



# Access to key generic HIV medicines in Mozambique

## *Current & future opportunities*

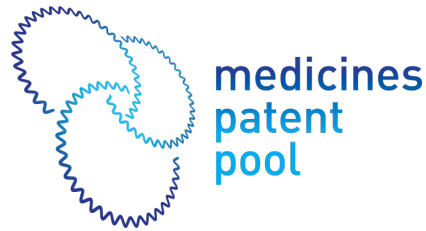
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Thanks also to the entire MPP team!

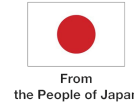


## Conflict of Interest Disclosure

- 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.





International AIDS Society [iasociety.org](http://iasociety.org)



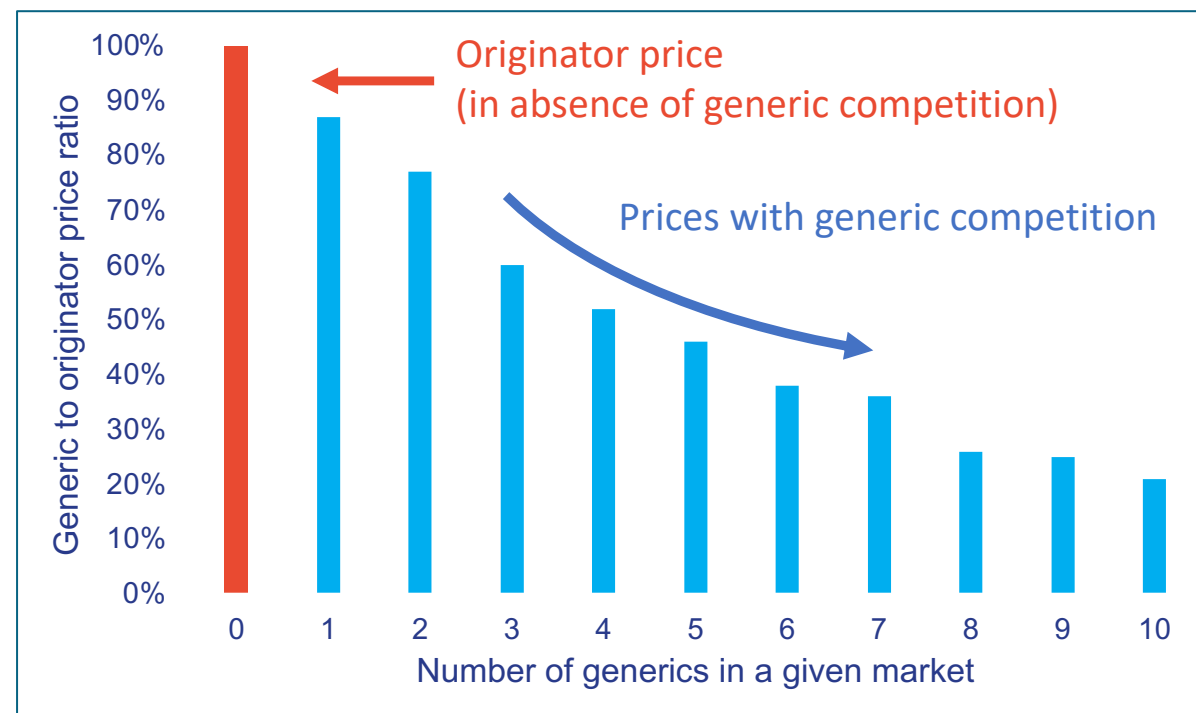
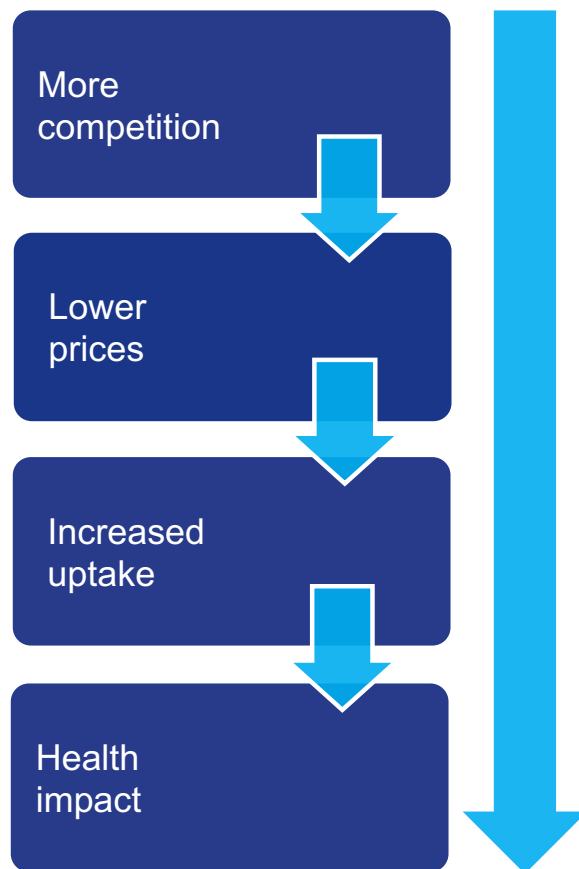
# Overview of MPP and voluntary licensing

Access to affordable quality-assured generic medicines



## Overview of MPP's voluntary licensing model

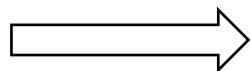
- Driving prices down through generic competition
- Accelerating timelines for generic product availability



