



**June 2025**

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**Long-Acting PrEP  
Market Assessment  
for Key Populations:**

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**Global Access  
and Readiness (2025)**



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# Executive Summary

This market assessment supports countries, donors, implementing partners, and advocates in making informed decisions about the introduction, scale-up, and equitable delivery of long-acting pre-exposure prophylaxis (LA-PrEP) among key populations (KPs) and other priority groups. Despite progress in HIV prevention, new infections continue to occur disproportionately among men who have sex with men (MSM), transgender people, sex workers (SW), and people who inject drugs (PWID)—groups facing heightened vulnerability due to social, legal, and structural barriers that limit access to health services.

This work comes at a pivotal moment. In early 2025, stop-work orders issued by the U.S. government disrupted critical HIV prevention services globally. According to GBGMC's Frozen Out report, these disruptions affected over 60 partner organizations across 21 countries, with 78% reporting direct service interruptions to KPs. CAB-LA rollout was delayed or suspended in multiple contexts, and existing KP-led programs were defunded without transition plans. In countries like Kenya, Nigeria, and Ghana, organizations documented closures of safe spaces, halted PrEP access, and growing mistrust between communities and health providers.

Long-acting HIV prevention options—including injectable cabotegravir (CAB-LA), injectable Lenacapavir (LEN), and monthly oral PrEP formulations currently in clinical trials—represent promising additions to the prevention toolkit. These products offer more discreet, durable, and potentially easier-to-use alternatives to daily oral PrEP. However, their rollout and uptake remain limited and uneven across countries and regions.

This assessment responds to the urgent need for innovative, accessible, and rights-based HIV prevention strategies tailored to KPs. Grounded in the UNAIDS 10-10-10 targets—which call for fewer than 10% of countries to have punitive laws, fewer than 10% of people living with HIV and KPs to experience stigma and discrimination, and fewer than 10% of countries to have service access barriers—this report offers a comprehensive landscape analysis of country-level readiness for LA-PrEP introduction and scale-up. It synthesizes data on HIV epidemiology, health system capacity, policy frameworks, and

community preparedness to highlight where targeted investments and implementation could have the greatest impact.

## Description of PrEP Power Project & GBGMC Collaboration

LA-PrEP Power: Shaping the Future of HIV Prevention for Key Populations is a three-year global initiative aimed at accelerating the introduction and uptake of long-acting pre-exposure prophylaxis (LA-PrEP) among KPs. The project is a collaboration between Global Black Gay Men Connect (GBGMC), AVAC, and the Global Key Population HIV Prevention Advisory Group, with support from Gilead, ViiV Healthcare, and Merck.

LA-PrEP Power focuses on co-creating evidence-based, community-led solutions that align PrEP delivery methods—including injectable and monthly oral options—with the specific needs of those most at risk. The initiative operates at the intersection of access, policy, and equity to ensure that prevention innovations reach the populations they're intended to serve.



# Glossary of Terms

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**LA-PrEP:** Long-acting pre-exposure prophylaxis, including injectable cabotegravir (CAB-LA), lenacapavir (LEN), and emerging monthly oral PrEP.

**Key Populations (KPs):** Groups at elevated risk of HIV including men who have sex with men (MSM), transgender people, sex workers (SW), and people who inject drugs (PWID).

**Policy Score Index (PSI):** A composite readiness score capturing national PrEP policy strength, regulatory status, and health system preparedness.

**PEPFAR COP:** The United States President's Emergency Plan for AIDS Relief Country Operational Plan guiding U.S. HIV funding priorities.

**Generic CAB pricing:** Mechanism under WHO and the Medicines Patent Pool to enable lower-cost access to CAB-LA in LMICs.

**CAB-LA:** long-acting injectable cabotegravir

**LEN-LA:** lenacapavir (injectable)

**GBGMC:** Global Black Gay Men Connect

# Introduction & Objectives



The HIV epidemic remains a significant public health concern, with approximately 40 million people living with HIV worldwide. KPs continue to bear a disproportionate burden of new infections, driven by stigma, discrimination, and limited access to healthcare. HIV PrEP has emerged as a critical prevention tool. While daily oral PrEP has demonstrated high efficacy, its real-world impact—particularly among KPs—has been limited by challenges related to adherence, access, and individual preferences.

