

# CAB PrEP: the winding path from research to rollout

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MOSAIC Project Director

15 June 2024

CAB PrEP = injectable cabotegravir for PrEP = long-acting cabotegravir = CAB-LA





# MOSAIC PROJECT OVERVIEW

- 5-year global project funded by PEPFAR through USAID (2021-2026)
- Focuses on introduction and access for new biomedical prevention products to prevent HIV for women in sub-Saharan Africa
- Works across multiple countries – Botswana, Eswatini, Lesotho, Kenya, Namibia, Nigeria, South Africa, Uganda, Zambia, and Zimbabwe
- Supports a multi-product market with informed choice for HIV prevention as new products enter the market

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## OUR VALUES

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COUNTRY-LED

WOMEN-  
FOCUSED WITH  
EMPHASIS ON  
AGYW

INFORMED  
CHOICE

EQUITABLE CO-  
LEADERSHIP

INTENTIONALITY

# WE WORK IN COLLABORATION WITH STAKEHOLDERS ACROSS THE HIV PREVENTION ECOSYSTEM



## PEPFAR

GHSD, USAID, CDC, DOD, PEPFAR in-country coordinators, GHSC, global and bilateral programs

## MOSAIC Consortium

**FHI 360, Wits RHI, Pangaea Zimbabwe, LVCT Health, Jhpiego, AVAC, 2Stories, Afton Bloom, Avenir Health, Bar Hostess Empowerment & Support Programme, Columbia University, Mann Global Health, Path Kenya, RTI, Scott Hospital, The AIDS Support Organization, University of Nairobi, University of Pittsburgh, University of Washington**

## National & Regional Stakeholders

Civil society organizations, national ministries of health, district and local health authorities, implementing partners, program and research projects, private sector, etc.

## Global Stakeholders

WHO, UNAIDS, Global Fund, BMGF, CIFF, Unitaid, MedAccess, MPP, NIH, ViiV, Gilead, Population Council/IPM, Merck, Viatrix, IAS, MSF, MTV Shuga, etc.

# 2020-22: Excitement!

**aidsmap**

News

About HIV

Injectable & long-acting PrEP

## US approves injectable cabotegravir for PrEP

Liz Highleyman | 24 December 2021 | Estimated reading time 8 minutes



Home » News and Events » Press Releases » Long-acting Injectable Cabotegravir Is Highly Effective For The Prevention of HIV Infection In Cisgender Men and Transgender Women Who Have Sex With Men

May 18, 2020

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Home » News and Events » Press Releases » HPTN 084 Study Demonstrates Superiority of CAB LA To Oral TDF/FTC For The Prevention of HIV

FDA NEWS RELEASE

## FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

*Drug Given Every Two Months Rather Than Daily Pill is Important Tool in Effort to End the HIV Epidemic*



## WHO recommends long-acting cabotegravir for HIV prevention

New WHO guidelines advise countries to deliver long-acting cabotegravir as part of comprehensive approach to HIV prevention

