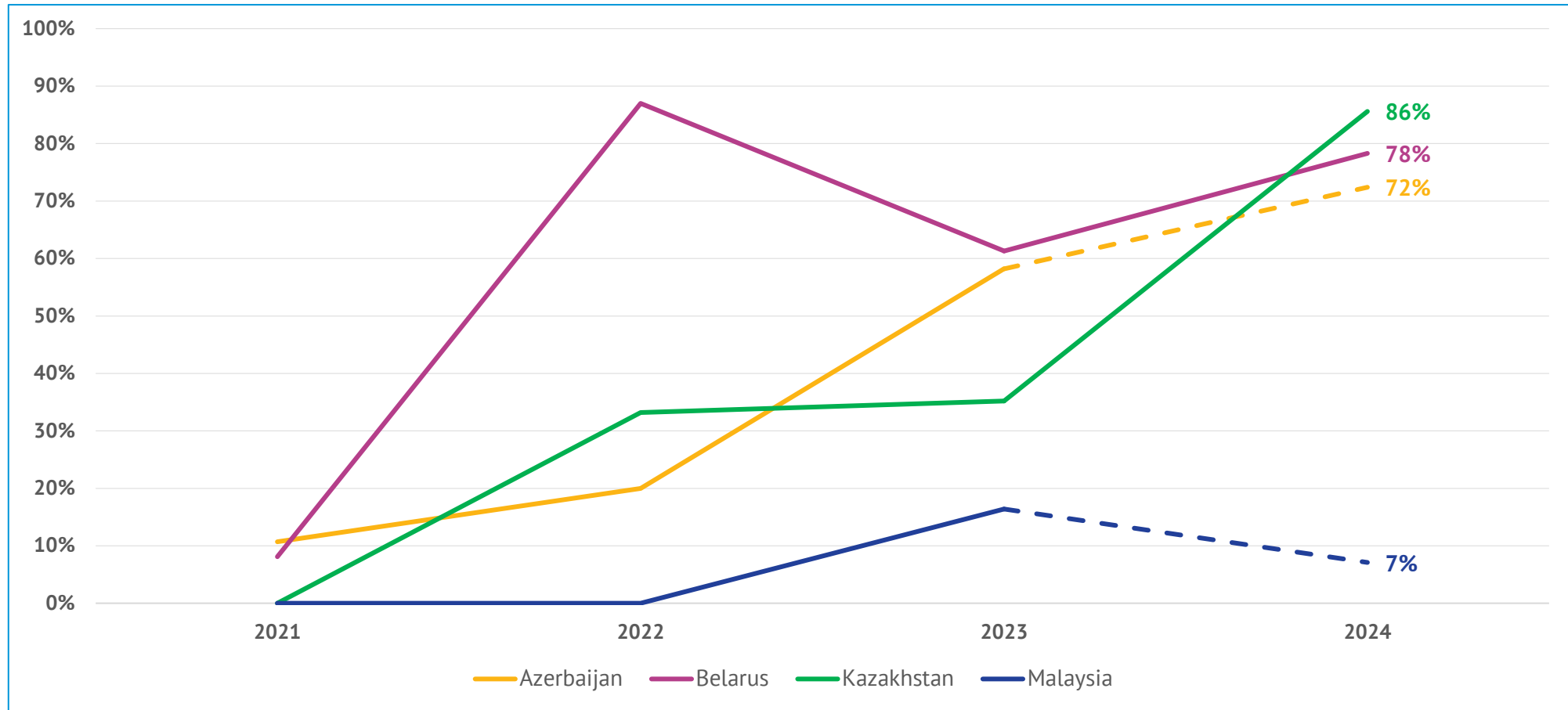
Hetero, Mylan and Sun manufacture DTG and TLD, registered (or are registering) the products in the four countries and supplying to the UMICs since 2021.

Licence does not set prices. However, the licence enables generics to come in and compete in tenders, which leads to lower prices

The licence does include royalties (confidential) which depend on the volumes being procured.