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

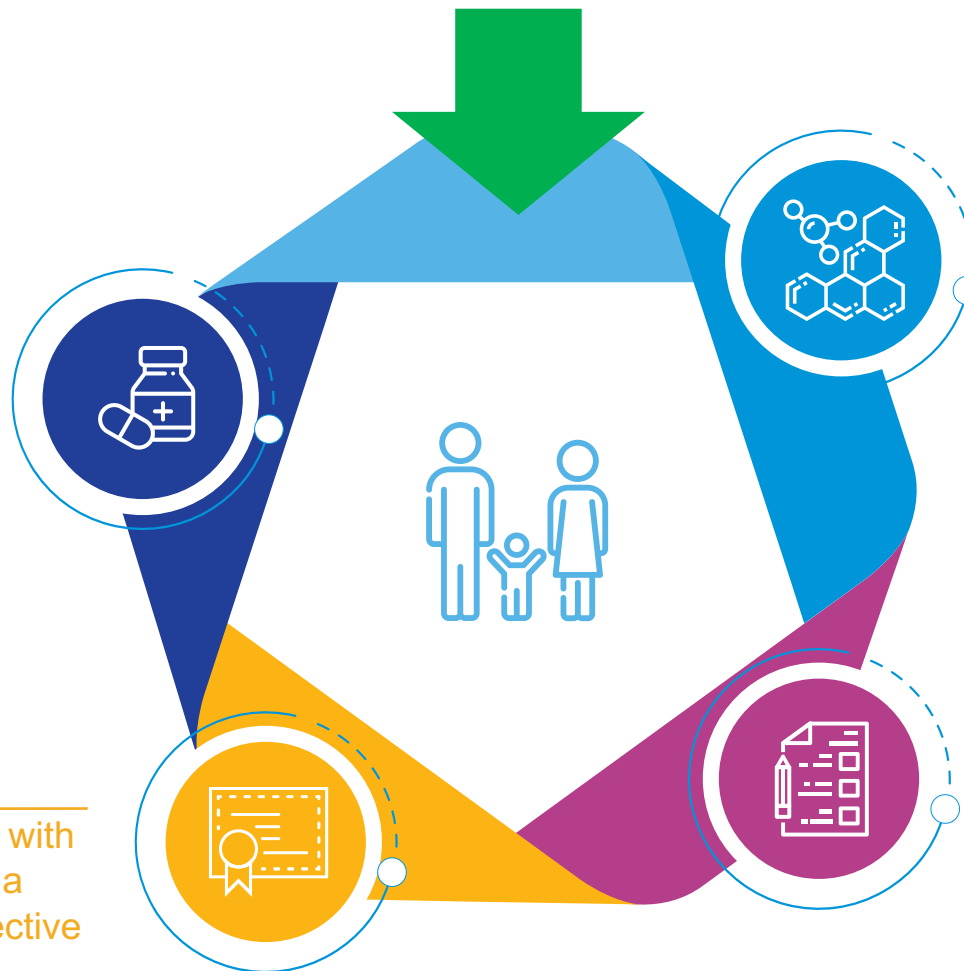
More at: <https://medicinespatentpool.org>

# 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



**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 table

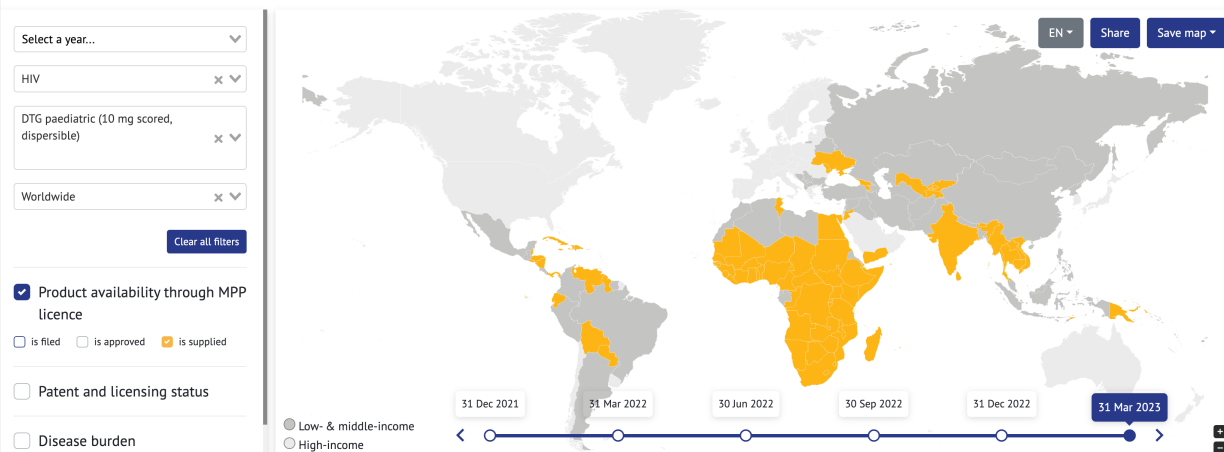
Key: ■ HIV ■ Hepatitis C ■ Tuberculosis

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
<b>DTG 50mg</b> Licensed from <a href="#">ViiV Healthcare</a> 	12			<b>Cipla</b> DESANO Emcure HETERO LAURUS Mylan SUN PHARMACEUTICALS	ALTECENSIO <b>Cipla</b> HETERO LAURUS INCLEOS 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>