# 2023: What's taking so long?



WHO WE ARE FOCUS AREA

GLOBAL HEALTH

The New York Times

## A New Shot Guards Against H.I.V., but Access for Africans Is Uncertain



SHARE

REGION/COUNTRY

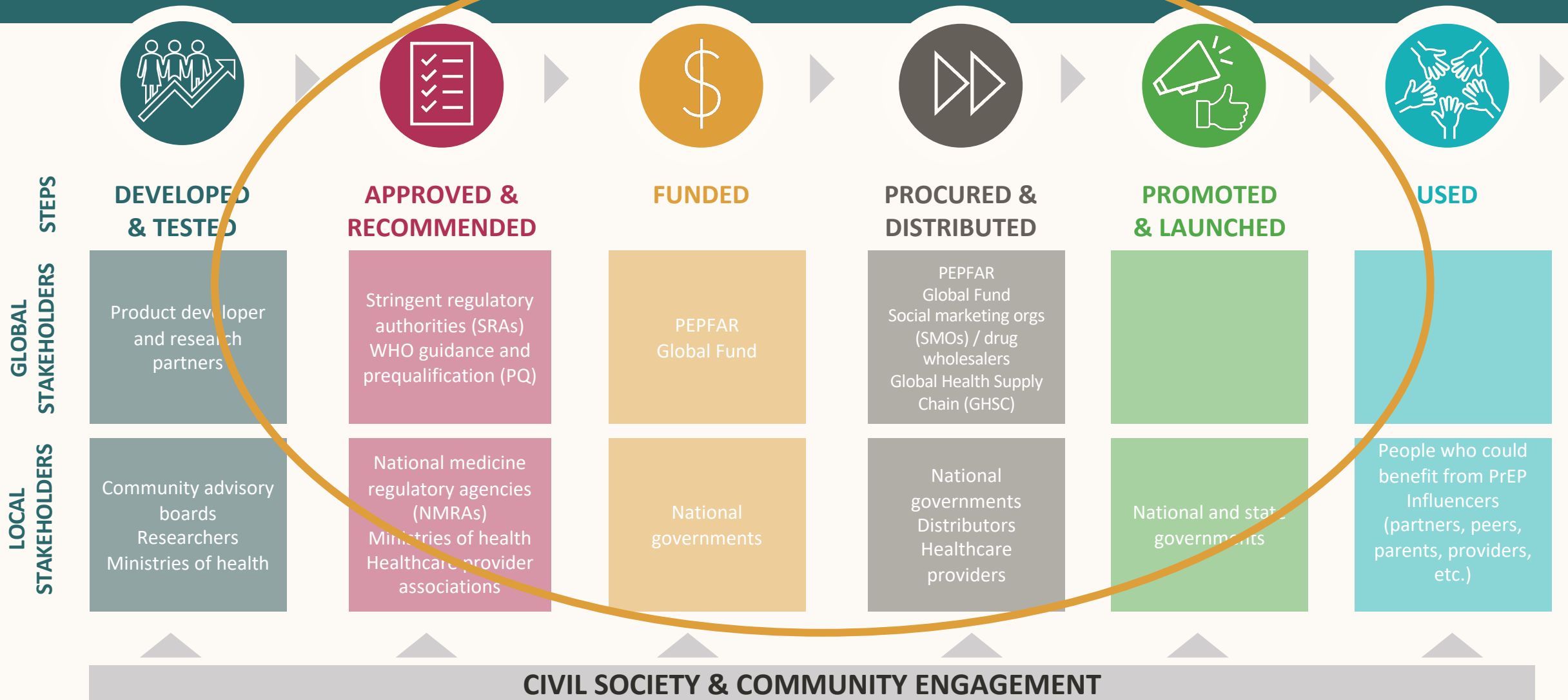
Eastern and Southern Africa

FEATURE STORY

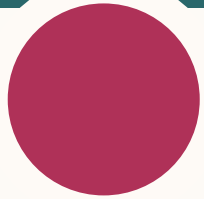
HIV Prevention Choice Manifesto for Women and Girls in Africa launched

12 SEPTEMBER 2023

# What does it take to move from R&D to users?



# Product must be approved and recommended



GLOBAL  
STAKEHOLDERS  
STEPS  
LOCAL  
STAKEHOLDERS

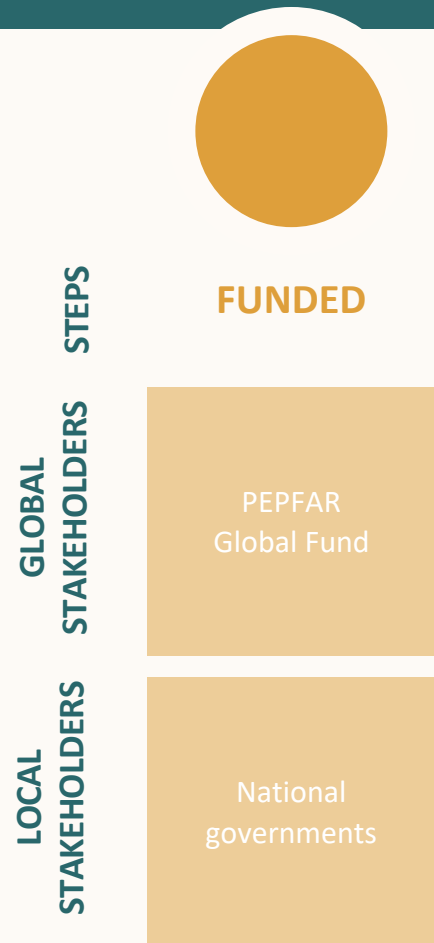
## APPROVED & RECOMMENDED

Stringent regulatory authorities (SRAs)  
WHO guidance and prequalification (PQ)

National medicine regulatory agencies (NMRAs)  
Ministries of health  
Healthcare provider associations

- The product developer develops regulatory strategy in consultation with various stakeholders – they often prioritize registration in countries where the clinical trials took place to facilitate post-trial access.
- The local approval process varies by country – some countries have NMRAs, others use a regional approval, others move ahead with securing import permits once WHO PQ is in place.
- An import waiver can be requested by the MOH to bring product into the country prior to NMRA approval.
- Additional steps may be needed prior to programmatic access in a country, e.g., the product being put on the Essential Medicines List (EML).
- Countries often wait to begin planning (updating national policies etc.) until WHO guidance is issued.

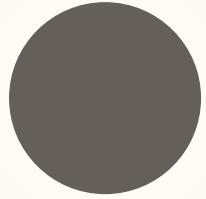
# Product must be funded



- Price negotiations between procurers and the product developer are a first step.
- Product eligibility for PEPFAR funding is determined by multiple factors such as US Government legislation, policy, and quality assurance rules.
- For both PEPFAR and Global Fund, countries submit proposals (or implementation plans) that include commodity requests and are based on technical guidance from the donor, e.g., PEPFAR country and regional operational plan (COP/ROP) guidance.
- Product eligibility for national government funding is also dependent on multiple factors, e.g., EML.



# Product must be procured and distributed



## PROCURED & DISTRIBUTED

PEPFAR  
Global Fund  
Social marketing orgs (SMOs) / drug wholesalers  
Global Health Supply Chain (GHSC)

National governments  
Distributors  
Healthcare providers

- For PEPFAR, the Global Health Supply Chain (GHSC) manages the importation process in most countries.
- Shipping requirements are unique to each product, e.g., CAB PrEP must be shipped within a set temperature range.
- Once product arrives in country, the customs clearance and importation process begins, as well as any product import testing requirements that may be in place.
- CAB PrEP requires additional commodities like needles and syringes, which must be procured in sufficient quantities and distributed alongside the product.
- Forecasting of CAB PrEP quantities and initiations must be carefully managed to ensure continued access for those who initiate.