Long-acting PrEP options, such as cabotegravir (CABLA) and lenacapavir (LEN), offer extended protection with less frequent dosing and may address some of these barriers. Evidence from the family planning field suggests that expanding the range of available methods can increase overall uptake, supporting the rationale for offering multiple PrEP options to better meet user needs (Ross et al., 2014).

This market assessment, conducted under the PrEP Power Project led by GBGMC in collaboration with technical partners including AVAC, seeks to:

- Evaluate the current state of LA-PrEP implementation globally
- Identify barriers and facilitators to LA-PrEP scale-up, with a focus on KPs
- Assess country-level readiness based on epidemiological data, policy environments, and health system capacities
- Provide strategic recommendations for stakeholders to support equitable and effective LA-PrEP delivery

Grounded in the UNAIDS 10-10-10 targets and aligned with WHO technical guidance, the report aims to inform strategic planning, policy alignment, and resource mobilization to enhance HIV prevention outcomes.

The assessment contributes to broader conversations about differentiated service delivery and the necessity of tailoring prevention approaches to the realities of diverse communities. It centers the voices and needs of KPs, including gay and bisexual men, transgender people, sex workers, and people who use drugs—all of whom face compounded structural, legal, and social barriers.

The landscape for long-acting PrEP is rapidly evolving. While early rollouts have begun in high-income and donor-supported settings, global access remains limited and inequitable. This is particularly true in LMICs, where the burden of HIV is highest and the cost, regulatory, and logistical demands of LA-PrEP pose significant challenges.

Recognizing these disparities, this assessment serves as a call to action for donors, governments, and implementing partners to:

- Prioritize funding, policy creation, and swift implementation for LA-PrEP in underserved settings
- Establish inclusive planning mechanisms that engage KP-led organizations in national decision-making
- Support community-driven demand generation strategies grounded in cultural and local contexts
- Ensure timely forecasting and procurement, particularly with anticipated generic CAB-LA and LEN availability by 2027

# Methodology & Data Sources

This market assessment draws on a landscape analysis combining epidemiological modeling, programmatic review, desktop review, and policy mapping to inform the scale-up of LA-PrEP for key populations (KPs). Our methodology integrates available data with pragmatic assumptions to produce regionally tailored insights relevant to stakeholders, implementers, and donors.

## Regulatory Status and Product Pipeline

Daily oral HIV PrEP is approved and available in over 100 countries, but implementation varies widely. Injectable cabotegravir, the first commercially available long-acting PrEP, is approved in a growing number of countries, but rollout is slow due to policies, pricing, and infrastructure barriers. Urban areas are more likely to have clinics, trained providers, and pharmacy access; rural areas often depend on mobile or community-based models, which are under-resourced. As the field of HIV prevention evolves, the regulatory approval, availability, and innovation pipeline of LA-PrEP products critically influence global implementation timelines and equity.

### 7.1

#### CAB-LA (Injectable Cabotegravir)

Cabotegravir long-acting (CAB-LA), branded as Apretude®, was the first injectable PrEP product approved by a stringent regulatory authority (U.S. FDA, 2021). While the dapivirine vaginal ring (DVR) received a positive opinion from the European Medicines Agency (EMA) earlier, CAB-LA marked a milestone as the first injectable option.

As of mid-2025, CAB-LA is approved in over 50 countries, including the 29 under EMA, and in South Africa, Kenya, Nigeria, Zimbabwe, Brazil, Australia, and others. Vietnam's regulatory review is ongoing; India has not yet received a submission.

