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TOPIC: Launch of Lenacapavir in South Africa for HIV prevention

South Africa Helped Create Lenacapavir, Gilead Should Not Decide Who Gets It

– Civil Society Groups

Background:

South Africa is preparing to rollout lenacapavir, the innovative, game changing twice-yearly injectable HIV pre-exposure prophylaxis (PrEP) drug that was also researched in the Global South.

On June 5, the President and the Health Minister will officially launch the roll-out of lenacapavir in South Africa in Secunda, billed as a 'historic event'. But as our country – one with the world’s largest HIV epidemic - prepares to launch the drug that could end the epidemic, we must ask why we are being asked to celebrate when South Africa’s rollout plan is unambitious, low-scale, and in danger of being more about the pomp than the public health impact. The targets are too low; the population groups targeted in the short term are not broad enough; and the volumes from Gilead are minuscule.

It does not have to be that way. South Africa did not come to this point as a bystander— researchers, clinicians, trial sites, communities, and participants helped generate the evidence that established lenacapavir as one of the most promising HIV prevention tools ever developed. So just like in COVID, despite helping produce the science, South Africa continues to be dependent on decisions made elsewhere about how much we can receive, when it will arrive, how quickly we can scale production, and who and which groups will ultimately gain access.

That is the contradiction that is our reality — a country carrying the world's largest HIV burden is dependent on a pharmaceutical company to determine how and when we can properly protect our people.

The need:

Globally, [1.3 million](#) people became newly infected with HIV in 2024. In South Africa, this number stood at 170 000, accounting for about 13% of the world's new infections that year.

Lenacapavir, if rolled out in a timely manner and comprehensively, with greater volumes, could avert up to [52 200](#) new infections per year in South Africa alone.

Modelling from [HE2RO](#) shows that around **two million people in South Africa** need to be taking lenacapavir per year for it to have a real impact on the number of new HIV infections — and possibly end the epidemic within the next 8 years.

The roll-out and the targets that the President and the Minister are asking us to celebrate, fall embarrassingly short of this goal, because of artificial scarcity.

Delays, funding, testing requirements (in Ireland)

While South Africa has received some funding to buy lenacapavir from the GFATM, due also to a situation of global scarcity and patent monopoly power exercised by Gilead, [only 37 920](#) doses landed on South Africa's shores in late March and early April. This was then subject to post importation testing (a regulatory requirement), but which delayed South Africa's initial plans for an earlier roll out date of April 2026 (as it was done in Ireland).

The official roll-out is now planned for early June 2026, nearly two years after the first major prevention efficacy results were announced. And, Gilead could have sought an exemption from the testing requirement; it did not.

The Health Department has shared that it also plans to use public money to [secure cheaper generics](#) once and if they become available, presumably by 2027. But it has been silent on whether this includes a scale up in targets, and by how much.

“South Africans helped generate the evidence that made lenacapavir possible. Our communities participated in the research, our clinics hosted the trials, and our scientists helped produce the data. Yet we are still waiting for Gilead to determine how much of the product we receive, when it arrives, and how quickly access can expand. We can see - yet again - that key decisions about South Africa's HIV response are still being made by a pharmaceutical company - and that should worry every person who believes in health justice” said Tian Johnson of the **African Alliance**.

“37 920 doses now, and the remaining promised doses over two years is far off the two million needed for South Africa to achieve the best public health impact”, said Fatima Hassan of the **Health Justice Initiative** (HJI). She added: *“It is a concern that both the Department and Gilead are not taking responsibility for the avoidable delays in the roll-out, and that the President has been brought on to bless this absurdly low volume roll-out, when he could be taking state action to alter the situation that we are in”*.

In **May 2026**, several civil society groups in South Africa working to secure equitable access to lenacapavir wrote to Gilead, GFATM, and the Health Department seeking clarity, inter alia, on whether Gilead had sought a post-import testing exemption from SAHPRA, and whether the Department and/or GFATM and/or the distributor or other stakeholders had requested Gilead to

seek the testing exemption, which has caused the most recent delay (because the testing is being done in Ireland).

