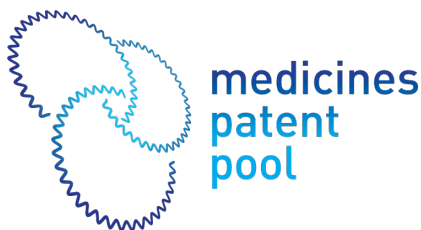


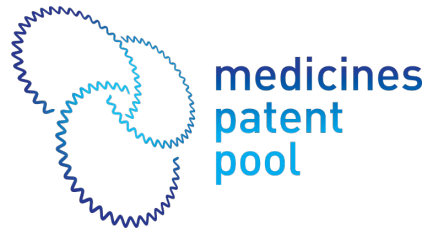
# Access to generic long-acting PrEP

## *Outlook and progress*

Presented by:

**Sébastien Morin**, PhD  
Policy and Advocacy Manager  
Medicines Patent Pool  
Geneva, Switzerland





Thanks also to the entire MPP team!

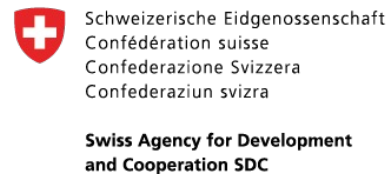


## Conflict of Interest Disclosure

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

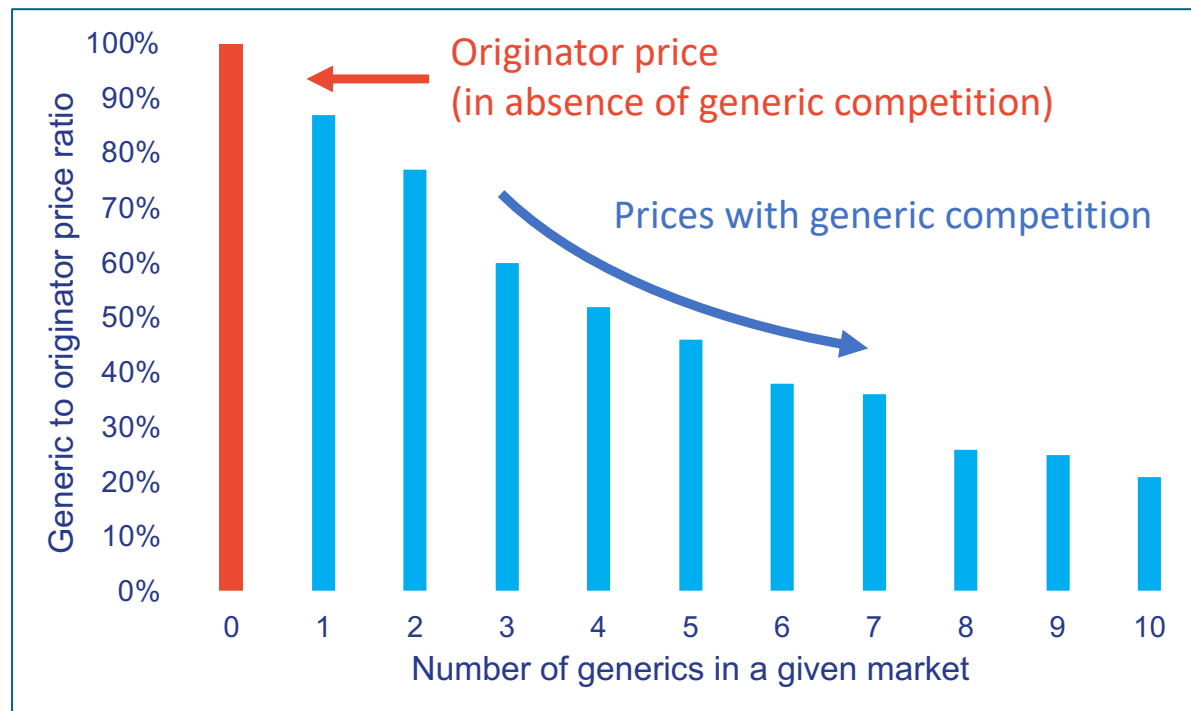
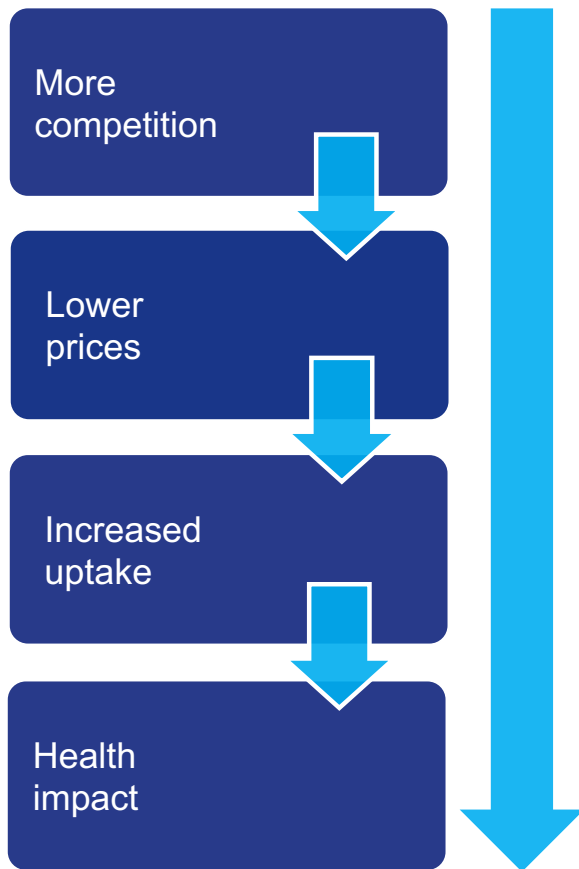
## Acknowledgments