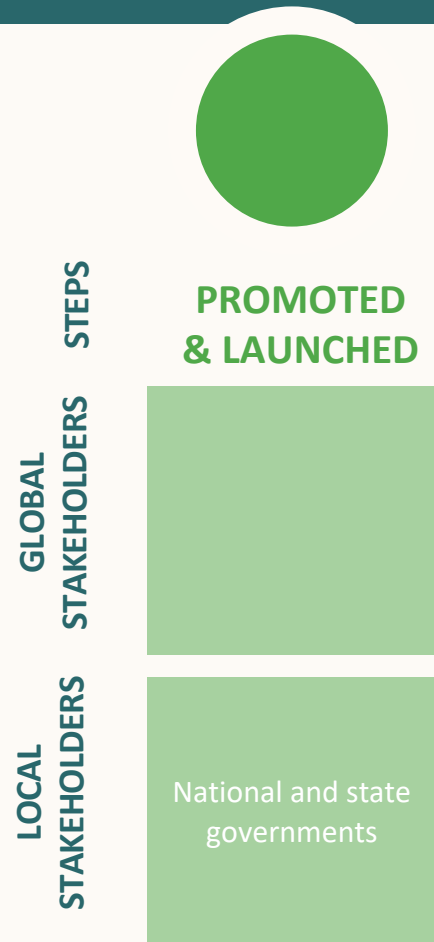


GLOBAL  
STAKEHOLDERS  
STEPS

GLOBAL  
STAKEHOLDERS

LOCAL  
STAKEHOLDERS

# Product must be promoted and launched



- Country preparations include updates to national PrEP guidelines, implementation plans (prioritizing geographies and/or populations), M&E systems and registers, provider curricula and job aids, and selection of implementing partners (IPs). Activities usually coordinated through national technical working groups (TWGs).
- Provider training often starts with a training of trainers (ToT) in advance of launch so the MOH and IPs are well trained in the new product and can inform guideline updates. Training is usually cascaded to facilities right before the product is available.
- National demand generation strategies and campaigns may need to be updated to address the expansion of PrEP as a category that now includes choice across multiple products.
- Many countries prefer to start small (pilot program) and then expand based on early learnings.

# 2024: Where are we now?

## Injectable HIV-prevention Drug Launches in Zambia

February 13th, 2024 | NEWS



Photo Credit: JSI

The Herald

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The Herald Classified

April 11, 2024

### Zimbabwe introduces injectable HIV drug

SCIENCEINSIDER | AFRICA

## Long-lasting, injectable HIV prevention drug set for “aggressive” roll-out in Africa

U.S. government agency plans to make inexpensive shots widely available for people at risk

25 MAR 2024 • 2:30 PM ET • BY [JON COHEN](#)



# 2024: Where are we now?

🕒 10 Jun Share   

## In The Spotlight - HIV prevention injections exist, but hardly anyone can get them

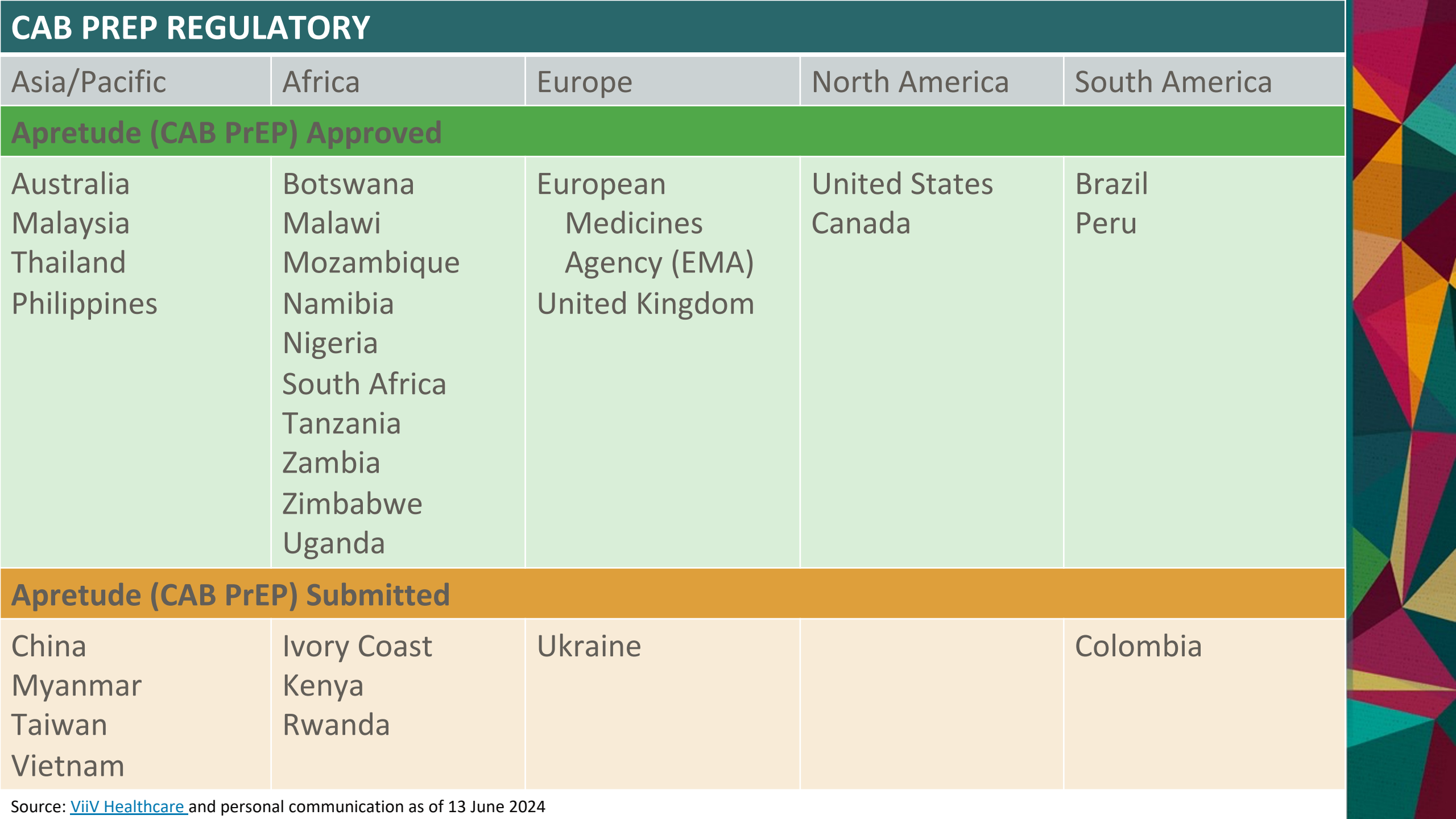
Catherine Tomlinson

**spotlight** Comments Bookmark

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# CAB PREP REGULATORY

Asia/Pacific	Africa	Europe	North America	South America
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## Apretude (CAB PrEP) Approved

