



Press Statement: For immediate release

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Activists Demand \$40-a-year Generic Price for Breakthrough HIV Prevention Drug be Made Available to all Low- and Middle-Income Countries
Health Groups Announce Global Campaign to Challenge Gilead's Patent, Registration Barriers and Secure Global Access to Long-Acting PrEP for All

A global coalition reacted to [two deals announced today](#) to make long acting lenacapavir (LEN-LA), a 6 monthly HIV PrEP (pre-exposure prophylaxis) injection that provides virtually 100% protection against HIV infection, at \$40 per person per year in 2027. Dr Reddy's and Hetero, two Indian generic manufacturers, will offer the price.

But generics at this price will be restricted only to the 115 low- and middle-income countries (LMICs) and 5 territories covered by Gilead's voluntary license for LEN-LA ([announced October 24, 2024](#)), which blocks the supply of affordable generics in many countries where HIV incidence is high and rising fastest, particularly among at-risk populations that continue to bear the brunt of new infections. These include transgender and other gender diverse people, gay and bisexual men, sex workers, and young adolescent girls and women for whom clinical trials showed that LEN-LA was vastly superior when compared with oral daily PrEP.

"Lenacapavir holds the potential to defeat the HIV pandemic, if delivered urgently, at scale; any restrictions on access to an affordable generic price for this essential prevention tool is unacceptable," said Asia Russell of Health GAP. "Gilead's greed will relegate communities around the world to inferior HIV prevention, unnecessarily prolonging this pandemic."

More than one in four new HIV acquisitions occur in the 26 countries and territories that are excluded by Gilead from its license, including Argentina, Brazil, Mexico, and Peru, countries where people participated in pivotal LEN-LA clinical trials that generated the data used by Gilead to secure US FDA approval. Gilead intends to maximize profit in excluded countries through opaque tiered pricing deals that will result in unaffordable prices, according to activists.

[In May 2025, global estimates of new HIV infections rose sharply from 3500 to 5800 HIV infections daily](#), due to the Trump administration's abandonment of HIV prevention

programs globally, including the majority of global PrEP programs, which had reached 3.5 million people. An estimated 20 million people worldwide need PrEP. The [Global Fund and the US State Department recently re-confirmed a plan with Gilead](#) to reach only 2 million people in 9-12 countries over three years. Instead of ensuring LEN-LA is available to all who need it, experts estimate this sharp, early rationing of LEN-LA will have little or no effect on overall HIV incidence and will set a low-bar for needed scale-up.

Health groups convening alongside the U.N. General Assembly in New York announced a global campaign to make this generic price and long-acting PrEP available worldwide by challenging Gilead's patents, pricing and registration barriers, through legal challenges and advocacy pushing governments and Gilead to make PrEP available and accessible to all. The groups have filed patent oppositions and compulsory license requests to overcome intellectual property barriers, in key generics producing countries as well in countries excluded from Gilead's license.

"In just a few months, we've seen historic scientific breakthroughs: FDA approval of lenacapavir, WHO guidance, and new momentum for injectable PrEP," said Othoman Mellouk, Access to Medicines and Diagnostics Lead at the International Treatment Preparedness Coalition. "But science alone doesn't end epidemics. Monopoly control, high prices, and slow registration are standing in the way of access. That's why this meeting is urgent: so civil society and communities set the terms of access."

"Today we are announcing a global campaign to make long-acting PrEP affordable and available for all," said Peter Maybarduk, Access to Medicines Director at Public Citizen. "Health groups from around the world will work together to challenge Gilead's patent barriers in the courts, fight the exclusion of many developing countries from affordable pricing, and push governments to make long-acting PrEP readily accessible in communities. We will remove barriers to help end AIDS."

Activists noted that sufficient US funding is available now to procure LEN-LA from Gilead, at their secret "access price" of \$100 per person per year, at volumes far beyond the inadequate 2 million person goal the US will contribute towards. However these funds, approximately \$2.3 billion already appropriated for expenditure by PEPFAR in FY2026, are being [illegally withheld by President Trump](#) and Russell Vought, the Director of the Office of Management and Budget, who has refused to release the funds. In addition to donors, countries must commit resources to scale-up, issue long-acting PrEP guidance, train health workers, and rebuild programs to reach key populations.

"We urge all governments to fulfill their duty to guarantee universal and timely access," said Luz Marina of GHP Corp in Colombia. "It is essential to strengthen PrEP strategies and to coordinate regional efforts to fully leverage all legal, technical, and cooperative tools to ensure access to LEN-LA, which represents real hope for the control and prevention of HIV in the region."

Activists also noted the need for rapid action by the government of India. "These deals will not move forward until generic versions are registered in India and cleared for export. India must now act with urgency to fast-track regulatory approval, so generics can obtain the Certificate of Pharmaceutical Product (CoPP) and enter global supply chains. Any regulatory delays in India risk slowing down access to LEN-LA at \$40 per person per year," said Leena Menghaney, an access to medicines legal expert.

Further background:

- Briefing document on Gilead's License and Implications for Access: ["No Borders, No Barriers, No Excuses"](#)
- Review of global access priorities: [Lessons for long-acting lenacapavir: catalysing equitable PrEP access in low-income and middle-income countries - The Lancet HIV](#)
- On July 14, WHO published [global guidelines](#) recommending LEN-LA for all people at risk of HIV infection.
- In addition to concerns about high prices, activists have been pressing Gilead to commit to registering its product rapidly across all LMICs. Thus far, Gilead has only indicated they will register LEN-LA in a set of 18 "priority countries" and Brazil, Argentina, Peru and Mexico. Track the status of global LEN-LA registration [here](#).
- LEN-LA can be produced [for as little as \\$25 per year](#); the U.S. price is \$28,218 per year.
- Potential PrEP users have consistently expressed strong preference for six-month injectables, indicating uptake will likely be much greater than oral PrEP. (Additional LEN-LA clinical trials are underway for people who inject drugs.)

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