- This work was made possible by the financial support of Unitaid to the Medicines Patent Pool.
- We thank them, as well as our other current funders.



## 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*

More at: <https://medicinespatentpool.org>

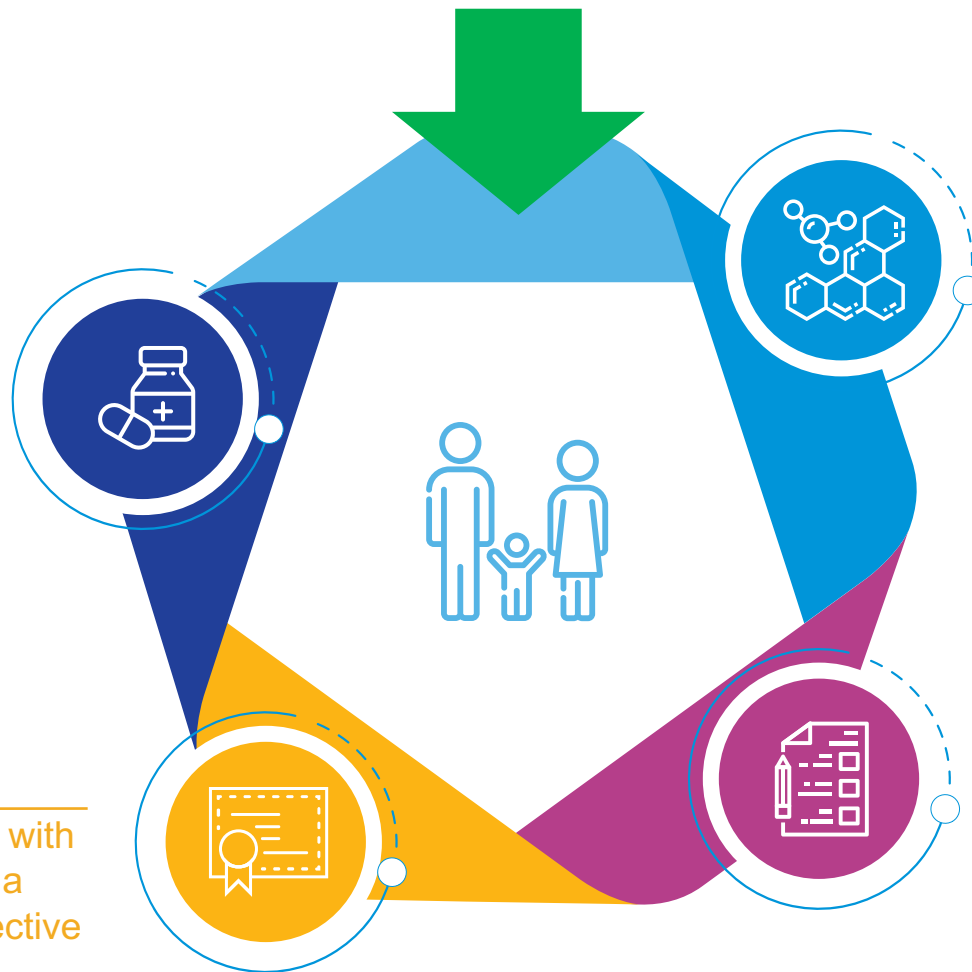
**1.**  
**Identify medicines** needed in low- and middle-income countries where licensing can improve access

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

**5.**  
**Collaborate with various partners** to increase access and improve health in LMICs

**4.**  
**Work with generic manufacturers** to accelerate the development and registration of adapted formulations for LMICs