Australia Malaysia Thailand Philippines	Botswana Malawi Mozambique Namibia Nigeria South Africa Tanzania Zambia Zimbabwe Uganda	European Medicines Agency (EMA) United Kingdom	United States Canada	Brazil Peru
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## Apretude (CAB PrEP) Submitted

China Myanmar Taiwan Vietnam	Ivory Coast Kenya Rwanda	Ukraine		Colombia
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Source: [ViiV Healthcare](https://www.viiiv.com) and personal communication as of 13 June 2024

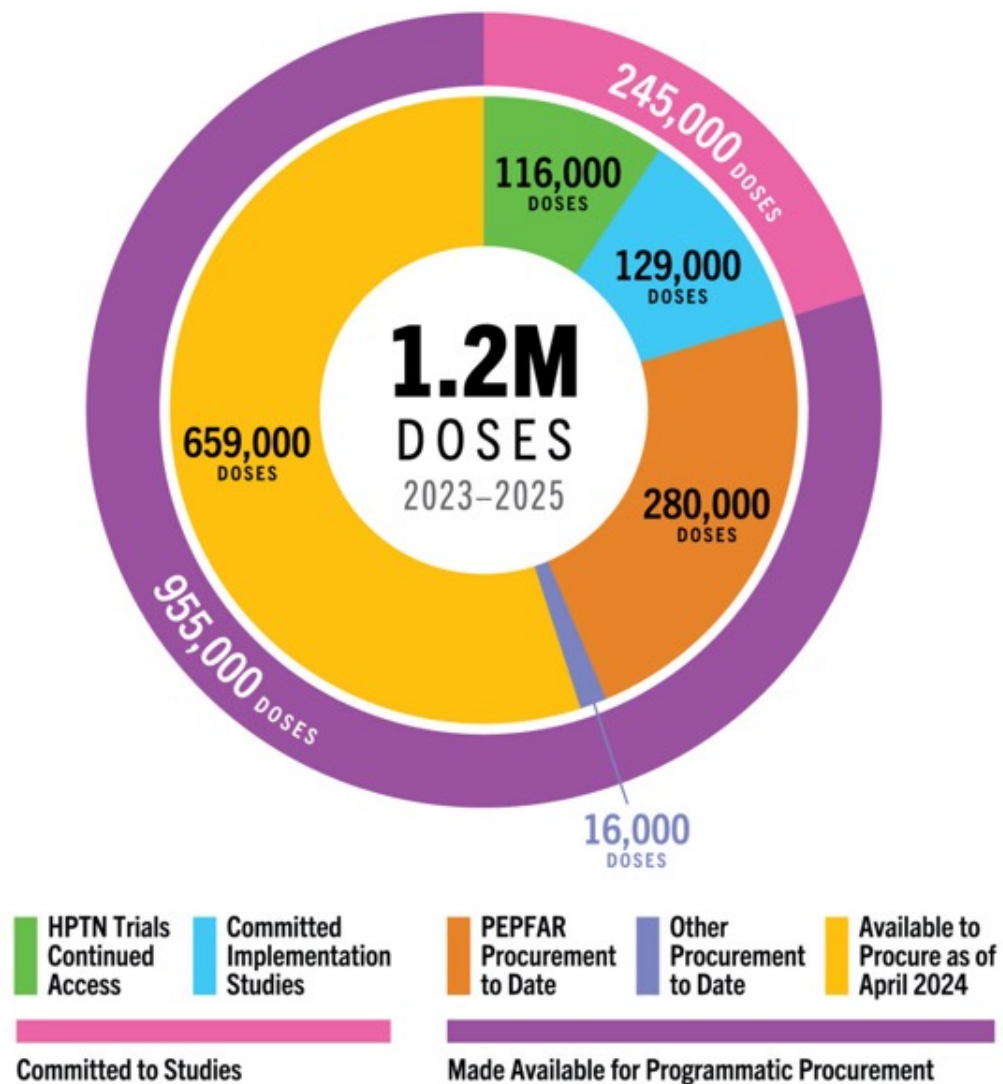
# CAB PrEP Manufacturing

- ViiV currently manufactures CAB PrEP utilizing one mill in the United Kingdom; plans are in progress to get other mills operationalized over the next 3 years to increase supply.
- The [Medicines Patent Pool](#) and ViiV have a voluntary licensing agreement to help enable access to generic CAB PrEP in least developed, low-income, lower middle-income and Sub-Saharan African countries (July 2022).
  - Knowledge transfer agreements have been signed with 3 India-based manufacturers: Aurobindo, Cipla and Viatrix; Cipla plans to manufacture in South Africa as well.
  - All generic products will need to undergo bioequivalence testing and get WHO PQ or SRA approval before entering the market; estimated availability of generics in 2027 at the earliest.

