



SHOTS COST PENNIES
GREED COSTS LIVES



HEALTH GAP
GLOBAL ACCESS PROJECT

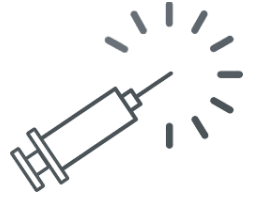
**HEALTH JUSTICE
INITIATIVE**



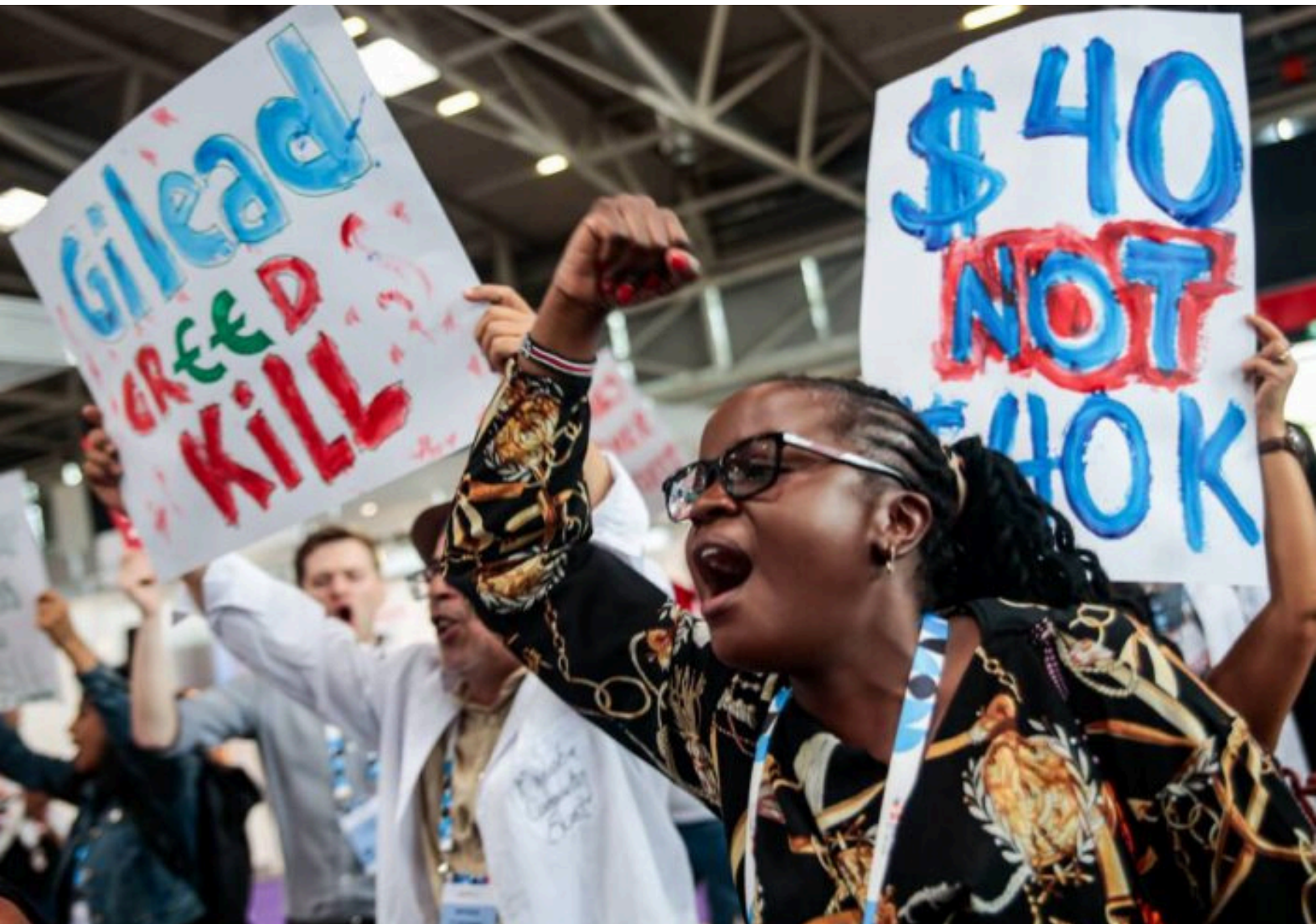
ABIA
ASSOCIAÇÃO BRASILEIRA
INTERDISCIPLINAR DE AIDS

just TREATMENT

ACTIVIST TOOLKIT WORLD AIDS DAY 2024



[Health GAP](#)
[Health Justice Initiative](#)
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WE DEMAND: GLOBAL ACCESS TO AFFORDABLE LONG-ACTING ANTIRETROVIRALS



World AIDS Day 2024 marks 60 days since Gilead announced its strategy for long-acting lenacapavir (LEN) for PrEP including voluntary licensing deals with 6 generic manufacturers.

LEN is the latest in a class of revolutionary new prevention tools called long acting antiretrovirals (LA-ARVs). **LA-ARVs have near 100% efficacy in stopping new HIV seroconversions and are vastly superior to current prevention options.** LEN could accelerate the end of the pandemic if it was deployed rapidly to everyone, everywhere who needed it at an affordable price.

But the marginalised groups—queer and trans communities, people who use drugs, straight women, and sex workers—who have been failed by existing, inferior prevention methods, are at risk of being denied access to LEN thanks to Gilead's profiteering.

Unless Gilead's deeply flawed plan is changed, their greed will unnecessarily prolong the HIV pandemic.

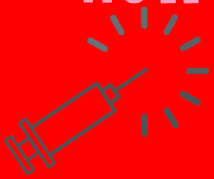
This World AIDS Day toolkit contains steps you can take to fight for accelerated global access to LEN, and cabotegravir (CAB-LA), the LA-ARV made by ViiV.