CAB-LA was added to the WHO Essential Medicines List in July 2023, reinforcing its global public health value. However, access in LMICs remains limited due to:

- Constrained manufacturing: For several years, CAB-LA was produced at a single facility due to its complex manufacturing process.
- Pricing: While the LMIC price is approximately \$160 USD per person/year, prices in high-income settings still range from \$300 to over \$4,000 USD/year.
- Delayed rollout: National guideline updates and health system readiness often lag regulatory approvals, delaying implementation.
- No generics expected until 2027, pending WHO prequalification. Licensing and tech transfer via the Medicines Patent Pool are in progress.

# Methodology & Data Sources (Cont.)

## 7.2

### LEN (Lenacapavir)

LEN is a long-acting antiretroviral administered subcutaneously every six months. Initially approved for HIV treatment under the brand name Sunlenca, LEN is now advancing as a promising PrEP option.

Gilead has fully enrolled and unblinded both Phase III PrEP trials:

- **PURPOSE 1** evaluated LEN for PrEP among adolescent girls and young women in South Africa and Uganda, reporting 100% efficacy with zero HIV infections in the LEN arm.
- **PURPOSE 2** focused on cisgender men, transgender women, and nonbinary people who have sex with men across multiple regions, showing a 96% reduction in HIV incidence compared to background rates.

Based on these results, Gilead applied to the U.S. FDA for LEN's PrEP indication in late 2024. The FDA granted priority review, and officially approved LEN for use as long-acting PrEP on June 19, 2025.

Pending approvals, LEN is positioned to become the first biannual PrEP option, with WHO guidance expected by mid-2025 and global access strategies in development for 2026 rollout in partnership with major donors.

## 7.3

### Oral Long-Acting and Novel Delivery Platforms

- **MK-8527 (Merck):** An investigational monthly oral PrEP agent developed after the discontinuation of Islatravir for prevention. MK-8527 has a distinct chemical structure and exhibited promising safety and pharmacokinetics in Phase I/II trials through December 2024. As of 2025, it is in Phase II testing for PrEP, with no regulatory filings expected before 2028.
- **Implants & Microneedle Patches:** Early-stage technologies include cabotegravir- or TAF-based subdermal implants and dissolvable microneedle patches. These aim to provide semi-annual or annual HIV prevention delivery, with improved adherence and simpler cold-chain logistics. Research remains at the preclinical/Phase I stage.
- **Multipurpose Prevention Technologies (MPTs):** MPTs—combining HIV prevention with contraception and STI protection—are emerging in forms like vaginal rings, implants, and microneedle patches. Preclinical and early trial work shows high user preference and dual-use potential.

## 7.4

### Generic Access Outlook

CAB-LA is under a Medicines Patent Pool voluntary license, with multiple generic manufacturers currently undergoing technology transfer. Generic versions of CAB-LA are expected to submit for regulatory approval in late 2026 or early 2027. Modeling by CHAI and Unitaid suggests that with generic access, the cost could drop to well below \$100 per patient per year, dramatically improving affordability for LMICs.

Similarly, generic versions of LEN are expected to begin regulatory submission processes by late 2026, according to manufacturer-reported timelines. These developments are critical to expanding equitable access to long-acting HIV prevention.