**3.**  
**Sublicense** to selected generic pharmaceutical companies committed to supplying LMICs

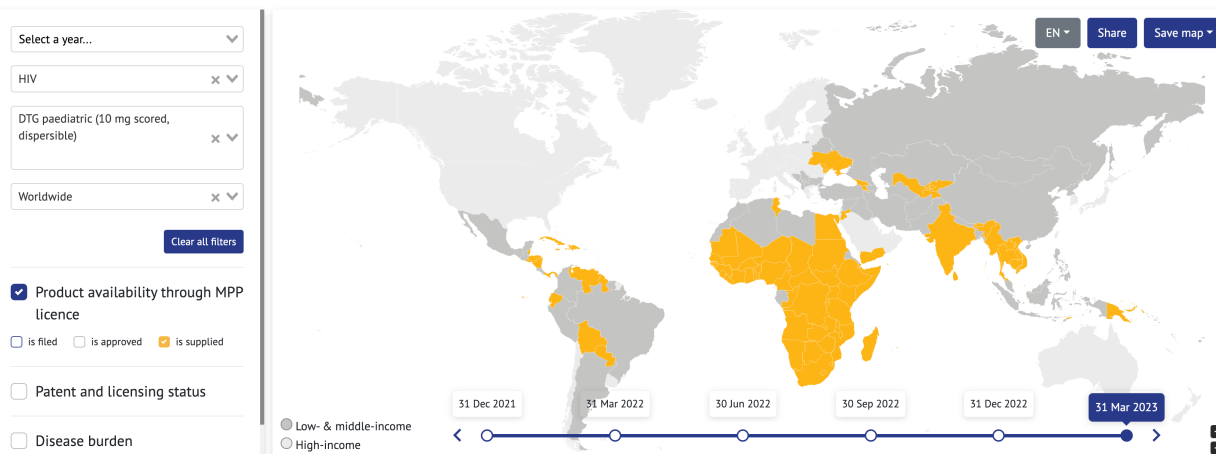


## MedsPaL

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

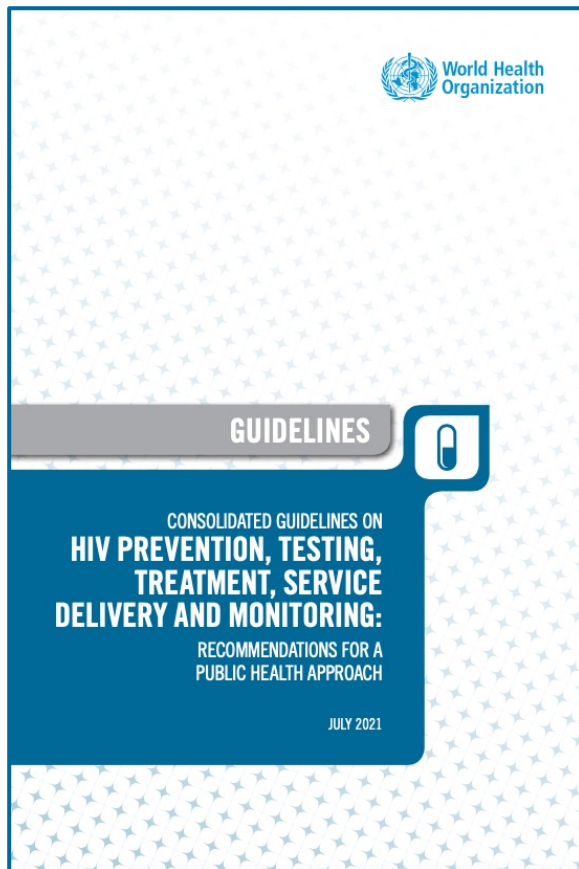
PRODUCTS	COMPANIES DEVELOPING THE PRODUCT	PENDING APPROVAL		READY TO SUPPLY			COUNTRIES WHERE		
		WHO-PQ*	USFDA**	WHO-PQ* APPROVED	USFDA** APPROVED	ERP*** APPROVED	PRODUCT IS FILED	PRODUCT IS APPROVED	PRODUCT IS SUPPLIED
DTG 50mg Licensed from ViiV Healthcare	12			Cipla DESANO Emcure HETERO LAURUS Mylan SUN PHARMACEUTICALS	ALTECENSIO Cipla HETERO LAURUS MACLEODS Mylan		Benin, Bolivia (Plurinational State of), Burkina Faso, Burundi, Cameroon, Dominican Rep, El Sa Gal	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