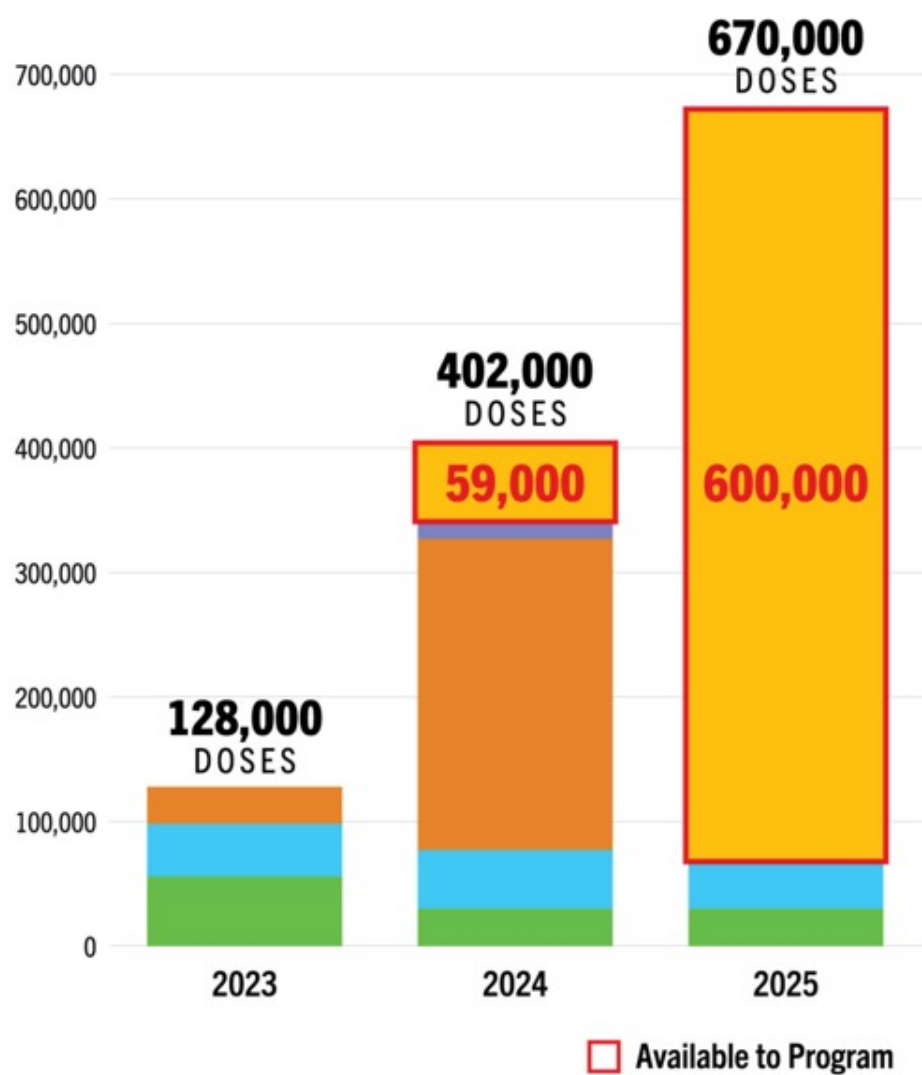
# CAB PrEP Pricing

- Low-income access price is \$30/injection or \$180/year.
- This price applies only to low income (World Bank), least developed (UN) and sub-Saharan African countries through donor and public programs.
  - As of Feb 2024, negotiations are underway for middle-income pricing (which includes most of southeast Asia).
- This price applies only to the multi-vial pack, which includes vials only (no syringes or needles) and does not include distribution from UK warehouse to countries.

Current (April 2024) allocation of Non-Commercial CAB for PrEP Supply in Low- and Middle-Income Countries, 2023-2025\* — **BY CATEGORY**



Current (April 2024) allocation of Non-Commercial CAB for PrEP Supply in Low- and Middle-Income Countries, 2023-2025\* — **BY YEAR**