## Access to medicines tracker – Interactive map

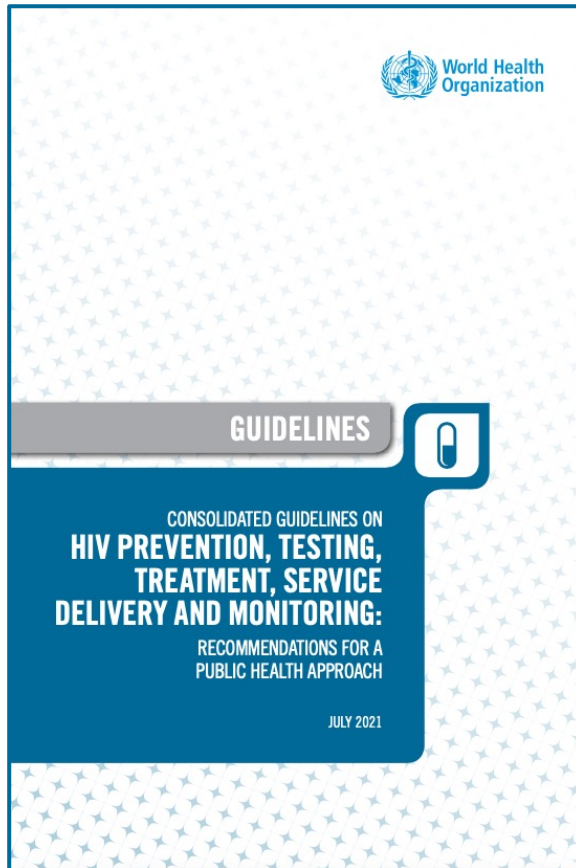


<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>

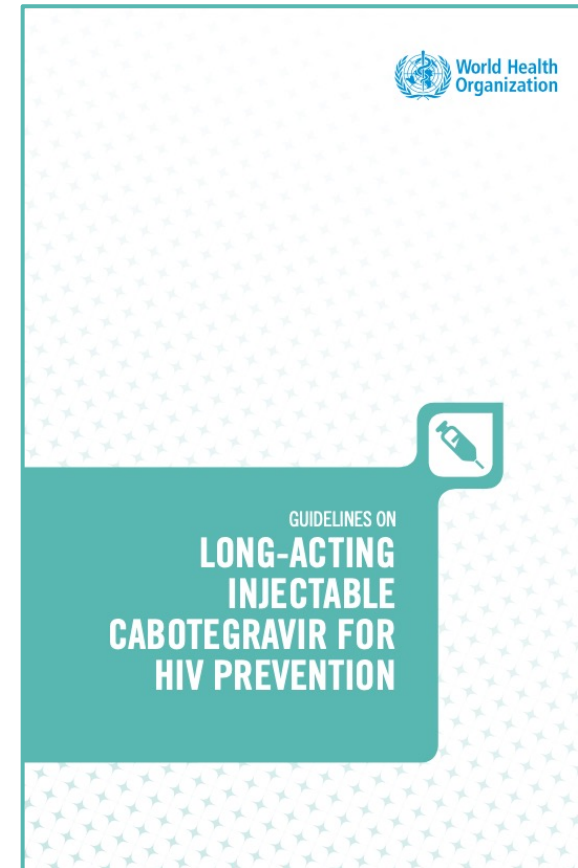
## LAPaL

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**

Mozambique can access generic versions of most of these products through MPP-licensed manufacturers

\* Please note that generic versions of CAB-LA are currently being developed.



International AIDS Society [iasociety.org](http://iasociety.org)