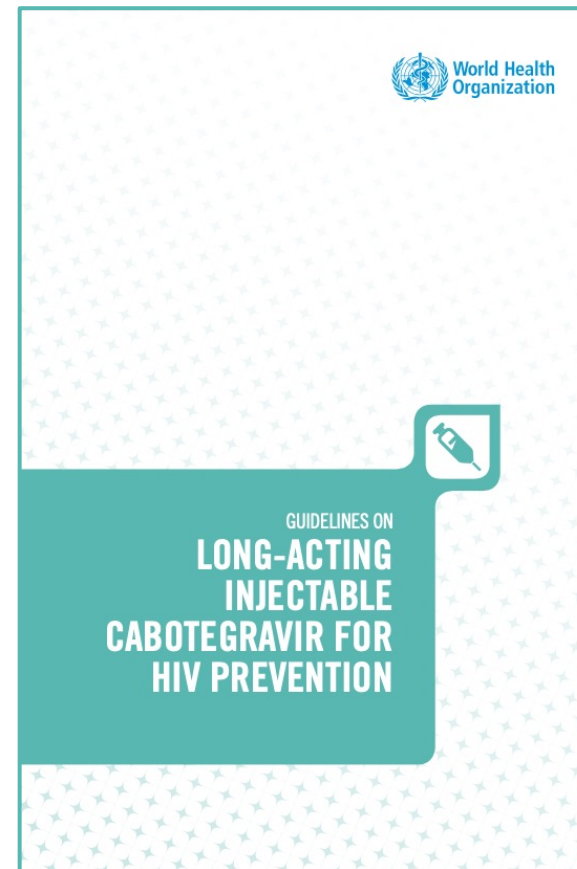
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

<https://www.lapal.ch>



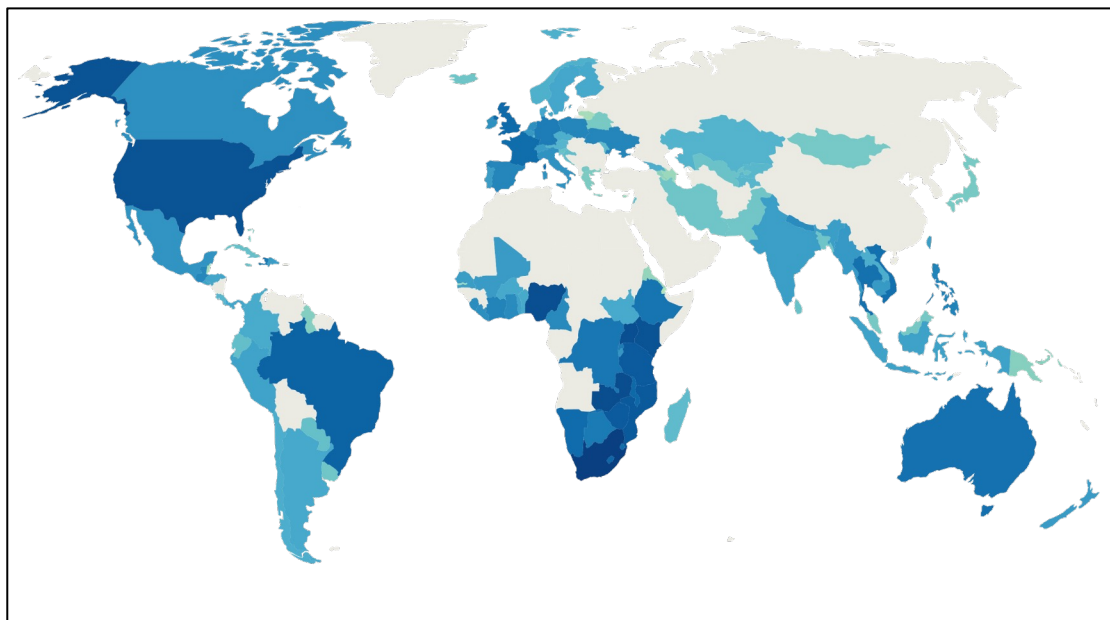
Treatment

- Adults:  
DTG 50 mg and TLD fixed-dose combination  
**MPP licence**
- Children (3-20 kg):  
DTG 10 mg scored dispersible  
**MPP licence**
- Children (6-20 kg):  
pALD dispersible fixed-dose combination  
**MPP licence**



Prevention

- Oral PrEP (TDF/XTC)  
**Patent expired**
- Dapivirine vaginal ring  
**Population Council**
- Long-acting injectable cabotegravir (CAB-LA)  
**MPP licence**