The agreement is structured so that higher volumes lead to lower prices

Percentage of adult people living with HIV on ART transitioning to DTG regimens, based on procured volumes

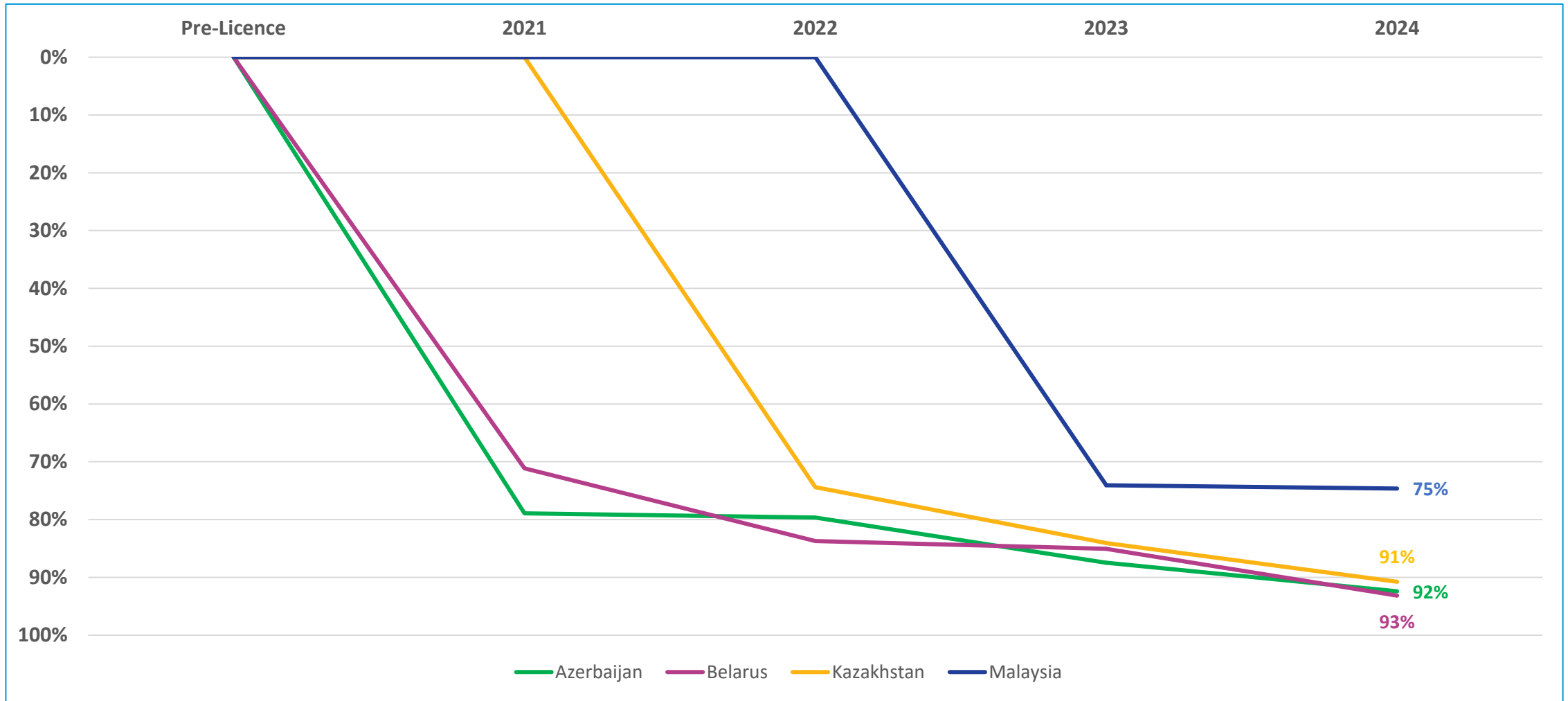


Volume includes DTG 50mg, TLD and ALD (ALD procured only in KZ)

Solid line - Procurement completed or confirmed purchase orders

Dashed line - based procurement plans provided by MoH - to be confirmed

Percentage of price reduction as compared to originator prices at the start of licence negotiations