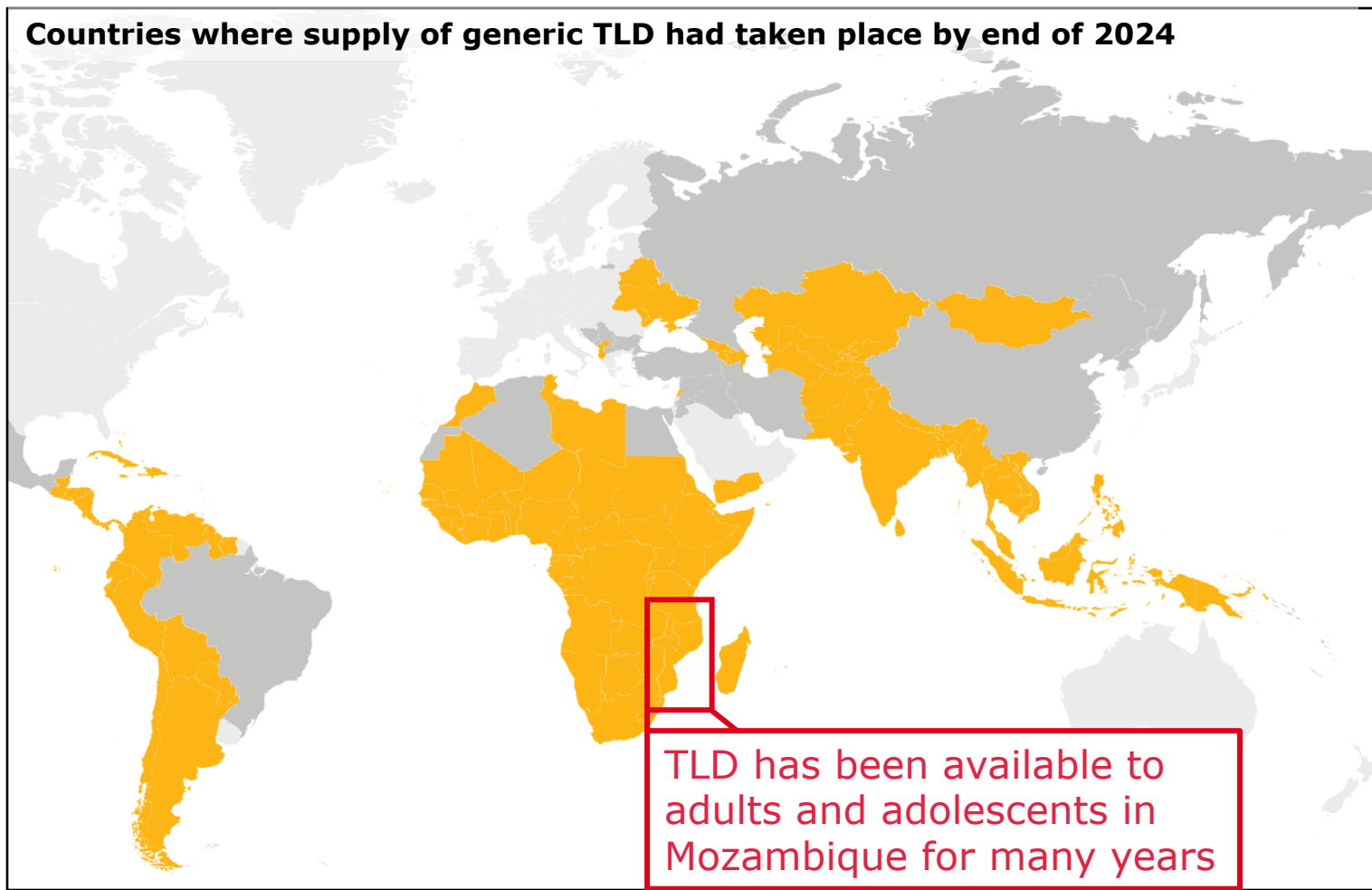


# Access to HIV treatment

Access to fixed-dose combinations for adults and children

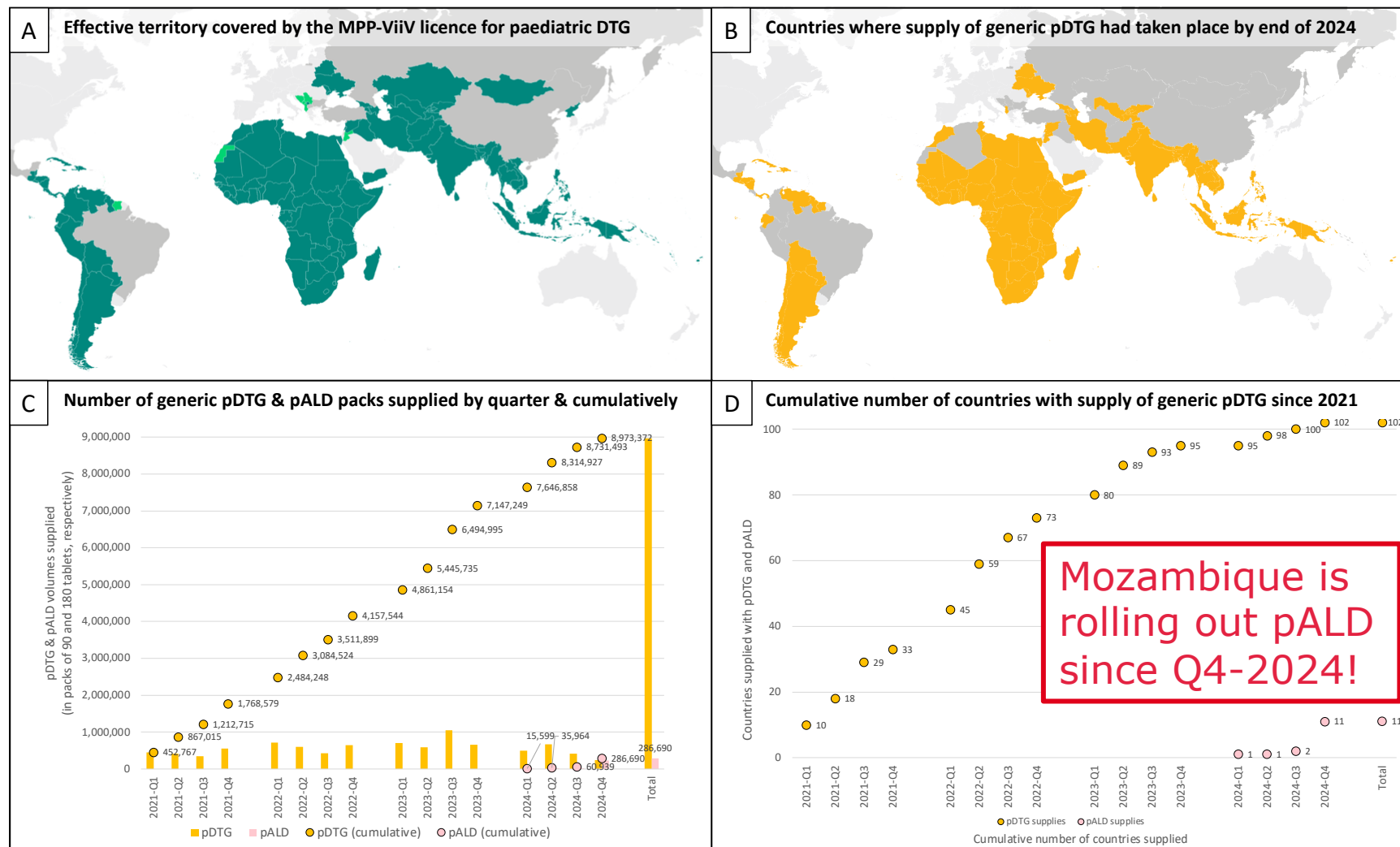


- Adults and adolescents living with HIV have benefitted from access to a fixed-dose combination treatment option, **TLD**, for many years
- Generic **TLD** is now widely available, having been supplied in 118 countries to date, including in Mozambique
- The **pDTG and pABC/3TC** dispersible tablets for young children have been available for a few years, including in Mozambique, but an optimal paediatric fixed-dose combination dispersible HIV treatment option had not been available until recently
- **pALD** is now starting to be rolled out (including in Mozambique)!



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

- **pDTG** has been rolled out widely (102 countries to date) but **pALD** scale up is still starting...
- **11 countries (including Mozambique) had accessed pALD by the end of 2024**
- Transition to pALD has started at a slow pace, due to concerns about wastage, costs, and transition fatigue
- Wastage can be managed
- Costs are likely not an issue
- Transition fatigue can be overcome



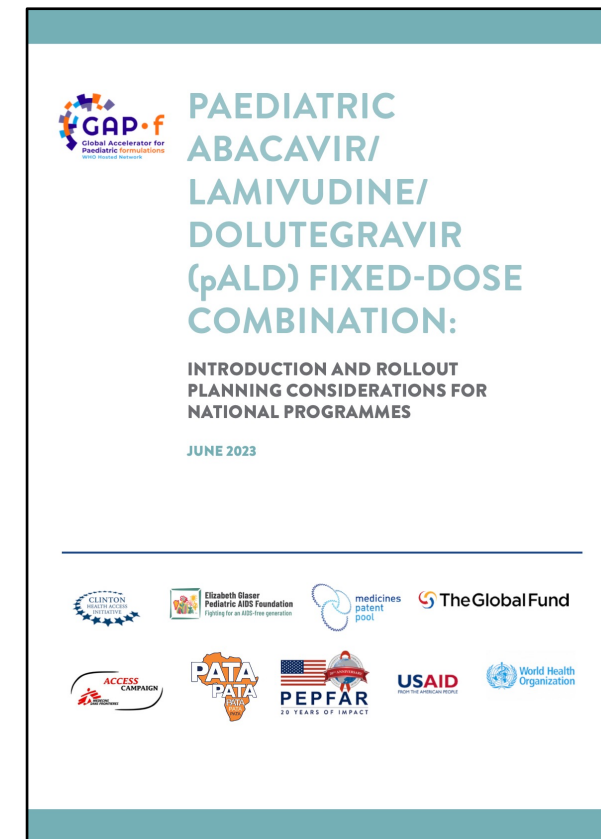
More at: <https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>

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

→ *This is especially true in the current challenging funding context!*

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](mailto: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](mailto:smorin@mppf.ch)) and:
  - Report any product-side challenges (including registration, supply, quality)