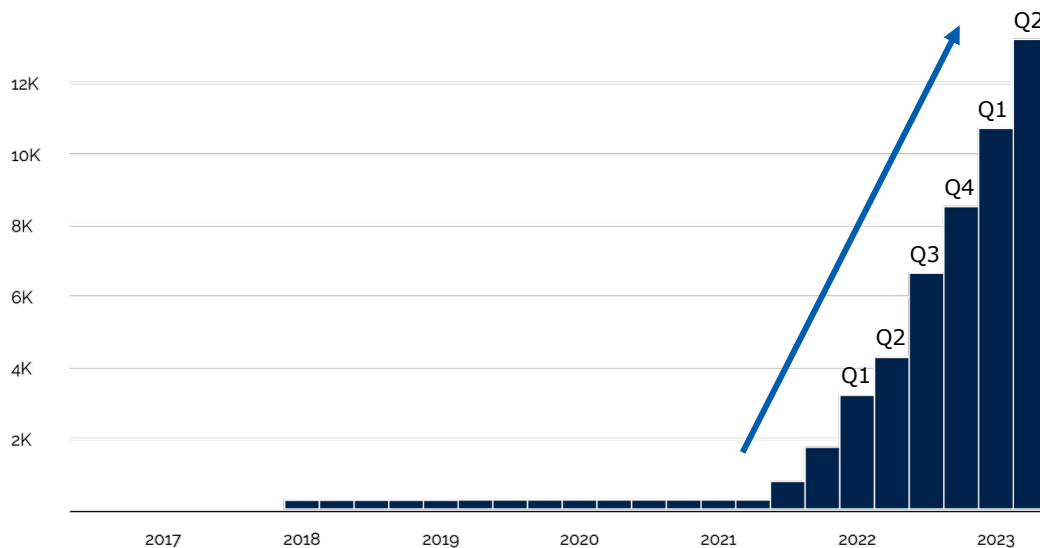


## PrEP in Philippines

### Available PrEP Products

In Philippines, PrEP is offered as Oral PrEP TDF/xTC (TDF products and generic), and Injectable PrEP.

### Number of PrEP Initiations Over Time



More at: <https://data.prepwatch.org>  
<https://www.prepwatch.org/countries/philippines>



## 1. Fields of application

- The licence covers patents for the use of **CAB-LA for pre-exposure prophylaxis (PrEP)**, which is the WHO priority
- The licence enables MPP-licensed manufacturers to develop and supply generic versions

## 2. Quality assurance

- Licensees must obtain **WHO prequalification or approval from a “stringent” regulatory authority (SRA)**, such as USFDA or EMA

## 3. Regulatory exclusivity

- **Data exclusivity is lifted in countries in the territory** benefiting from such a form of protection, which facilitates regulatory approval of generics

## 4. Royalties

- The licence is **royalty-free for most countries**
- There are **5% royalties for 10 countries** in which ViiV holds patent rights (Algeria, Egypt, India, Indonesia, Kyrgyzstan, Morocco, **Philippines**, Tajikistan, Ukraine, Vietnam); **in these countries, sales of generics are also only authorized on the public market**

## 5. Transparency

- The full text of the licence is **published online**



More at: <https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-exposure-prophylaxis-prep>



## 1. Selection of three generic manufacturers completed

- Following a public call for applications for interested companies and an anonymized selection process
- These are:
  - **Aurobindo** (India)
  - **Cipla** (India + South Africa)
  - **Viartis / Mylan** (India)

## 2. Transfer of technical know-how completed

- Tech transfer took place at the end of 2023 directly between ViiV Healthcare and MPP-licensed generics

## 3. Development ongoing, to finalize in 2026-2027

- Development will likely take another 3 years
- Meanwhile, the only source of CAB-LA for PrEP will be ViiV Healthcare's product

## 4. Ongoing collaborations




- MPP works in collaboration with several partners, including members of the Coalition to Accelerate Access to Long-Acting PrEP (**LA PrEP Coalition**)