# Barriers and Facilitators to LA-PrEP Implementation

Key Barriers to LA-PrEP Scale-Up	Facilitators and Opportunities
<p><b>1. Cost and Procurement Constraints</b></p> <p>While the access price for CAB-LA has been negotiated at approximately \$160 USD per person per year for LMICs, high-income countries face significantly higher list prices—ranging from \$300 to over \$4,000 per person annually. Even at access pricing, many LMICs require sustained donor support for procurement. The absence of generic CAB-LA until at least 2027 and fragmented procurement pathways have hindered national integration. In 2024, PEPFAR purchased the majority of global CAB-LA supply, limiting access for other buyers and highlighting current supply fragility.</p>	<p><b>1. Differentiated Service Delivery (DSD) Platforms</b></p> <p>Task-shifting—delegating specific clinical tasks from physicians to nurses or trained lay health workers—has also facilitated the scale-up of HIV services, including PrEP. As noted in multiple WHO and PEPFAR reports, task-shifting is an established strategy in HIV service delivery and is being explored for LA-PrEP integration in contexts with limited provider availability.</p> <p>Sources: <i>WHO Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery (2021)</i>; <i>AVAC LA-PrEP implementation briefs</i></p>
<p><b>2. Regulatory Delays and Policy-Practice Gaps</b></p> <p>While regulatory approvals for CAB-LA exist in countries like the U.S., South Africa, Kenya, and France, this has not guaranteed programmatic rollout. France, for instance, approved CAB-LA but has not implemented it in the public system due to cost-effectiveness concerns, not outdated protocols. In other contexts, delays in translating guidelines into fully funded, operational programs have stalled rollout.</p>	<p><b>2. Civil Society Leadership</b></p> <p>Key population-led and civil society organizations have played a critical role in expanding PrEP access through advocacy, demand generation, and community-centered service design. In South Africa, community organizations have been actively involved in the CAB-LA implementation framework and related research efforts. In Brazil, civil society contributed to the ImPrEP study, which evaluated peer-led strategies for recruitment and retention. In Vietnam, CBOs have driven demand creation within Global Fund- and PEPFAR-supported programs. Through the PrEP Power Project, civil society actors—including Global Black Gay Men Connect (GBGMC)—are leading targeted demand generation, research, and forecasting to support long-acting PrEP rollout among KPs across multiple regions.</p>
<p><b>3. Health System Capacity and Delivery Design</b></p> <p>Though CAB-LA and LEN do not require cold chain, challenges remain: service delivery infrastructure is often under-resourced, especially in rural or lower-tier facilities. These include clinic congestion, provider time constraints, and lack of provider training on LA-PrEP counseling. In high-volume settings, providers may default to oral PrEP for faster turnaround, particularly when choice counseling is deprioritized due to time limits.</p>	<p><b>3. Coordinated Donor and Technical Support</b></p> <p>Multilateral partners like PEPFAR, the Global Fund, and Unitaid have supported the introduction of LA-PrEP through procurement, demonstration projects, and operational research. However, as of 2025, PEPFAR has paused funding for PrEP programming for KPs due to delayed U.S. Congressional reauthorization and political constraints, creating gaps in service delivery and implementation. Civil society-led initiatives, including the PrEP Power Project co-led by GBGMC and AVAC, have helped fill gaps through demand forecasting, national planning support, and community-led advocacy.</p>

# Barriers and Facilitators to LA-PrEP Implementation (Cont.)

<b>4. Low Awareness and Provider Readiness</b> <p>Awareness of LA-PrEP remains low among both users and providers in many regions. Hesitation persists among providers due to side effect concerns, eligibility uncertainty, or resistance to change. Among users, especially KPs, mistrust in health systems, fear of injections, and low demand generation have limited uptake.</p>	<b>4. Community Education and Stigma Reduction</b> <p>Awareness campaigns—delivered in local languages and led by trusted peers—have increased interest and uptake in Johannesburg, Nairobi, Bangkok, and Rio de Janeiro. These campaigns focus on reducing stigma and normalizing PrEP as a routine health option.</p>
<b>5. Legal, Structural, and Social Barriers</b> <p>Criminalization of homosexuality, sex work, and drug use continues to limit access in many countries. These legal frameworks, compounded by healthcare stigma, police surveillance, and discrimination, create hostile environments for KPs seeking LA-PrEP. In high-income countries, medical gatekeeping, transphobia, and systemic racism also block access—particularly among Black and Latino MSM, transgender people, and undocumented migrants.</p>	<b>5. Policy Frameworks and Normative Guidance</b> <p>WHO's updated technical brief on long-acting HIV prevention options and clinical guidelines, alongside UNAIDS' emphasis on KP inclusion in national HIV strategies, offers a roadmap for countries to integrate LA-PrEP into comprehensive prevention programs.</p>
<b>6. Donor Instability and Limited Domestic Financing</b> <p>As of June 2025, delays in the U.S. Congress' reauthorization of PEPFAR and proposed cuts to foreign aid have raised uncertainty for many national LA-PrEP programs that rely on donor funding. With no widespread domestic financing mechanisms in place, most countries—both high- and low-income—lack the budgetary capacity to absorb LA-PrEP procurement and scale-up should donor funds decline.</p>	<b>6. Promise of Generic Access</b> <p>Efforts by the Medicines Patent Pool and the Clinton Health Access Initiative to license generic CAB-LA may lead to broader access by 2026–2027. In parallel, Gilead has issued voluntary licenses directly to manufacturers for generic production of LEN (Lenacapavir), potentially enabling affordable access in LMICs. If aligned with domestic procurement plans and community readiness, these developments could unlock sustainable scale-up in multiple low- and middle-income countries.</p>
<b>7. U.S.-Specific Access and Equity Barriers</b> <p>In the United States, additional barriers to LA-PrEP access include provider bias, systemic racism, and low PrEP literacy in marginalized communities. Research from PrEP4All and community advocates highlights that many Black, Latino, and transgender individuals encounter medical mistrust, inconsistent insurance coverage, and limited access to culturally competent providers. Additionally, many potential users remain unaware of their PrEP options or face logistical hurdles like transportation or clinic hours, reducing uptake despite national availability.</p>	

