

NDA CLEARS NEW HIV INJECTABLE DRUG

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The Uganda National Drug Authority (NDA) has approved lenacapavir, a new HIV-prevention drug taken only twice a year.

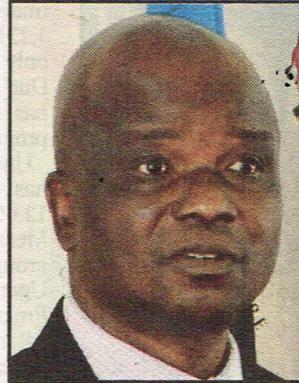
The life-saving drug is expected to be marketed in Uganda and distributed through the US President's Emergency Plan for AIDS Relief (PEPFAR).

The NDA approval means that data on the drug has been reviewed and found to have benefits that outweigh its side effects. It also means that the drug can legally be marketed, distributed and sold in Uganda.

The development comes barely six months after the World Health Organisation (WHO) recommended the drug as an additional HIV prevention choice, as part of combination HIV-prevention approaches.

The WHO recommendation also came after the US Food and Drug Administration approved lenacapavir for HIV prevention in mid-June last year.

Since Uganda is among the 10 high-burden HIV countries around the world. It is set to benefit from the subsidised HIV-prevention drug this year through a US government



Dr Nelson Musoba

initiative.

Lenacapavir offers a highly effective and convenient HIV prevention option for individuals at high risk of HIV acquisition. Clinical trials show that more than 99% of people on lenacapavir have remained HIV negative.

In a statement yesterday, NDA said the approval is expected to be a game-changer for HIV prevention, especially for those at high risk.

"This is a great step towards ending AIDS by 2030," the statement said.

Late last year, the US embassy in Uganda said Uganda, being among the 10 countries benefiting from the subsidised drug, will advance its fight against HIV/AIDS, particularly for pregnant and breastfeeding mothers.

"The US government and the Global Fund, of which the US government is the largest donor, are co-funding this advanced market commitment to purchase lenacapavir for up to two million individuals by 2028 in countries with the largest HIV/AIDS epidemics," the US embassy said.

The embassy noted that the drug manufacturer, Gilead, had agreed to provide its intellectual property to generic manufacturers, who can produce the drug and help bring down the price so that future purchases can be sustained by local governments.

COST OF LENACAPAVIR

Generic versions of the injectable HIV-prevention drug should be available for \$40 (about sh140,000) a year in more than 100 countries from 2027, Unitaid and the Gates Foundation said last year.

The two organisations entered into separate agreements with Indian pharmaceutical companies to produce cheaper generic versions of lenacapavir for low and middle-income countries.

Marketed under the brand name Yeztugo by California-based Gilead Sciences, lenacapavir currently costs about \$28,000 (about sh98m) a year in the US.



The lenacapavir drug will only be taken twice a year

HEALTH MINISTRY COMMENTS

This PrEP injection, administered every six months, will start next month with 94,560 doses for 47,280 people in the high-risk populations, said Dr Herbert Kadama, the national PrEP co-ordinator at the health ministry.

The high-risk populations include adolescent girls and young women aged 15 to 24, pregnant and breastfeeding mothers, female sex workers and their male clients. Other key populations at high risk are fishermen, long distance truck drivers and those in multiple sex relationships.

According to Kadama, a total of 17,280 doses have been procured with financial support from the Global Fund, while PEPFAR has donated 30,000 doses. The drug will be available in over 180 public health facilities at no cost, he said.

The Uganda AIDS Commission General Director, Dr Nelson Musoba, described the move as a game changer, "because it will help interrupt transmission of HIV, considering that the person at risk will be protected, consequently enabling the country to meet the target of ending AIDS by 2030."

HIV BURDEN IN UGANDA

As of December 2023, the estimated number of people living with HIV in Uganda stood at 1.492 million. While

the HIV prevalence has declined to 5.1%, women remain disproportionately affected.

Additionally, 38,000 new

infections are recorded annually, with a third occurring among youth aged 15-24 years.

Dr Flavia Kiweewa Kiwanuka, the principal investigator of HIV trials in Uganda, said the decision was the last one in the needed approvals and unlocks years of preparations.

She also said the development places Uganda among the first African countries ready to deploy the highly anticipated injectable pre-exposure prophylaxis (PrEP), which requires only two injections per year.

"The Ministry of Health wanted NDA to be the last step," she said, adding: "They have already selected nine sites and facilities in Uganda offering PrEP using lenacapavir. The ministry has already been training health workers; all I know is that this has been one of the most long-awaited steps before the ministry can start giving out lenacapavir."