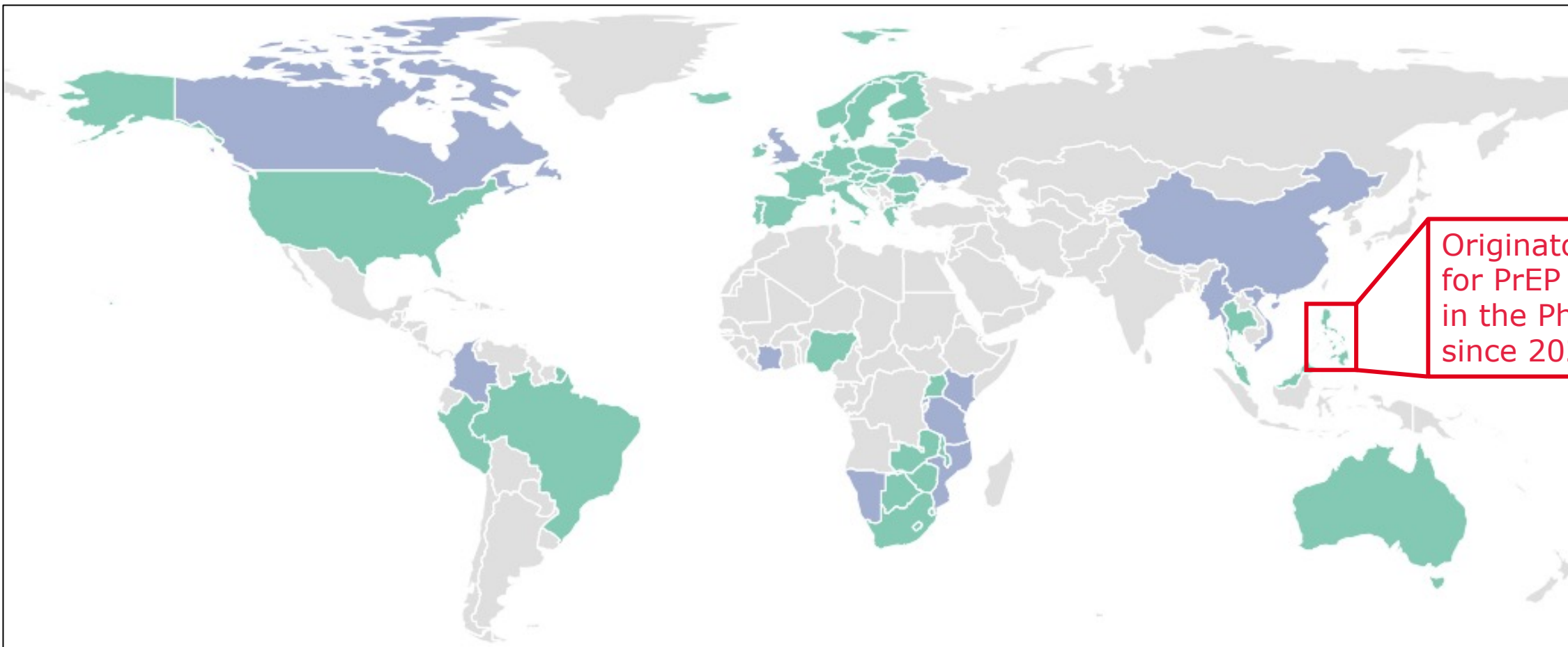
[News & Publications](#) » [News & Press Releases](#) » [Press Releases](#)

Medicines Patent Pool signs sublicences with Aurobindo, Cipla and Viartis to produce generic versions of ViiV Healthcare's innovative long-acting HIV prevention medicine

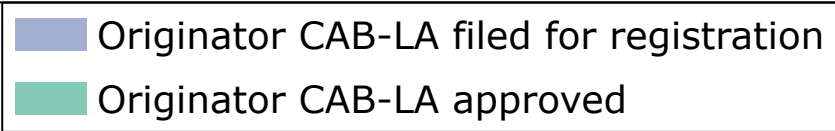
30 March 2023

- *Licences should enable potentially millions of people living in areas most impacted by HIV to access this innovative prevention medicine through low-cost generic manufacturers*
- *Announcement includes potential for large scale manufacturing on the continent of Africa*



Originator CAB-LA for PrEP registered in the Philippines since 2023-09-15.



More at: <https://lapal.medicinespatentpool.org/landscape>

## Direct territory

- The licence allows generics to supply **90 countries**:
  - **All low-income countries**
  - **All lower middle-income countries**
  - **All sub-Saharan African countries**
  - **All least-developed countries**