# Additional Considerations



- **Urban vs. Rural Dynamics:** Urban centers across all countries have stronger infrastructure, more trained providers, and concentrated epidemics. Rural access remains a challenge due to provider shortages, stigma, and logistical barriers. Community-based delivery and task-shifting models are key to bridging these divides.
- **Health System Type:** Countries with strong public-sector delivery (e.g., South Africa, Brazil, Zambia) are well-positioned for national scale-up. In mixed or insurance-driven systems (e.g., USA, Nigeria), strategies must include payer alignment, cost mitigation, and community trust-building.
- **Policy Levers:** Regulatory approval alone is insufficient; countries need updated HIV guidelines, procurement mechanisms, provider training, and investment in demand generation to successfully integrate LA-PrEP.

## 3.1 Forecast Modeling and Readiness Index

This section presents two complementary tools developed to support country and donor planning:

1. Modeled LA-PrEP uptake scenarios
2. A Policy Score Index (PSI) that reflects readiness to integrate LA-PrEP into national programs

Together, these tools help identify where investment, procurement, and technical support may be most impactful.

Forecast modeling estimates future uptake of LA-PrEP products under varying assumptions. For this assessment, a modified version of Avenir Health's PrEP modeling platform was used to project person-years (PY) of LA-PrEP across selected countries through 2030. These are not predictions, but decision-support tools that simulate different scenarios based on program, product, and policy inputs.

### **Model inputs include:**

- National and subnational HIV burden data
- Oral PrEP uptake trends (from PEPFAR and national datasets)
- Policy and regulatory readiness (e.g., CAB-LA and LEN approval)
- Introduction timelines, including expected generic access
- Method mix assumptions reflecting client preferences and program focus

## 3.2 Policy Score Index (PSI)

The PSI evaluates countries on PrEP preparedness and integration using multiple indicators, based on <https://www.hivpolicylab.org/methods>. We averaged responses across measures to develop the composite score.

### Indicators include:

- Presence of national PrEP policies
- Availability of oral and LA-PrEP
- Integration into public health systems
- Inclusion in essential medicines lists
- Community engagement and equity-driven planning
- Routine monitoring and evaluation

Countries scoring highest typically have centralized health systems, active civil society, and a strong donor presence. Urban regions generally reflect higher PSI performance due to infrastructure and concentration of services.

## Scoring

### Adoption score

**Definition:** Progress toward implementation of policies is scored based on adoption of each policy, as 'Not adopted,' 'Partial,' or 'Adopted.'

NOT ADOPTED PARTIAL ADOPTED

### Overall and policy category score

**Definition:** For each policy category and overall, adoption scores are combined and scored for progression by quintile: 'Very few,' 'Few,' 'Some,' 'Many,' and 'Most.'