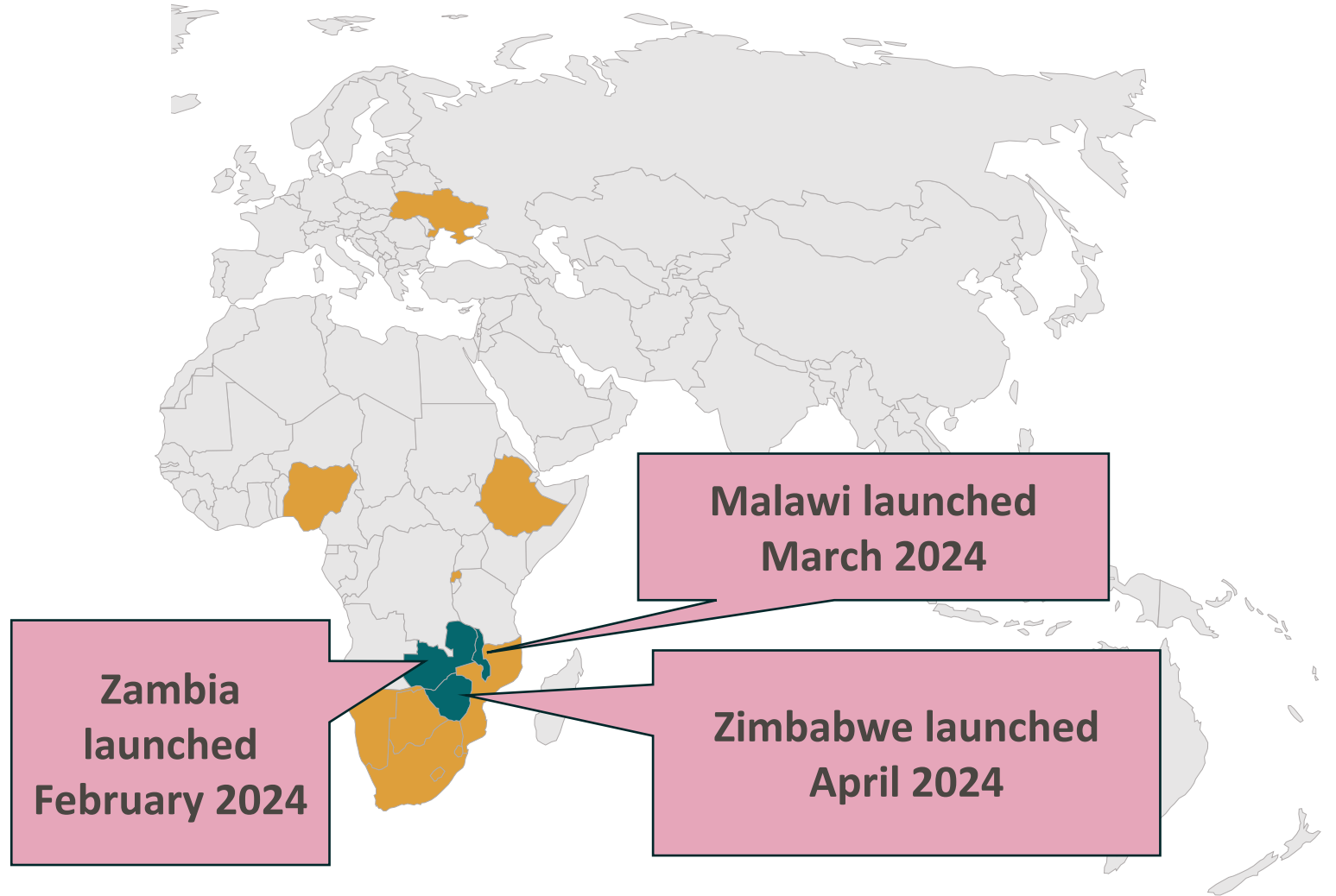
# PEPFAR Programmatic Rollout

## Launched (Q1/Q2 2024)

- Malawi
- Zambia
- Zimbabwe

## Pending (Q3/Q4 2024)

- Botswana
- Eswatini
- Ethiopia
- Lesotho
- Mozambique
- Namibia
- Nigeria
- Rwanda
- Ukraine



# Global Fund Programmatic Rollout

- Botswana
- Cambodia
- Eswatini
- Nigeria
- Uganda

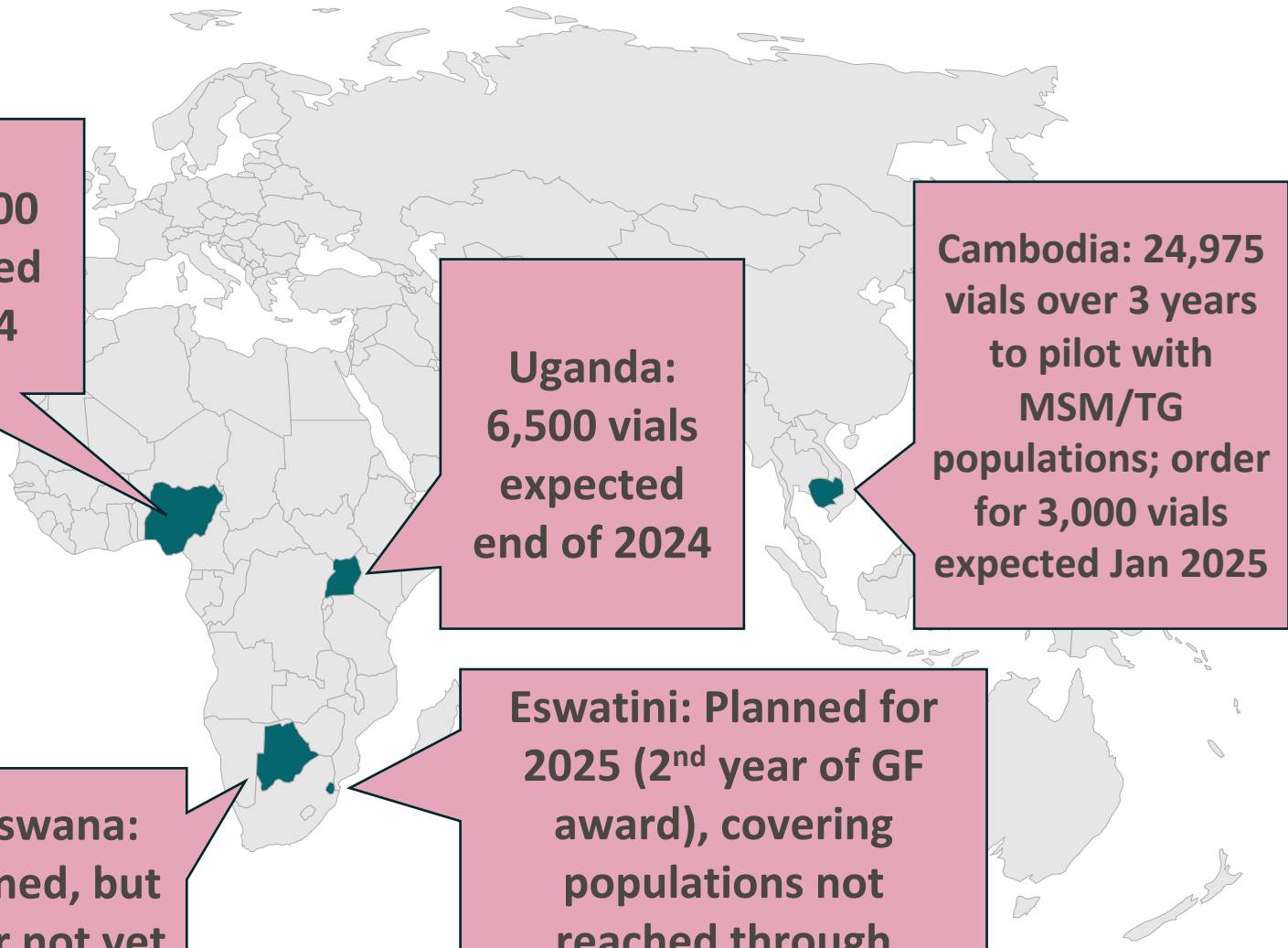
**Nigeria: 5,400 vials expected end of 2024**