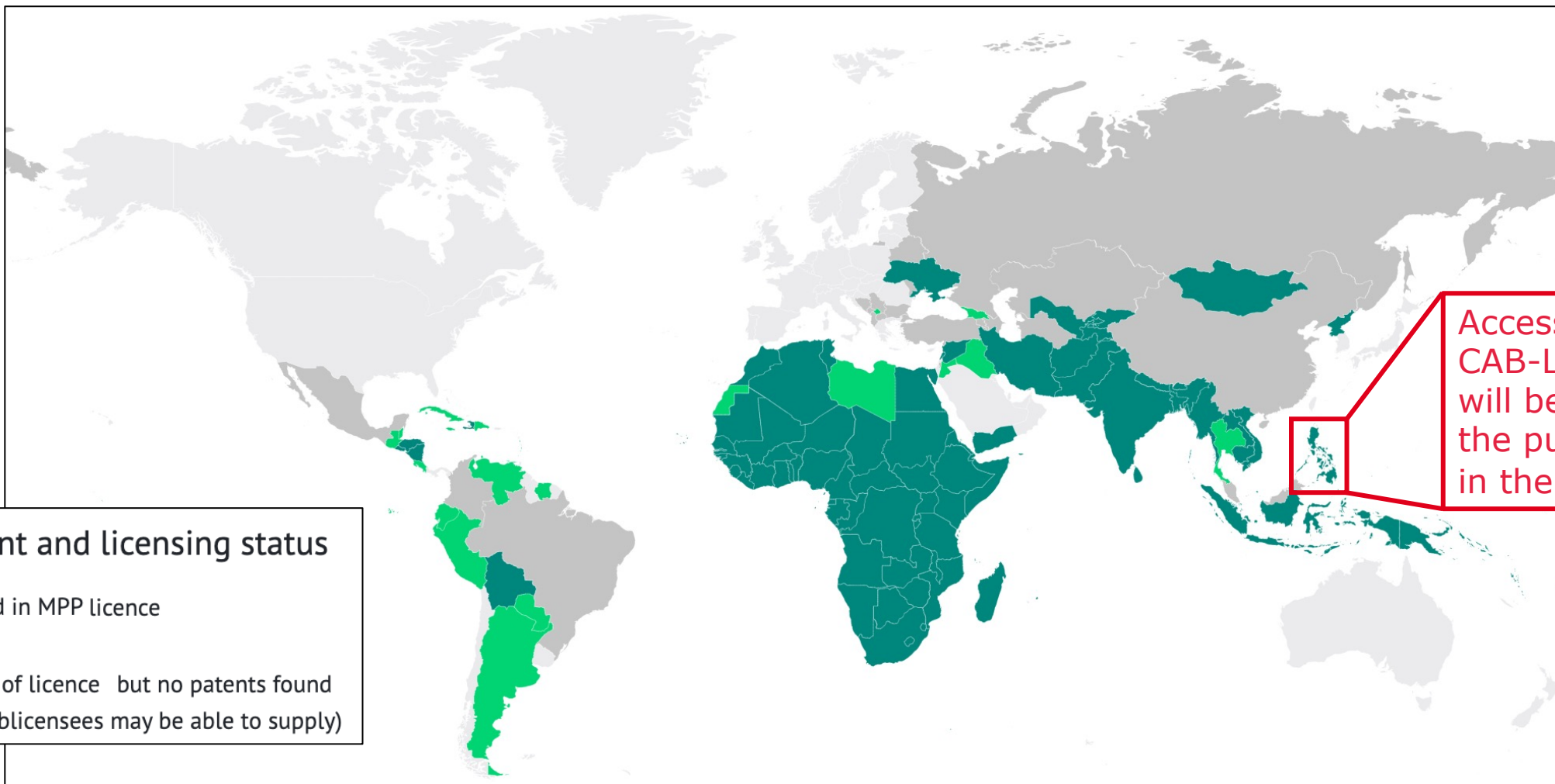
## Indirect territory

- **Sales outside the licence territory** may be permitted in certain circumstances (where there are **no patents on CAB-LA in force**)

## Effective territory

- The effective territory therefore includes the list of **countries included in the licence**, as well as any **other countries where there is no patent in place**
- *However, the existence of periods of exclusivity for regulatory data in certain countries outside the direct territory could be a barrier to the registration of generics*