VERY FEW FEW SOME MANY MOST

## 3.3 Country Prioritization

To support targeted planning and investment, we applied a country prioritization framework to identify where long-acting PrEP (LA-PrEP) introduction could have the greatest immediate and long-term impact. The goal of this exercise is to inform decision-makers—including national governments, donors, and technical partners—on where early adoption, program expansion, and additional support may be most feasible and impactful, based on readiness and HIV prevention need.

A five-point scoring matrix was used to assess and prioritize countries using the following criteria:

- HIV burden (total population size estimates of people living with HIV)
- Estimated PrEP need (size of the adult sexually active population)
- Policy and regulatory readiness (as measured by the PSI indicators)
- Proportion of new infections among key populations
- Health system and implementation feasibility (approximated by current PrEP initiations)

Countries were ranked using a multi-step weighting approach to balance HIV prevention needs with readiness for implementation. The process identified 20 countries as high-potential settings for LA-PrEP impact, including both near-term and future rollout opportunities—particularly once generic CAB-LA becomes more widely available post-2026.

From this broader list, we identified **seven countries** as recommended priority settings for early adoption and scale-up. These countries represent diverse contexts—mature, emerging, and high-need—and were selected based on their strong PrEP infrastructure, policy readiness, and ongoing or planned LA-PrEP implementation activities

Country	Income	Pop. M+F 15-49y	Pop. Score (/20)	HIV+	Prev. Est.	Prevalence Score	Total Initiations	Initiation Score (20)	Policy Est.	Policy Score	KP New Infection %	KP Score	Total Weighted Scores
USA	High	157,638,814	20	637,818	0.00	0.45	525825	14	0.77	17.09	84	20	72
South Africa	Upper Mid	32,164,559	4	5,738,369	0.18	20.00	1795844	20	0.46	10.20	7	1.75	56
Nigeria	Lower Mid	111,388,295	14	1,174,958	0.01	1.18	716654	19	0.50	11.11	34	8.5	54
Zambia	Lower Mid	9,779,082	1	1,058,258	0.11	12.13	895585	20	0.76	16.88	8	2	52
China	High	673,566,136	20	1,071,526	0.00	0.18	0		0.27	5.96	80	20	46
Brazil	Upper Mid	114,434,517	15	652,175	0.01	0.74	238071	6	0.47	10.43	50	12.5	44
Zimbabwe	Lower Mid	8,641,895	1	951,541	0.11	12.34	337010	9	0.79	17.65	14	3.5	44
Mozambique	Low	15,854,449	2	1,839,285	0.12	13.01	446318	12	0.65	14.51	4	1	43
Viet Nam	Lower Mid	51,888,834	7	171,958	0.00	0.37	83825	2	0.67	14.81	72	18	42
Uganda	Low	21,179,245	3	1,074,819	0.05	5.69	743696	20	0.51	11.38	9	2.25	42
Philippines	Lower Mid	61,194,696	8	159,340	0.00	0.29	29747	1	0.55	12.16	92	20	41
Thailand	Upper Mid	33,979,776	4	364,726	0.01	1.20	78125	2	0.66	14.74	72	18	40

# Priority Countries for LA-PrEP Scale-Up

The following countries have been identified as priority settings for the introduction and expansion of long-acting PrEP (LA-PrEP). Each presents unique regulatory, policy, and implementation conditions. Country profiles will be developed separately for further detail.

## 1. United States

The U.S. Food and Drug Administration (FDA) approved CAB-LA for HIV prevention in December 2021. Despite its availability, uptake has remained limited, especially among Black and Latino gay and bisexual men, transgender individuals, and residents of Southern states. Barriers include high out-of-pocket costs, insurance restrictions, limited provider awareness, and systemic racism in healthcare delivery. Advocacy groups have documented these disparities. Public delivery channels such as Medicaid and Title X providers offer infrastructure for expanded LA-PrEP access, but program reach remains uneven.