Details	Sum of Packs(30)
Albania	20.6K
DTG adult (50 mg)	1.6K
DTG paediatric (10 mg scored, dispersible)	60
TLD - TDF/3TC/DTG (300/300/50 mg)	19.0K
Armenia	190.0K
DTG adult (50 mg)	7.7K
DTG paediatric (10 mg scored, dispersible)	408
TAF/FTC/DTG (25/200/50 mg)	1.4K
TLD - TDF/3TC/DTG (300/300/50 mg)	180.4K
Azerbaijan	71.9K
DTG adult (50 mg)	20.9K
DTG paediatric (10 mg scored, dispersible)	600
TLD - TDF/3TC/DTG (300/300/50 mg)	50.4K
Georgia	285.1K
DTG adult (50 mg)	53.6K
DTG paediatric (10 mg scored, dispersible)	924
TAF/FTC/DTG (25/200/50 mg)	12.2K
TLD - TDF/3TC/DTG (300/300/50 mg)	218.4K
Kazakhstan	526.9K
ALD - ABC/3TC/DTG (600/300/50 mg)	33.2K
DTG adult (50 mg)	300.6K
TLD - TDF/3TC/DTG (300/300/50 mg)	193.0K











Kyrgyzstan	321.1K
ALD - ABC/3TC/DTG (600/300/50 mg)	3.5K
DTG adult (50 mg)	23.3K
DTG paediatric (10 mg scored, dispersible)	3.0K
TLD - TDF/3TC/DTG (300/300/50 mg)	291.3K
Moldova, Republic of	493.1K
DTG adult (50 mg)	48.5K
DTG paediatric (10 mg scored, dispersible)	6.1K
TAF/FTC/DTG (25/200/50 mg)	6.0K
TLD - TDF/3TC/DTG (300/300/50 mg)	432.4K
Tajikistan	541.8K
DTG adult (50 mg)	13.6K
DTG paediatric (10 mg scored, dispersible)	648
TLD - TDF/3TC/DTG (300/300/50 mg)	527.6K
Ukraine	7.35 M
ALD - ABC/3TC/DTG (600/300/50 mg)	106.8K
DTG adult (50 mg)	1.73 M
DTG paediatric (10 mg scored, dispersible)	38.8K
TAF/FTC/DTG (25/200/50 mg)	125.5K
TLD - TDF/3TC/DTG (300/300/50 mg)	5.36 M
Uzbekistan	954.8K
DTG adult (50 mg)	275.9K
DTG paediatric (10 mg scored, dispersible)	6.0K
TLD - TDF/3TC/DTG (300/300/50 mg)	672.9K

Grand Total	10.76 M
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MPP licence for paediatric DTG products