TAKE ACTION



Learn more and get involved in this global campaign: [sign up here.](#)

HOW DOES GILEAD'S ACCESS PLAN FAIL COMMUNITIES?



DISCRIMINATORY: Gilead has made only 120 territories eligible for their licensing deal with 6 generic manufacturers. They exclude many middle-income countries in Asia, Latin America, and the Middle East where HIV incidence is rising fastest. **Gilead even blocks Peru, Mexico, Brazil and Argentina**, countries where people participated in the clinical trials that generated data Gilead will use to generate massive profit.

OBSTRUCTIVE: Excluded countries are barred from importing generic versions of LEN made by Gilead's licensed manufacturers, even if those countries issue compulsory licenses or have no LEN patents in force. Excluded countries will be held hostage by Gilead, and will have to accept whatever bilateral price deal Gilead offers, consistent with Gilead's strategy of aggressive global LEN-LA patenting in countries with robust generic manufacturing capacity.

PLAYING DOCTOR AND BLOCKING LIFE SAVING RESEARCH: The licensees are restricted to manufacturing LEN for PrEP and to the indication of "heavily drug-resistant HIV," even if people need LEN for other treatment indications. Licensees are also barred from co-formulation of LEN with other products. Researchers who need study drug are being denied access by Gilead, obstructing potentially life saving clinical trials into LEN use in combination with Gilead's commercial competitors.

PROFITEERING: Gilead's "access price"—not yet disclosed— will be restricted to the poorest countries; in other countries, Gilead will charge whatever they think they can extract, despite the fact that LEN can be made for as little as \$40 per year, or one thousand times cheaper than Gilead's current price of \$42,250/year. As a result, millions of people at high risk of HIV infection will be relegated to inferior prevention options.

LENACAPAVIR CAN BE MADE
1,000X
CHEAPER THAN GILEAD'S
\$42,250/YEAR PRICE

GILEAD CEO DANIEL O'DAY: FIX YOUR FATALLY FLAWED ACCESS PLAN



Remove geographic exclusions—Include all Middle Income Countries (MICs) currently excluded by Gilead's voluntary licensing deal.

Remove prohibitions on export even if a compulsory license is issued or there are no patent barriers—Permit countries cut out of Gilead's deal to import generic lenacapavir made by the 6 licensed companies.

Announce one "access price" for all whether in licensed territories or not, comparable with oral PrEP. Gilead's access price should not be more than \$40. The price must be transparent, and Gilead must not require price secrecy from any procurement entity.

The license must be permitted for all indications, not just salvage therapy.

Remove restrictions that prohibit licensees from co-packaging or co-formulating generic lenacapavir.

Supply researchers with lenacapavir at low cost so that they can urgently study the treatment combinations people with HIV need and want.

Expand the number of licensed generic producers to include qualified generic producers in sub-Saharan Africa.

Disclose quality standards and allow access to and reliance on Gilead's regulatory submissions and approvals to obtain rapid marketing approval for generic entrants.

Support rapid registration of long-acting lenacapavir in all LMICs, not merely the 18 priority countries identified, and apply promptly to the WHO prequalification programme and participate in WHO collaborative registration procedures.



During the week of World AIDS Day December 1 - 6 and beyond, email Gilead's CEO Daniel O'Day and demand he immediately overhaul his access strategy. Share and post using our sample social media materials here.



INDIA, SOUTH AFRICA, BRAZIL: DEFEAT PANDEMICS WITH REAL SOLIDARITY



Gilead's weak LEN pending patent applications in India—and beyond—should be rejected.

Non-voluntary measures must become the norm. Countries with generic manufacturing capacity such as Brazil, South Africa, India, Argentina, Colombia and others should commit to issuing compulsory licenses to allow supply domestically and to countries excluded from Gilead's voluntary license.

Fast track national registration of LEN across drug regulatory authorities.

Launch and fund new PrEP scale-up campaigns to build community literacy and demand for injectable PrEP, particularly among those groups facing the greatest need for effective prevention options.

TAKE ACTION



During the week of World AIDS Day December 1-6, demand governments of global majority countries immediately show real global solidarity in the fight for affordable generic lenacapavir. Share and post using our sample social media materials here.

WORLD HEALTH ORGANIZATION: AGGRESSIVELY CHAMPION LONG-ACTING PREP SCALE UP

WHO must Issue emergency LEN guidance, supporting widespread, culturally appropriate PrEP health literacy.

WHO must prequalify long-acting lenacapavir for pre-exposure prophylaxis and treatment in relying as appropriate on US FDA or EMA approvals and encourage company and country participation in WHO Collaborative Registration procedures to expedite national approval.

FURTHER READING:

[How South Africa can help secure immediate, global access to HIV prevention drug lenacapavir | Daily Maverick](#)

[A twice-yearly shot could help end AIDS. But will it get to everyone who needs it? | Associated Press](#)

[Declaration of Mar del Plata/Declaración de Mar del Plata | Latin American Network for Access to Medicines/Red Latinoamericana por el Acceso a Medicamentos](#)

[Not in our name: African HIV treatment advocates react to Gilead's voluntary licensing agreement on lenacapavir](#)

[Gilead under fire over HIV drug licensing | The Lancet](#)

[Twice-yearly lenacapavir for HIV prevention in men and gender-diverse persons | New England Journal of Medicine](#)

[Why Gilead's 'generosity' on HIV jab belies a betrayal | Mail & Guardian](#)

[Why the fuss about long-acting antiretrovirals for HIV? | Spotlight](#)

[Statement on Gilead's lenacapavir access strategy | Grupo de Trabajo Sobre Propiedad Intelectual](#)