## 2. South Africa

CAB-LA was approved by the South African Health Products Regulatory Authority (SAHPRA) in 2022. The country has a robust oral PrEP program and began CAB-LA pilot implementation through both public sector and donor-supported platforms. While urban rollout has advanced, rural coverage remains limited. Government and civil society have emphasized reaching adolescent girls and young women (AGYW) and men who have sex with men (MSM) as key priorities. Ongoing Unitaid- and USAID-funded pilot programs are informing scale-up.

## 3. Brazil

Brazil has one of the most established public PrEP programs in Latin America. CAB-LA is being piloted through the Ministry of Health and research partnerships such as ImPrEP CAB-Brasil. The public health system (SUS) supports broad access to oral PrEP, and the government has expressed commitment to incorporating LA-PrEP into national protocols. Urban infrastructure supports efficient service delivery, though rural access remains a concern. Civil society organizations are actively involved in awareness and demand generation.

## 4. Nigeria

Nigeria approved CAB-LA for HIV prevention in 2023 and is in the early stages of introducing long-acting PrEP into national programming. Revisions to national PrEP guidelines are underway, with initial investments—approximately \$6.8 million—allocated through the Global Fund GC7 grant to support CAB-LA rollout. Implementation efforts to date have focused on provider training and development of communication materials. While oral PrEP is included in Nigeria's HIV strategy, uptake remains uneven, with most access concentrated in urban areas. The HIV epidemic in Nigeria is concentrated among AGYW, MSM, sex workers, and people who inject drugs. Effective scale-up of LA-PrEP will require strengthened service delivery infrastructure, targeted outreach, and continued community advocacy to reach KPs beyond urban centers.

## 5. Zambia

Zambia maintains a strong HIV prevention program, with support from the Global Fund and PEPFAR. Oral PrEP is included in national policy and moderately scaled. CAB-LA is not yet approved, but early policy engagement is underway. However, in 2025, PEPFAR restructured its funding and paused PrEP programming for KPs, focusing instead on pregnant and lactating individuals. This has resulted in service delivery disruptions for KPs and challenges for LA-PrEP introduction.

## 6. Vietnam

Vietnam granted regulatory approval for CAB-LA in 2024. Initial rollout is being supported by PEPFAR and Global Fund initiatives, alongside strong community engagement by civil society organizations. Vietnam's concentrated HIV epidemic among MSM and sex workers positions it well for targeted scale-up. Donor-supported technical assistance and differentiated service models are being applied in urban areas. Gaps remain in rural outreach and domestic sustainability planning.

## 7. France

CAB-LA received approval from the European Medicines Agency (EMA) and became available in France in 2023. However, the French National Authority for Health (HAS) did not recommend reimbursement under the public health insurance system due to cost-effectiveness concerns. CAB-LA is currently available only via private providers or research settings, with annual out-of-pocket costs ranging from €3,000–€4,000. This limits access for low-income individuals, migrants, and racialized communities. National policy debates are ongoing regarding public sector coverage.

# Global Health Funding Cuts and Implications for LA-PrEP Rollout

Recent shifts in U.S. foreign assistance and global health funding threaten to disrupt the introduction and scale-up of long-acting PrEP worldwide. This section outlines the fiscal trends, political drivers, and consequences for implementation.