In response, we received a non-committal statement from Gilead, without a firm commitment that it is seeking an exemption or any commitment to accredit a local laboratory to conduct future testing, where required. The Health Department has to date not responded.¹

In any event, our assessment is that the reason South Africa is only getting a few thousand doses when it needs millions, is because the manufacture and shipment of lenacapavir remains controlled by Gilead, GFATM, and also the US government — whose directive to PEPFAR to exclude South Africa because of ideological and trade tensions in US-SA relations, has dismantled several HIV prevention programmes across the country. Since Gilead is currently the *only manufacturer* of lenacapavir and generics are not available² on the market yet, there is no alternative path available here and elsewhere, to secure more doses for the rollout, for some time at least.³

While the South African government and Gilead have announced an *intent* to grant a voluntary license via the administrative function of the South African National AIDS Council ([SANAC](#)) (March 2026) that process is far from complete, and the final decision to award the license remains with Gilead and the Medicines Patent Pool (MPP), who have all the power in this deal-making announcement. Again, it will be some time before a South African made generic version will become available to people in South Africa so that the roll out can truly expand to have great public health benefit.

And even if all these significant issues causing delays in the rollout of lenacapavir were to be swiftly addressed, it would only serve to reveal the true elephant in the room: the *abysmal scale of the roll-out* itself.

Because of the factors highlighted above, the [planned roll-out](#) between 2026 and 2028 largely depends on GFATM's funded doses, which may put around 456 000 people on the drug over two years. Not the two million or more needed. South Africa needs to ambitiously scale up the lenacapavir roll-out, prioritise key population groups, and communicate the challenges it faces in doing so, honestly, and upfront.

'We need millions more doses, but we cannot access them when we need them the most - the President and the Minister have the power to act against Gilead, and once again, in our AIDS crisis, they are not. Their leadership can take the form of state action against Gilead, they can insist on millions of more doses, they can support regulatory exemptions to speed up the programme, they can expand the priority groups...', said Bellinda Thibela of **Health GAP**.

'A programme that does not adequately prioritise key and vulnerable populations such as sex workers, outside of clinics, will leave those most in need of HIV prevention services, even more vulnerable. Sisonke acknowledges the arrival of a few thousand doses of lenacapavir in some clinic settings, but before any premature celebration, the government must take all steps to ensure that the rising hostility sex workers face in the health system is addressed. A prevention programme, which could be game changing, will only be effective if the public health evidence to properly include those most at risk is considered', said Katlego Rasebitse, **SISONKE Movement**.

Instead of celebrating the arrival and roll-out of the 37 920 doses, Government, with the GFATM, should be working to make sure important research and science benefits all, everywhere, and *scale up* volumes, to avoid, once again, being '[beggars](#)' for supplies.

'TAC urges President Ramaphosa to use the launch to call on Gilead to refrain from advancing their prejudicial and exclusionary behaviour towards other low- and middle-income countries, who have been deprived of access - social justice requires solidarity with all affected and excluded countries' said Sibongile Tshabalala-Madhlala, **TAC National Chairperson**.

Gilead must stop its PR stunts – it must commit to drastically expand its current license territories to help manufacture lenacapavir, and scale up volumes for South Africa and not ration countries such as South Africa in the Global South, that desperately and immediately need more supplies. It must also urgently invest in the laboratory capacity in South Africa to conduct product testing where needed, and at least commit to seeking the necessary regulatory exemptions in the meantime to avoid future delays in the programme.

Ends

For media queries and interviews:

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Additional resources:

1. [FAQs: Gilead's LENACAPAVIR \(LEN-LA\) license and implications for access; No Borders, No Barriers, No Excuses](#)
2. [PRESS STATEMENT: Africa Demands Lenacapavir for All: The South African Government Should Act Decisively Against US bullying and for Equitable Access](#)
3. [OP-ED: Who controls South Africa's lenacapavir rollout? Not South Africa](#)
4. [OP-ED: We are managing HIV with selective lenacapavir roll-out, not ending it](#)