More at: [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)  
<https://www.youtube.com/live/5Q6omqnmzcs?si=WO3w404kWCwUt9Pz&t=87>



International AIDS Society [iasociety.org](http://iasociety.org)

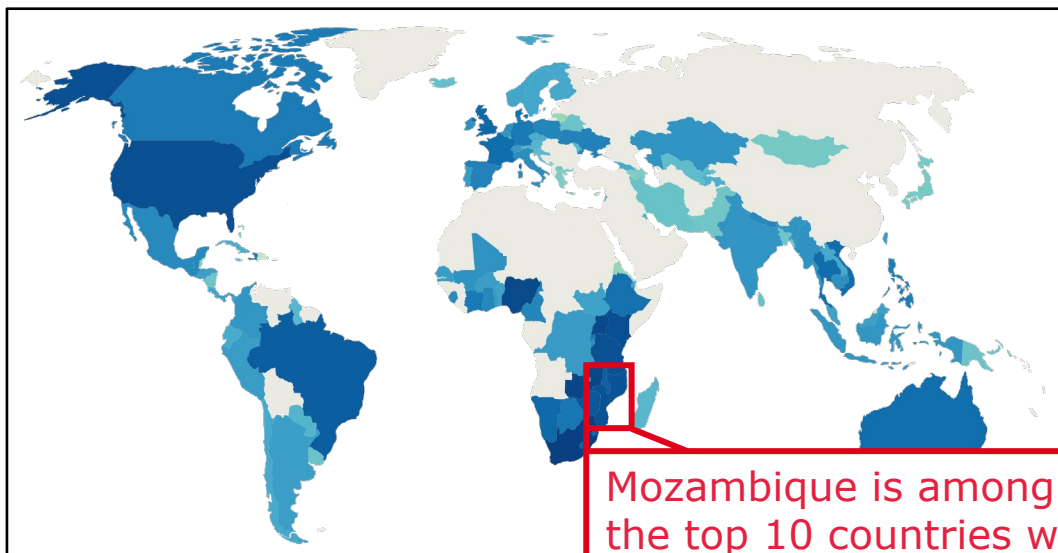


# Access to HIV prevention

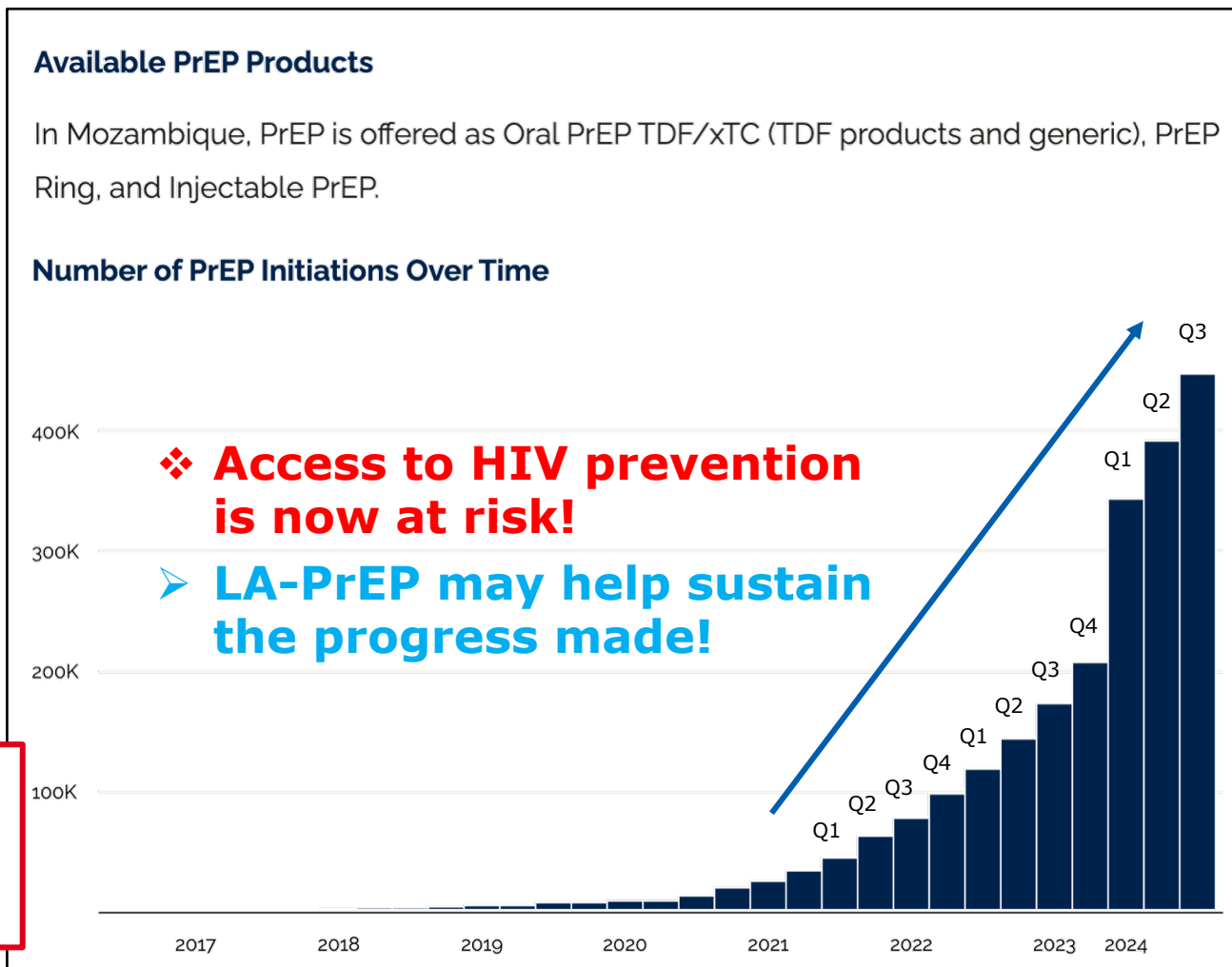
Access to (long-acting) pre-exposure prophylaxis (PrEP)