**Uganda: 6,500 vials expected end of 2024**

**Cambodia: 24,975 vials over 3 years to pilot with MSM/TG populations; order for 3,000 vials expected Jan 2025**

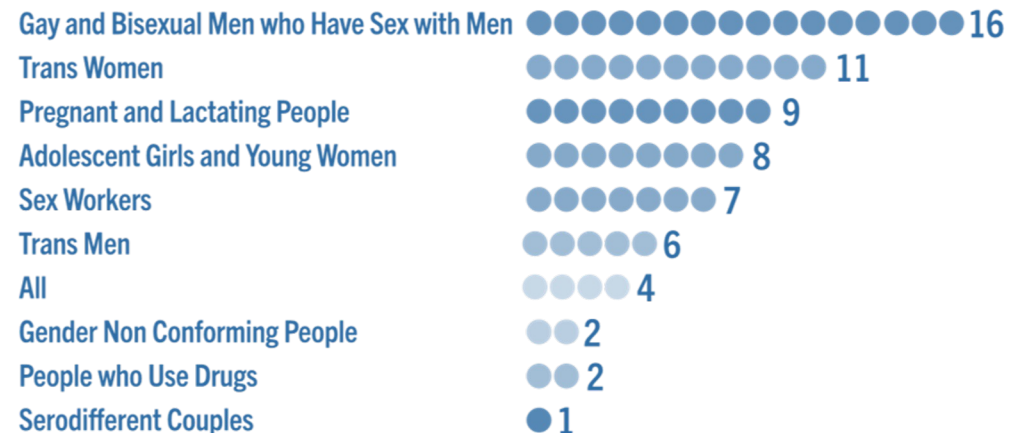
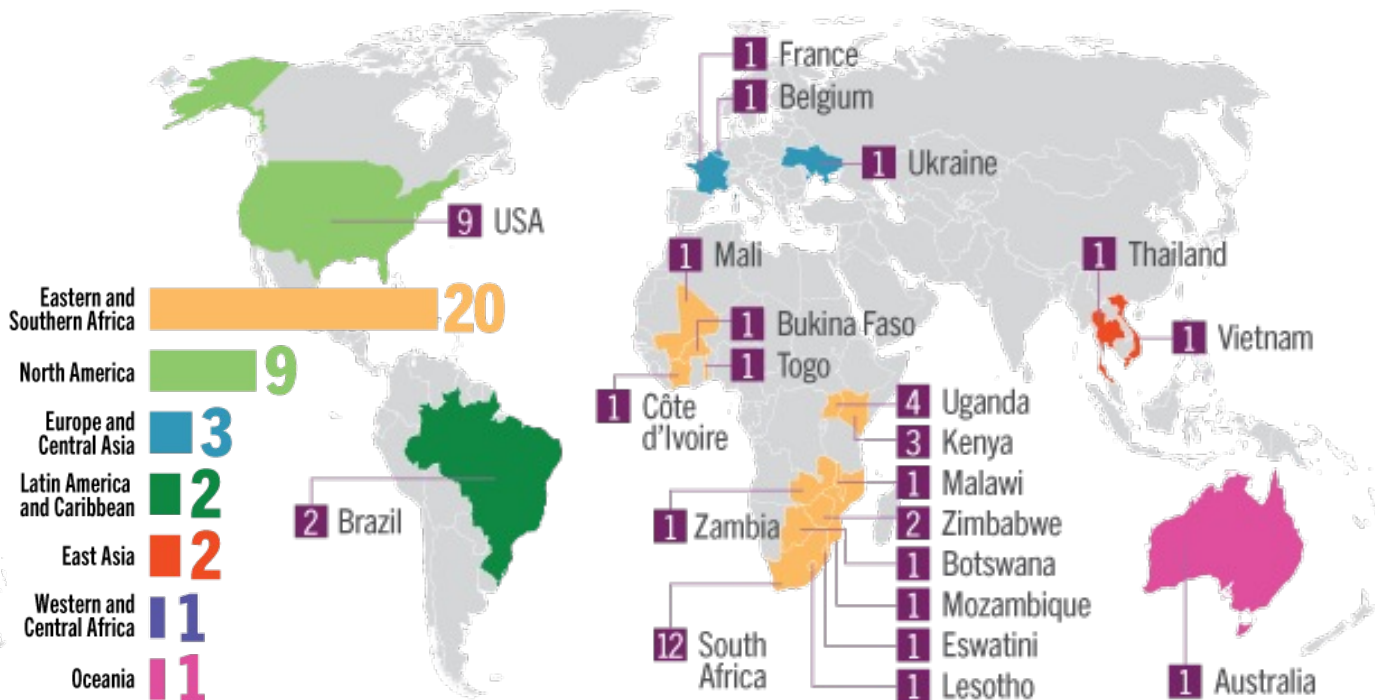
**Botswana: Planned, but order not yet placed**

**Eswatini: Planned for 2025 (2<sup>nd</sup> year of GF award), covering populations not reached through PEPFAR**



# CAB for PrEP – Delivery & Supply Chain

As of March 2024, of the **38 ongoing** and planned implementation studies for CAB for PrEP, **11** have committed supply from ViiV and **5** are receiving supply from PEPFAR.\*



As of April 2024, only four countries are in active programmatic rollout – the USA, Malawi, Zambia, and Zimbabwe

\*Note that since some studies are multi-country, the # of countries does not match to the # of studies.



**LA PrEP studies that are currently fielded**

Study Name	PrEP Products	Country(ies)	Funder
Axis	Oral, CAB	South Africa	BMGF
CATALYST	Oral, Ring, CAB	Kenya, Lesotho, South Africa, Uganda, Zimbabwe	PEPFAR/USAID
EBONI	CAB	USA	ViiV
FASTPrEP/ PrEPared to CHOOSE	Oral, Ring, CAB	South Africa	BMGF
ImPrEP	Oral, CAB	Brazil	Unitaid
LAPIS	Oral, Ring, CAB	South Africa	BMGF
Path To Scale	Oral, CAB	Malawi	BMGF
PILLAR	CAB	USA	ViiV
PrEP1519	Oral, CAB	Brazil	Unitaid
Project PrEP	Oral, Ring, CAB	South Africa	Unitaid
SEARCH	Oral, Ring, CAB	Uganda, Kenya	NIH

# Catalyzing access to new prevention products to stop HIV

The CATALYST study, under the MOSAIC project, will use mixed methods to characterize and assess the implementation of an enhanced service delivery package providing choice of PrEP products among women at PEPFAR delivery sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe.

