HIV Leadership Forum

A community of practice of Director Generals of National AIDS Coordinating Authorities of Africa, Asia

TECHNICAL BRIEF TO THE GLOBAL FUND BOARD MEMBERS OF THE EAST AND SOUTHERN AFRICA, AND WEST AND CENTRAL AFRICA CONSTITUENCIES

Audience: Global Fund Board Members (ESA & WCA Constituencies)

From: The HIV Leadership Forum *(Director-Generals of AIDS Commissions of Africa, Asia and Latin America)*

Purpose: Provide a technical note on LENACAPAVIR (LEN) implementation for Global Fund Board members to inform their input to the upcoming Special Board meeting on LENACAPAVIR.

Background

In 2024, while countries advanced HIV sustainability plans, Director-Generals of AIDS Commissions from Africa, Asia and Latin America developed a position paper—"Leveraging Country Leadership to Advance Resilience for a Sustainable HIV Response Pre and Post 2030"—to ground planning in real country systems and fiscal realities Leveraging Country Leadership to Advance Resilience for a Sustainable HIV Response Pre and Post 2030 | GPC.

The paper underscored that the globally driven HIV architecture produced vertical and fragmented programmes, with overlapping data tools and EMRs, parallel diagnostic platforms, and separate supply chains operating outside core government systems. This architecture was identified as the principal vulnerability to sustainability and country ownership.

The current status of HIV Prevention

In January 2025, following a U.S. government stop-work order, billions of dollars of investments, including health systems strengthening, fractured instantaneously. The most acute impacts have been in HIV prevention:

- Data systems, supply chains, laboratory platforms, and community services—including adherence support, HIV testing expansion, PMTCT mentor-mothers, and adolescent girls and young women (AGYW) interventions—were disrupted across many Sub-Saharan African settings.
- Across a 12-country sample, the Forum recorded attrition of 123,000 health workers: 56% clinical (doctors, nurses, pharmacists, laboratory technicians) and 35% community cadres.
- Primary and secondary health services are overstretched, with longer waits, heavier workloads, and declining quality of care—affecting HIV services and the broader health sector.

This context of system fragility, diminished human resources, and constrained fiscal space is the baseline against which LENACAPAVIR is being introduced and must be planned and assessed.

LENACAPAVIR as a HIV Prevention Option

Lenacapavir (LEN) is a long-acting injectable that expands the prevention toolkit, particularly for populations struggling with adherence to daily or frequent dosing. Nine early-adopter countries in Sub-Saharan Africa, supported by the Global Fund, are preparing for LEN introduction in January 2026.

However, LEN planning is proceeding amid the heightened fragility described above: supply chain disruptions, reduced community platforms for demand generation, and severely depleted workforce capacity for injection-based delivery, pharmacovigilance, and follow-up—functions that long-acting prevention requires to demonstrate real-world effectiveness and earn public trust.

A brief historical reflection on introduction of HIV prevention products:

- Previous PrEP introductions (e.g., Truvada, Cabotegravir) were launched with high global publicity, donor-industry agreements, and subtle pressure on governments to sign demand statements. Significant donor investments funded community-led demand creation with the promise of population level prevention impact.
- However, despite these investments and political mobilization, the real-life impact of previous PrEP interventions remains unclear. It was difficult to sustain individuals on product and over time, PrEP programme reporting was quietly shifted from adherence and continuation measurements to reporting the number of people initiated on PrEP. This weakened the evidence link between PrEP investments and incidence reduction.

These lessons caution that current LEN efforts with high levels of global visibility may not automatically translate into prevention impact. The questions ‘What is the real-life prevention impact of PrEP and LEN given the lack of implementation science evidence remain?

Challenges to the current introduction of LEN include:

Financing:

- Current LEN investments of US$28,000 per person per year (for two yearly injections) are not affordable for government-funded scale. LEN introduction in the early adopter countries is being justified as pilots that are necessary to prove real-life effectiveness, which could, in turn, drive price reductions; yet at current unit costs and limited reach (such as 5,500 persons per year in Kenya, 19,000 doses for Uganda for 2026), population-level impact is unlikely in the near term.