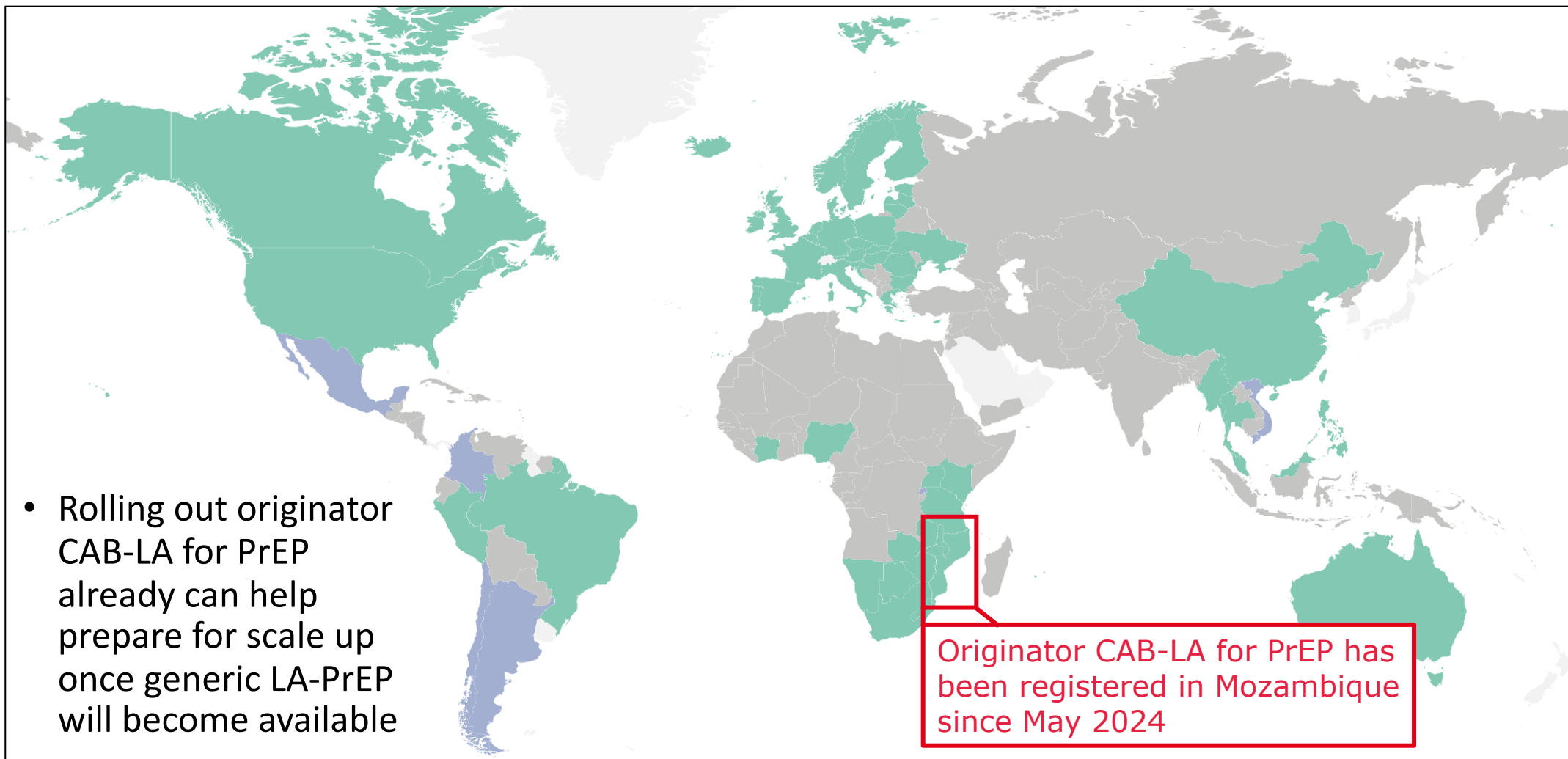
- Generic oral PrEP (TDF/FTC) is widely available and has started being rolled out in several sub-Saharan African countries, including Mozambique, for several years



Mozambique is among the top 10 countries with regards to the number of PrEP initiations to date