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



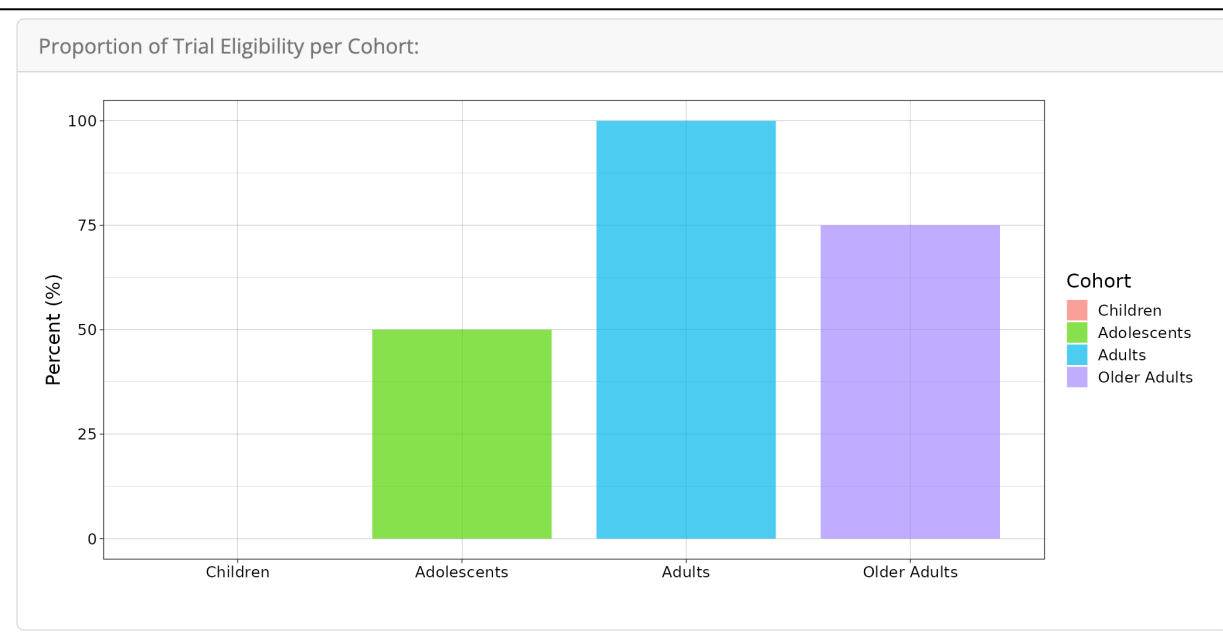
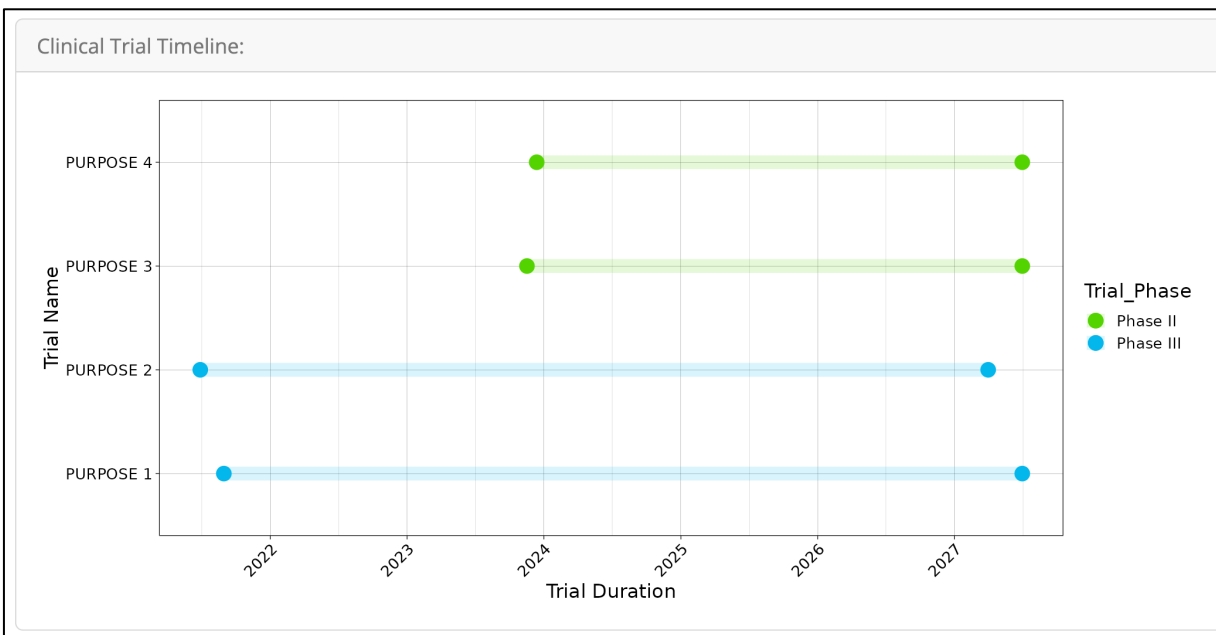
- ✓ Patent and licensing status
- ✓ Included in MPP licence
- ✓ Outside of licence but no patents found (MPP sublicensees may be able to supply)

Access to generic CAB-LA for PrEP will be possible in the public market in the Philippines

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

## Lenacapavir

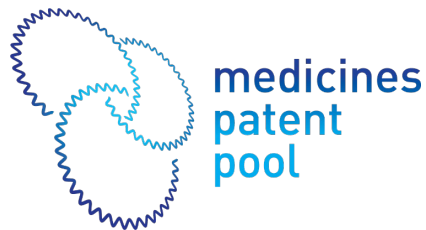
- Lenacapavir is an MPP priority since 2022 and has been prioritised by WHO in both PADO-5 and CADO-4
- Its mechanism of action + long-acting properties (up to 6 months dosing) will likely make it important in HIV
- Ongoing clinical programs continue to indicate favourable efficacy and safety profiles



More at: <https://lapal.medicinespatentpool.org/landscape>  
<https://medicinespatentpool.org/progress-achievements/prioritisation>

**Let's already collectively plan for broad access to this medicine!**

Now is the time to start or continue expanding access to oral PrEP and plan for the introduction of CAB-LA for PrEP in anticipation of its future availability in generic versions!



# Thanks for your attention!

[WWW.MEDICINESPATENTPOOL.ORG](http://WWW.MEDICINESPATENTPOOL.ORG)

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