Key features

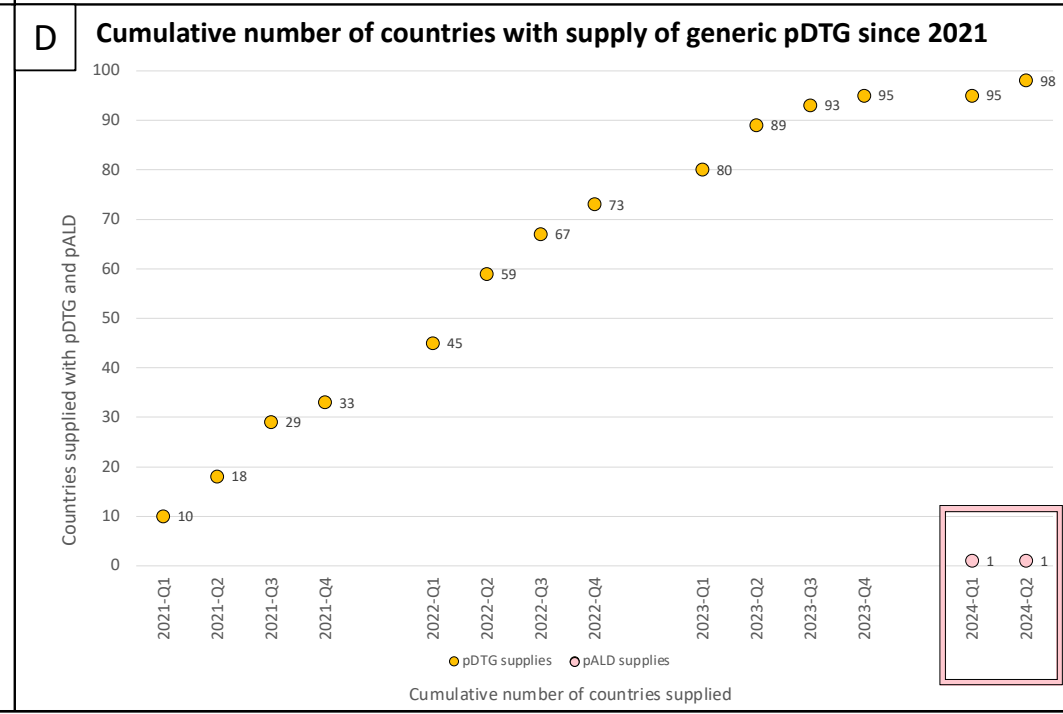
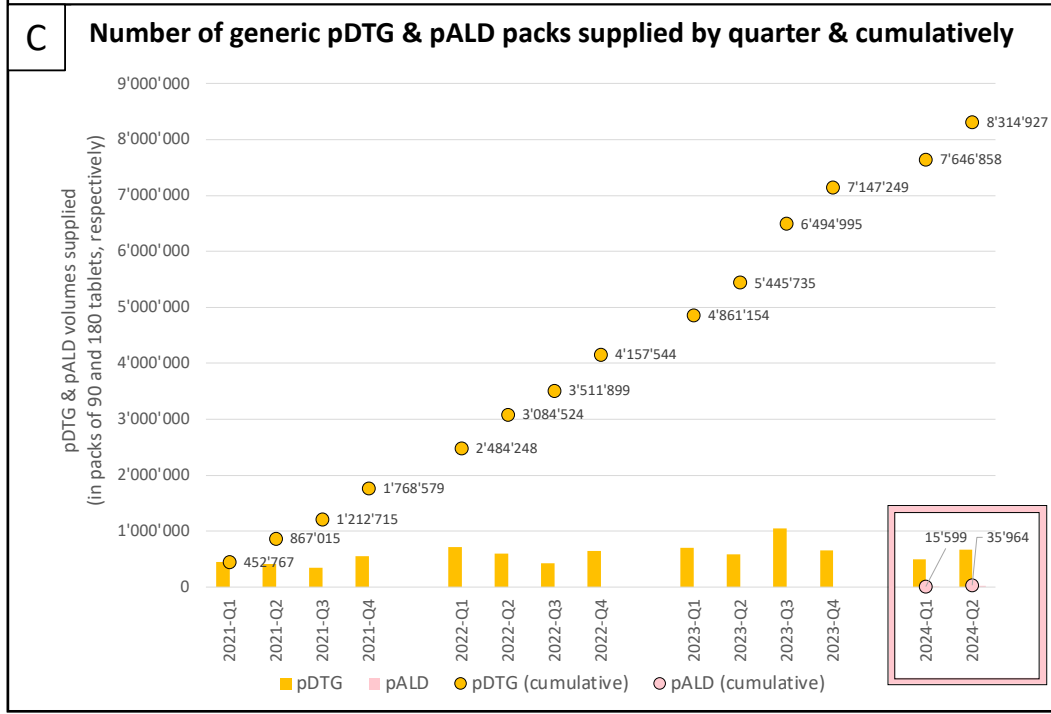
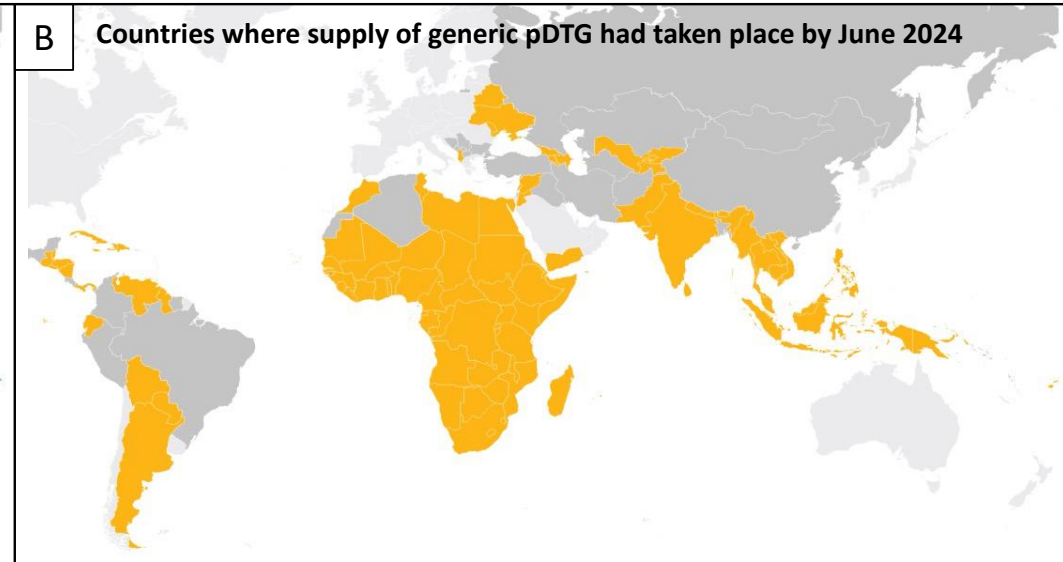
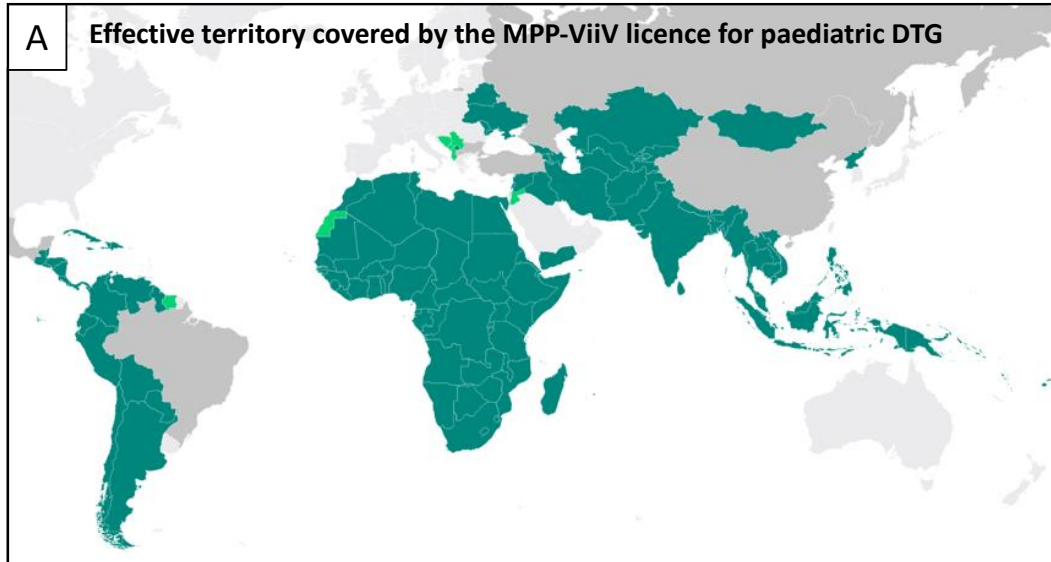
- The paediatric licence allows for sale in **123 countries** where >95% of children living with HIV
- Sales **outside the licensed countries** are **permitted where there is no granted patent** in force or where sales of a generic version do not infringe on an existing patent, such as in cases in which a compulsory licence has been issued
- There are **no royalties** for paediatric formulations
- Quality is ensured through approval of **WHO Pre-qualification or a Stringent Regulatory Authority**