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



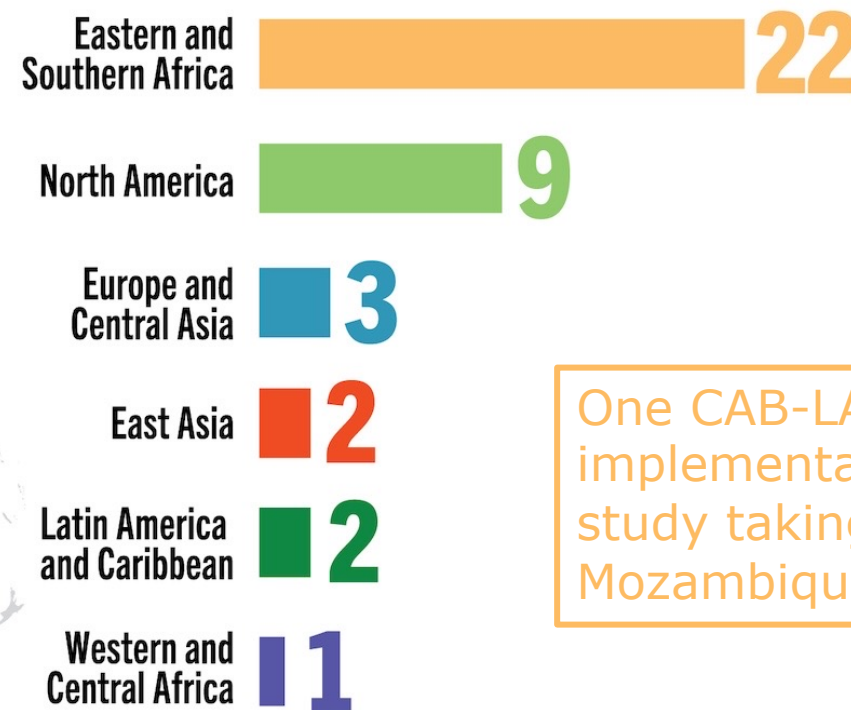
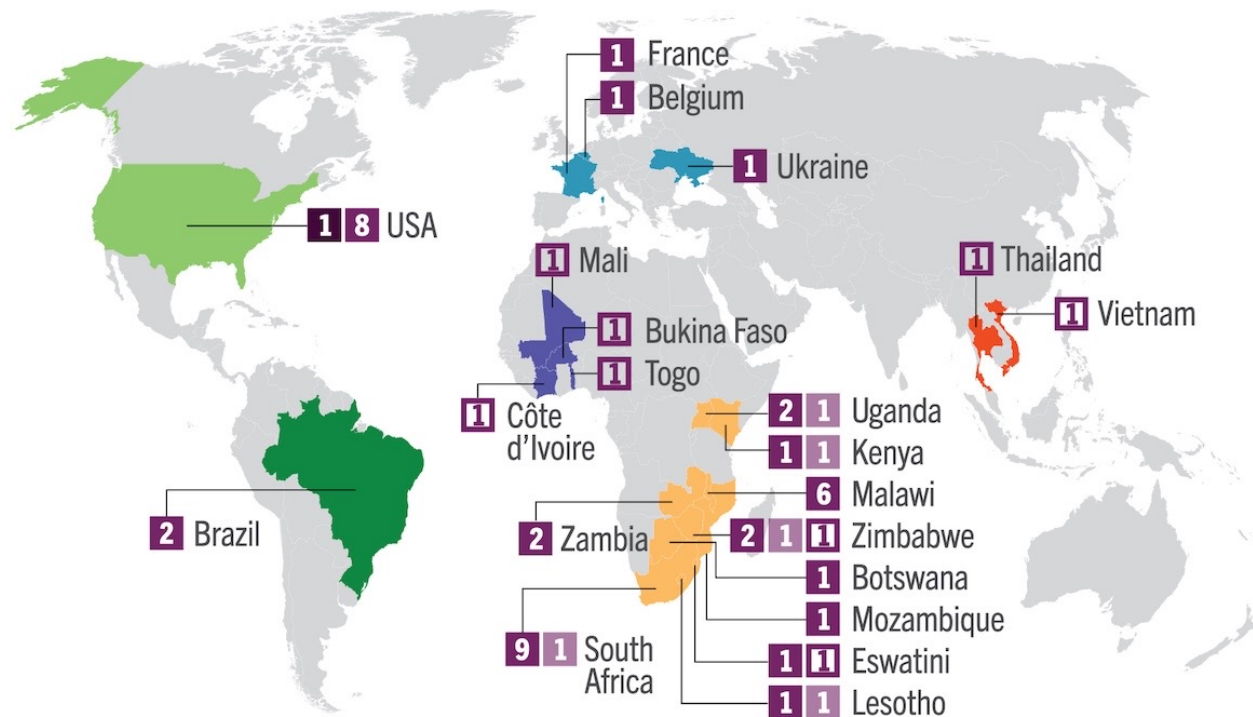
- Rolling out originator CAB-LA for PrEP already can help prepare for scale up once generic LA-PrEP will become available

Originator CAB-LA for PrEP has been registered in Mozambique since May 2024

	Originator CAB-LA filed for registration
	Originator CAB-LA approved

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

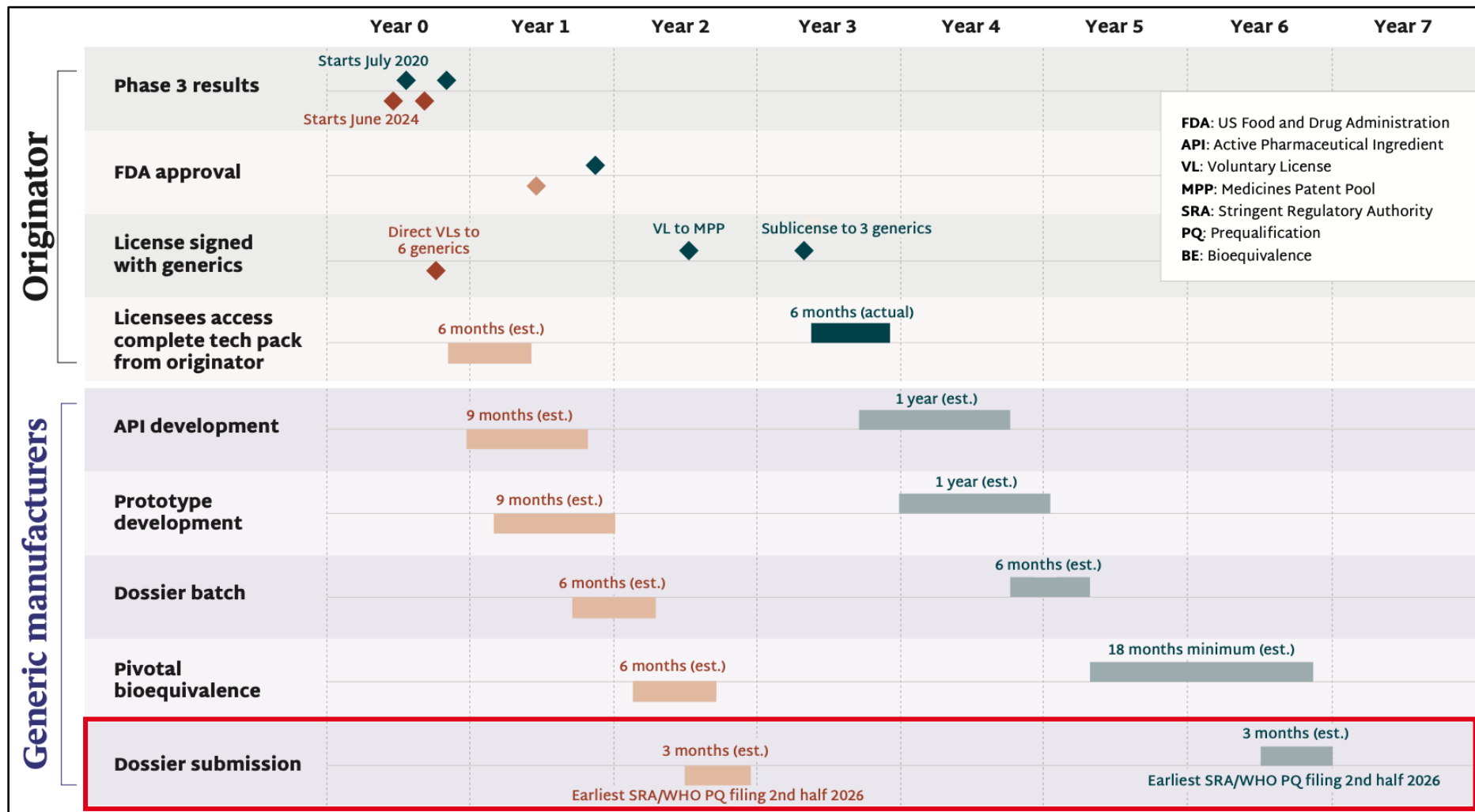
**38** implementation studies are completed, ongoing, or planned and **1** is on hold for CAB in **21** countries as of March 2025