<b>8.1</b> <b>U.S. Budget Reductions</b>	<p>The FY 2026 budget request proposes a reduction in global health spending from \$10 billion in FY 2025 to \$3.8 billion—a cut of over 60%. This includes reduced allocations for PEPFAR and other bilateral HIV programs.</p> <p>In June 2025, the White House submitted a \$9.4 billion rescission proposal targeting unspent funds from the U.S. Agency for International Development (USAID) and the Department of State. Approximately \$900 million is proposed to be rescinded from global health accounts.</p> <p>Despite these reductions, the FY 2026 President’s Budget Justification notes that the U.S. government will support access to the long-acting HIV prevention product Lenacapavir (LEN).</p>
<b>8.2</b> <b>Impact on Multilateral Programs</b>	<p>The U.S. contribution to the Global Fund remains at \$1.65 billion for FY 2025, consistent with previous commitments. However, reductions in bilateral and complementary global health funding—including proposed rescissions from USAID and State Department accounts—may impact coordinated HIV prevention efforts.</p>
<b>8.3</b> <b>Programmatic Impacts</b>	<p>Several countries preparing for LA-PrEP rollout—such as Nigeria, Kenya, and Vietnam—are facing uncertainty around technical assistance, provider training, and commodity support. Many national LA-PrEP plans rely on external funding and support to finalize guidelines and scale services. Cuts to U.S. funding may also affect ongoing implementation science and operational research, including monitoring of CAB-LA and LEN introduction.</p>
<b>8.4</b> <b>Civil Society and KP-Led Program Challenges</b>	<p>In several countries, KP-led programs receive support through U.S. bilateral mechanisms. Reduced funding has already resulted in scaled-back outreach, delayed training, and paused demand generation activities in some settings. Core support for civil society actors involved in tracking access and program equity is at risk.</p>
<b>8.5</b> <b>Global Fund Response and Future Outlook</b>	<p>The Global Fund continues to provide critical support for HIV prevention, but it has noted the need for increased replenishment commitments and expanded co-financing. Without sustained multilateral and bilateral coordination, efforts to expand access to LA-PrEP may be delayed—particularly in low- and middle-income countries.</p>

# Conclusion / Call to Action

The introduction of long-acting PrEP represents a game-changing moment in the global HIV response—one that offers real hope for communities historically left behind. But to turn that promise into progress, we must act with urgency, clarity, and commitment.

We must get enough people on long-acting PrEP—and fast. That means producing more quickly, accelerating regulatory and programmatic access, and ensuring that access reflects lived realities. Governments must be ready, communities engaged, and delivery models adapted to meet people where they are.

## WHAT NEEDS TO HAPPEN NOW

To make long-acting PrEP work—for real people, in real settings—every sector has a role to play.

**Governments in low- and middle-income countries** must move fast. That means fast-tracking regulatory approval, updating national HIV prevention guidelines, and integrating LA-PrEP into national programs with dedicated budget lines. But this is more than policy—it's about delivery. Governments must support community-led, differentiated models that reflect how people live, love, and access care.

**Donors and global funders** must not only sustain but expand prevention funding in this moment of disruption. We cannot afford another lost decade. Communities need resources to lead demand creation, design services that work for them, and advocate at every level. Procurement systems must be prepared to bring generics to scale—not in silos, not in the future, but now.

**Pharmaceutical companies and generic manufacturers** must meet the urgency of the moment. That means clear, transparent pricing; real commitments to technology transfer diverse geographies; and supply agreements that prioritize equity. Generic CAB-LA must be accessible in LMICs by 2026. Timelines must be public and accountability real.

**Civil society and KP-led organizations** are already at the frontlines. Their leadership must not only be acknowledged but funded. They are best positioned to co-create trusted delivery models, drive uptake, and hold systems accountable. Demand generation rooted in dignity, autonomy, and cultural relevance is non-negotiable.

And in high-income countries like the U.S., France, and the U.K., we must also confront a hard truth: innovation continues to reinforce inequity if left unchecked.

## WE CALL ON:

- **Public health agencies** to address persistent racial and regional disparities in PrEP access—particularly among Black and migrant communities.
- **Funders and academic institutions** to prioritize community-led research agendas like PrEP in Black America and PrEP in Europe, which directly confront stigma, structural barriers, and delivery gaps.
- **Advocates and civil society groups**, especially movements like PrEP4All, PrEP in Black America, to keep pushing for:
  - Transparent pricing and universal coverage of LA-PrEP
  - Investments in campaigns led by and for Black, Brown, and queer communities
  - Infrastructure that enables same-day access, mobile clinics, and low-barrier services

We cannot allow this moment to become more of the same. The rollout of LA-PrEP must be the turning point where we finally do things differently.

Across 20 countries, key populations have already stepped up—developing bold, community-led national plans to reimagine HIV prevention and last-mile service delivery. These plans reflect what's possible when communities are not consulted after the fact but lead from the start.





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