PRODUCTS	ACTIVE MPP LICENSEES	READY TO SUPPLY		
		WHO-PQ* APPROVED	USFDA** APPROVED	ERP*** APPROVED
^ DTG paediatric (10 mg scored, dispersible) [?]	5	1	2	0
	   		 	
^ ALD (paed) - ABC/3TC/DTG (60/30/5 mg) [?]	9	1	2	0
	  		 	



Progress rolling out paediatric DTG products

- **pDTG** has been rolled out massively (>8 mln packs by 2024, >100 countries)
- **pALD** scale up not yet happening
- A single country had accessed pALD by June 2024



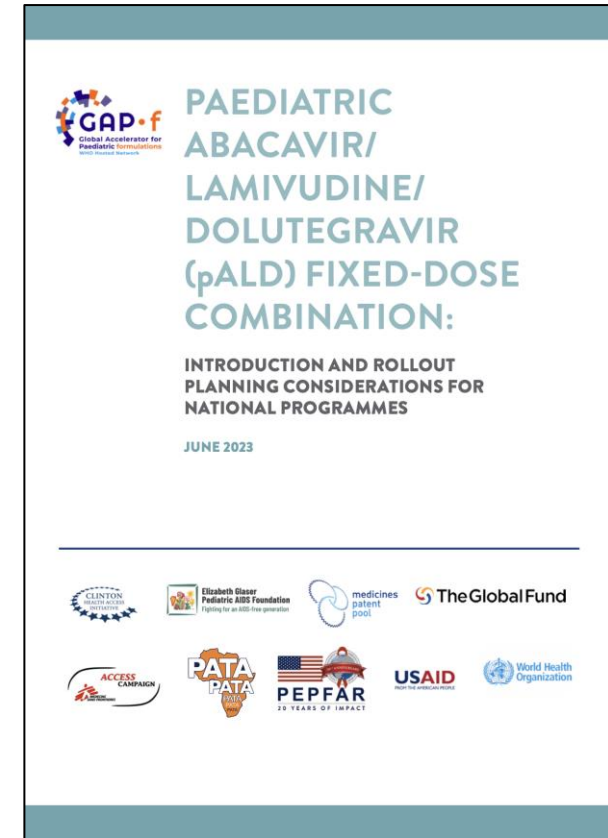
More at: <https://medicinespatentpool.org/licence-post/dolutegravir-paediatrics-dtg>
<https://medicinespatentpool.org/what-we-do/addressing-childrens-needs>
<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>

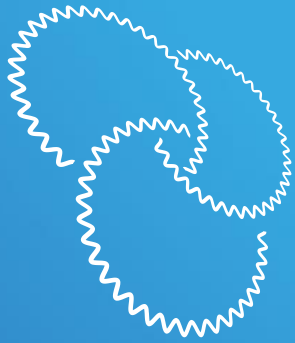
Advocacy towards non-delayed optimal treatment equity!

There are challenges, but pALD can further improve children's HIV treatment outcomes

Mothers, caregivers, healthcare workers, and treatment advocates can:

- **Reach out to their governments and:**
 - Ask about pALD transition plans (guidance update, strategy, timelines, volumes)
 - Share pALD transition resources (including the GAP-f brief, see footnotes)
- **Reach out to GAP-f (pALD Task Team and partners, at gap-f@who.int) and:**
 - Report any challenges faced (including policy, supply and implementation issues)
 - Share transition plans (guidance update, strategy, timelines, volumes)
 - Share transition success stories
- **Reach out to MPP (at smorin@mppf.ch) and:**
 - Report any product-side challenges (including registration, supply, quality)





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HIV prevention:

Update on CAB-LA for PrEP licence implementation

MEDICINESPATENTPOOL.ORG

Generic CAB-LA for PrEP

Effective licence territory

Countries listed (90)

- All low-income countries
- All lower middle-income countries
- All sub-Saharan African countries
- All least-developed countries