One CAB-LA for PrEP implementation study taking place in Mozambique

Completed
  Ongoing
  On Hold
  Planned

More at: <https://www.prepwatch.org/long-acting-status-update>

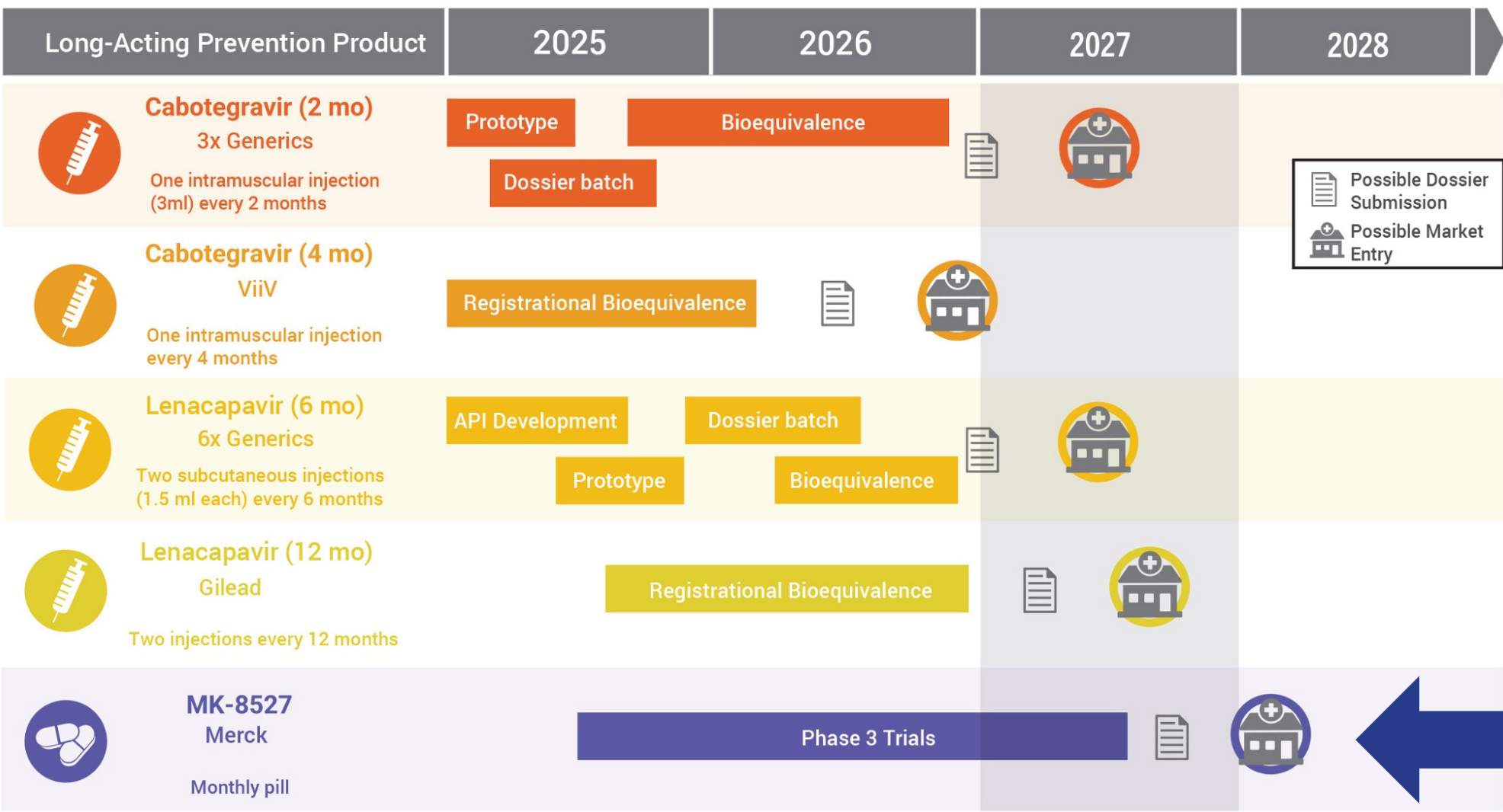


Generic CAB and LEN for PrEP may both be submitted for stringent regulatory approval in the second half of 2026 or early 2027, and access in countries, including Mozambique, could start during 2027

- This graphic shows average timelines: generic manufacturers may move at different timelines and unanticipated delays may happen at any step
- The overall timeline for generic LEN is expected to be shorter than for CAB because of differences in the drug formulation whereby bioequivalence (BE) testing for LEN is likely to be 6 months vs 18 months for CAB

More at: <https://www.prepwatch.org/long-acting-status-update>

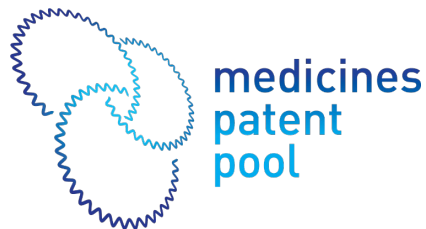
# A promising pipeline for long-acting PrEP



Most efforts focus on expanding the duration of injectable options

There is also one emerging long-acting oral option!

More at: [https://avac.org/wp-content/uploads/2025/05/PxWire\\_May2025.pdf](https://avac.org/wp-content/uploads/2025/05/PxWire_May2025.pdf)



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Now is the time to:

1. Transition all children living with HIV to the new pALD fixed-dose combination, thereby supporting their improved adherence and health outcomes
2. Further expand access to oral PrEP and plan for the introduction of LA-PrEP in anticipation of future availability of generic versions!

**Thanks for your hard work!  
Please reach out for anything...**



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