- DGs are reporting that budget reallocations to accommodate LEN that are being required by the Global Fund from already diminished GC7 envelops, are defunding other HIV prevention programmes at a time when investments are required to re-build prevention programmes and systems.
- Importantly, in some countries condom allocations are being reduced to finance LEN roll-out, which is undermining highly cost-effective interventions, and is weakening the primary prevention options available to countries.
- Per-person and set-up costs for LEN remain high, within constrained fiscal space and uncertain continuity financing. Affordability is expected to hinge on licensing and scale up, in a context where the prevention impact in real life is not evaluated. LEN planning risks creating fiscal liabilities at country level without clear affordability or continuity plans.

Policy and Programme

- Planning and target-setting for LEN are proceeding as stand-alone projects, which risks reverting to fragmented responses that cannot be sustained without extra donor resources.
- Severe workforce attrition has meant that government staff are already overstretched, even as LEN injection-based delivery, pharmacovigilance, adverse event reporting, and timely follow-up will require human resources for follow up.
- In some countries, PrEP introduction is occurring ahead of, or outside, national drug regulatory approval processes complicating stewardship, procurement timelines, and accountability.
- Transition pathways for individuals who are already on CAB-LA and oral PrEP are unclear, in a context where previous abrupt cessation of CAB-LA has already eroded community trust. This risks lower acceptance of future prevention and self-care innovations.
- Historically, PrEP demand creation relied on PEPFAR-funded community structures. With many of these platforms scaled back or closed, there is no clear strategy for LEN literacy, demand generation, risking Access.

Data and measurement

- In many settings routine health data collection is already strained by staff attrition. While the Global Fund may propose additional records clerks for LEN, this recreates parallel HR arrangements and masks the true implementation burden within national systems.
- Indicators must capture what matters: on-time dosing, continuation over time, safety outcomes, loss-to-follow-up, and incidence proxies—measured through government systems to ensure credibility, comparability, and sustainability.

DGs caution against repeating the Cab-LA experience, where metrics shifted from cohort retention/continuation to initiation counts, thus obscuring visibility of the impact on incidence reduction, which is the primary outcome of these PrEP investments.

Recommendations for consideration by Board Members:

1. **Retain and reinforce core prevention programmes**: The Global Fund must protect and increase condom funding even as LEN resources are carved out of the reduced GC7 envelope. This safeguards cost-effective population-level prevention and mitigates risk displacement from budget trade-offs.
2. **Condition LEN support on full systems integration**: Require that LEN is delivered through routine government systems—including data systems, human resources, supply chains, and laboratory platforms—without additional buffer resources. This is necessary to test real-world feasibility, assess true costs, and ensure continuity when donor funds decline.
3. **Establish shared accountability with written continuity/contingency commitments**: Recognizing the time and systems-wide change investments governments must make to introduce LEN, the Global Fund should provide formal country-specific commitments for continuity or contingency support. This is essential to rebuild donor–country trust and to mitigate the impact of any sudden funding withdrawal.
4. **Mandate independent LEN monitoring by the Office of the Evaluation Officer**: The evaluation mandate should include independent monitoring with non-negotiable indicators focused on: cohort continuation, adherence to dosing intervals, safety outcomes, and incidence proxies. Results should be reported to the Board on a fixed schedule and not adjusted post-hoc.
5. **Require real-world prevention effect before scale-up:** The Board should demand evidence of HIV prevention impact in real-life settings from early-adopter countries before endorsing any scale-up—even if additional resources become available. Evidence should demonstrate improvements in continuation, adherence, and incidence proxies, not only in initiation of LEN.
6. **Provide country-specific cost-effectiveness analyses**: The Secretariat should supply formal, written analyses of LEN cost-effectiveness relative to other prevention models (e.g., condoms, oral PrEP, CAB-LA), tailored to each country's epidemiology, delivery costs, and fiscal outlook, as part of the LEN introduction package.
7. **Adopt a total market approach (TMA) for introduction**: Test and report LEN delivery by leveraging private sector for clients willing and able to pay, while public subsidies focus on vulnerable and high-incidence populations. A total-market-approach can reduce fiscal burden, protect public budgets, and expand access without undermining public services.