+

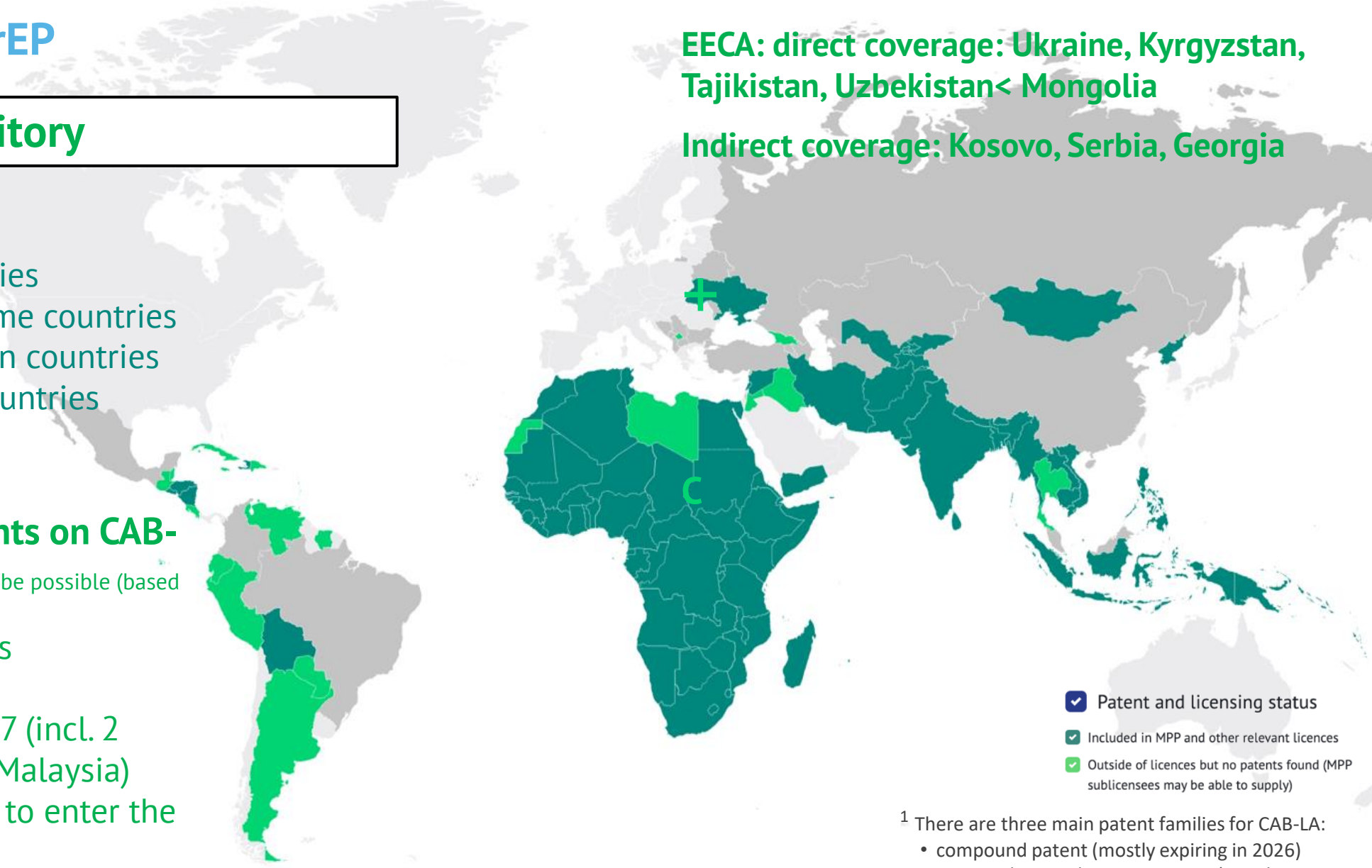
Countries with no patents on CAB-

LA¹ and where generic supply may be possible (based on data from MedsPaL)

- 46 additional countries (including 23 UMICs)
- 5 more past 2026/2027 (incl. 2 UMICs: Colombia and Malaysia)
- Generics are expected to enter the market in 2027-2028

EECA: direct coverage: Ukraine, Kyrgyzstan, Tajikistan, Uzbekistan < Mongolia

Indirect coverage: Kosovo, Serbia, Georgia



- Patent and licensing status
- Included in MPP and other relevant licences
- Outside of licences but no patents found (MPP sublicensees may be able to supply)

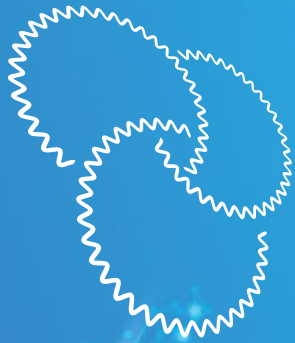
¹ There are three main patent families for CAB-LA:

- compound patent (mostly expiring in 2026)
- intermediate and process patent (mostly expiring in 2031)
- formulation patent relating to LAI (mostly expiring in 2031)

More at: <https://www.medsPal.org>
<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>
<https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-exposure-prophylaxis-prep>

Conclusions

- A key first step for enabling significant price reductions for ARVs in EECA was the availability of multiple generic versions of key treatments.
- This was possible thanks to voluntary licences negotiated with industry by MPP
- That enabled procurement mechanisms to benefit from generic competition
- Community and civil society advocacy also played a critical role at every stage of the process



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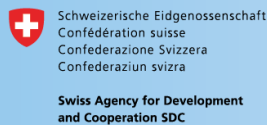
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Policy, Strategy and Market
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Geneva, Switzerland**

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Thanks for your attention!
*Do not hesitate to get in
touch*



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