## Offered PrEP methods

- Oral PrEP
- PrEP ring
- CAB PrEP



## STUDY DESIGN

- Observational **cohort study** and mixed-methods **process evaluation**
- Implementation of **an enhanced service delivery package that supports choice** among the PrEP products that have regulatory approval in each country, such as oral PrEP, PrEP ring and injectable cabotegravir for PrEP
- Uses **quality improvement methods** to refine components and identify a core service delivery package for PrEP choice

### OBJECTIVE 1

Characterize the implementation of an enhanced service delivery package for PrEP choice and assess individual-, provider-, facility-, community- and health system-level facilitators and barriers of the implementation process

### OBJECTIVE 2

Describe patterns of PrEP use and use effectiveness in the context of PrEP choice and assess sociodemographic and contraceptive use correlates of PrEP use patterns

### OBJECTIVE 3

Describe clinically relevant indicators among PrEP users, including rates of HIV infection and drug resistance among PrEP users who acquire HIV following PrEP exposure

## Early learnings from delivering LA PrEP

**There is demand** for both PrEP ring and CAB PrEP!

**Demand creation messaging** should position PrEP as a category of choices and not pitch one method over another.

**Clients take advantage of choice**, and their choices change over time depending on preferences and circumstances.

**Uptake is variable across sites and populations**; we will better understand the factors contributing to this over time.

**PrEP choice counseling is feasible and acceptable** to both providers and clients.

**Creating a welcoming environment** can help alleviate fear of injections and enhance client experience with CAB PrEP.



## Early learnings from delivering LA PrEP

**Investing time in provider training and job aids** is important, including refresher training for oral PrEP and recurrent trainings to address high staff turnover.

**Community delivery is feasible**, including storage, transport, and delivery of CAB PrEP through nurse-led mobile clinics in rural settings with high temperatures.

**There is uncertainty around HIV testing** for CAB PrEP in the context of limited HIVDR data to inform programmatic rollout.

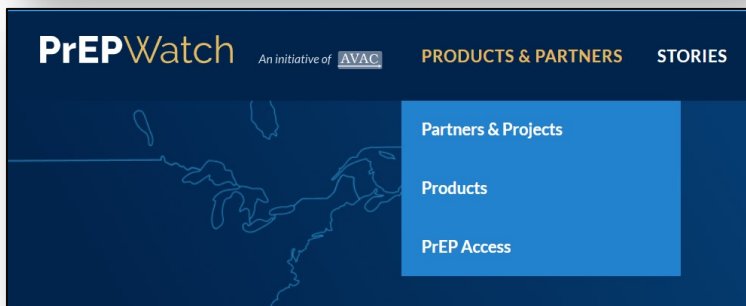
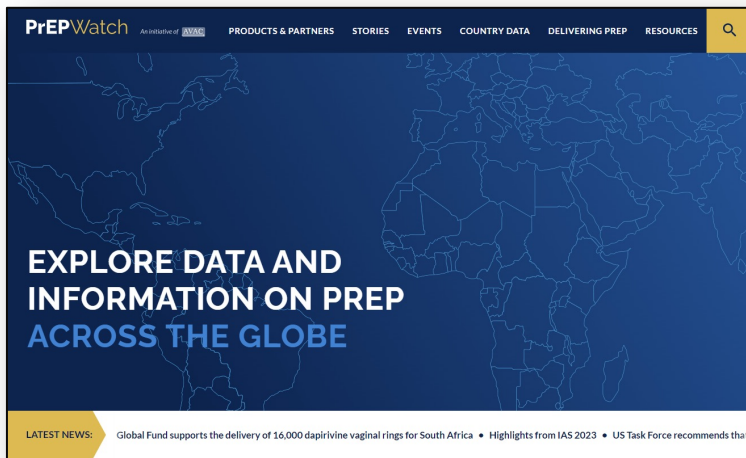
**Inventory management is critical** for CAB PrEP given the potential risk of HIVDR with any stockouts/gaps in coverage.

**Post-trial access is a major concern**; programmatic access is limited in Africa, and non-existent in Asia and Latin America.



# MOSAIC & CATALYST RESOURCE HUB

**PrEPWatch is a one-stop online clearinghouse for resources and information** to help the global community effectively deliver every proven method of PrEP to everyone who needs it.



- AVAC-led with support from MOSAIC and other funders.
- Launched in 2007 to track first oral PrEP trials, now tracks developments related to all PrEP methods (currently available and in the pipeline).
- Access all MOSAIC resources, including CATALYST study materials, by navigating to Products & Partners → [Partners & Projects](#) in the menu.
- All public-facing [resources produced by MOSAIC](#) are housed on PrEPWatch.



## Key Resources

[PrEP Guideline Template](#) and [PrEP Implementation Plan Template](#) designed to help countries efficiently launch new PrEP methods.

[HIV Prevention Ambassador Training Package](#): Created to prepare potential and current PrEP users to be “Ambassadors” in the rollout of PrEP for HIV prevention in their communities.

[PrEP category brand positioning materials](#): Ready to use materials to support local demand generation efforts for PrEP.



PrEP ❤️ IS  
CHOICE

Sorry not sorry  
for putting me first

Mercy, 22

# Upcoming Events



**Leading the Way:** Early learnings from CAB for PrEP introduction in Zambia and Zimbabwe

*Wednesday, 26 June, 2024- 1pm- 2pm GMT*

[Register here.](#)



**AIDS 2024 [CAB-LA for HIV PrEP skills workshop](#):** A skills building workshop on 26 July, will build essential clinical and counselling skills for CAB-LA delivery

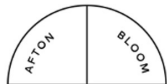


**AIDS 2024 [Welcome to the era of PrEP choice](#):** A pre-conference event held on 20 July, will include dynamic sessions on the PrEP product introduction landscape, the transformative potential of PrEP choice, key programmatic considerations, and early learnings from efforts to deliver PrEP choice around the world.



# ACKNOWLEDGMENTS

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*Photo Credit: MOSAIC Consortium*

