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## A Revolution in HIV/AIDS Treatment

By German Velasquez

On September 25, 2025, two voluntary licensing agreements were announced between Gilead, the patent holder, and generic drug manufacturers in India for the supply of generic lenacapavir at \$40 (instead of the original \$28,218) per patient per year. However, too many countries are excluded from the agreements.

*Le 25 septembre 2025, deux accords de licence volontaires ont été annoncés entre Gilead, le détenteur du brevet, et des fabricants de médicaments génériques en Inde pour la fourniture de lenacapavir générique à 40 dollars (au lieu des 28 218 dollars initiaux) par patient et par an. Cependant, trop de pays sont exclus de ces accords.*

*El 25 de septiembre de 2025, se anunciaron dos acuerdos de licencia voluntaria entre Gilead, titular de la patente, y fabricantes de medicamentos genéricos de la India para el suministro de lenacapavir genérico a 40 dólares (en lugar de los 28 218 dólares originales) por paciente y año. Sin embargo, son demasiados los países excluidos de los acuerdos.*

A new preventive drug against HIV/AIDS represents a true revolution in the fight against this disease: two injections a year would be enough to obtain almost 100% protection. This treatment, launched on the market by the U.S. company Gilead at an original price of \$28,218 per patient per year, would now be available for \$40 per patient per year.

The World Health Organization (WHO) published new guidelines on July 14 (2025) recommending the injectable administration of lenacapavir (a capsid inhibitor) twice a year as an additional option for pre-exposure prophylaxis against HIV infection. This is a major normative recommendation that could redefine global action against the infection. The guidelines were presented at the 13th International AIDS Society Conference on HIV Science, held in Kigali (Rwanda) last July.

On September 25, 2025, two voluntary licensing agreements were announced between Gilead, the patent holder, and generic drug manufacturers in India for the supply of generic lenacapavir at \$40 (instead of the original \$28,218) per patient per year. This substantial price reduction was made possible through arrangements in which organizations such as Unitaïd entered into advance purchase agreements with Gilead, thereby providing financial support for early procurement. The agreement covers 120 countries. Some consider this an opportunity to end the HIV/AIDS epidemic.[1]

Dr. Tedros Adhanom Ghebreyesus, Director-General of WHO, stated: *"Although we do not yet have an HIV vaccine, lenacapavir is a very good option: it is a long-acting antiretroviral which, according to trials, prevents infection in nearly all people at risk."*[2]

Lenacapavir is currently reserved for patients with therapeutic failure and multi-resistant strains, and it is not intended for routine use. However, a study presented at the 25th International AIDS Conference

(Munich, 2024) demonstrated the full efficacy of an antiretroviral used in prophylaxis, administered with only two annual injections, paving the way for a new large-scale prevention strategy.[3]

The enormous price reduction - from \$28,218 to \$40 - exposes the disproportionate profits practiced by the pharmaceutical industry. It is undoubtedly good news for the 120 countries included in the voluntary license, but such geographically restrictive licenses from Gilead do not allow access at affordable prices in many other countries, despite the fact that generic production is viable at low cost, as the announcements show and numerous studies confirm. According to the latest UNAIDS (Joint United Nations Programme on HIV/AIDS) statistics, an average of 1,300,000 new HIV/AIDS cases are reported annually, many of which occur in countries excluded by Gilead.

While the generic lenacapavir price of \$40 will expand access in the countries selected by Gilead, this voluntary license deliberately excludes countries such as Colombia, Brazil, Malaysia, Mexico, Argentina, Peru, China, and many others in Latin America, Asia, Eastern Europe, and the Middle East. Ultimately, it is Gilead that decides who can be treated.

The Third World Network (TWN) statement already cited notes that Gilead is using legal and regulatory tactics to block competition. In India alone, the company has filed 14 different patent applications for lenacapavir.

WHO and the governments of excluded countries should implement rigorous patent examination practices to avoid patent evergreening in addition to granting compulsory licenses to expand access to medicines, including lenacapavir.

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[1] Third World Network (TWN), "Price must decrease for ALL, activists react to \$40 generic lenacapavir", TWN Info Service on Health Issues, 25 September 2025. Available from <https://twn.my/title2/health.info/2025/hi250901.htm>.  
[2] Organización Mundial de la Salud (OMS), "La OMS recomienda el lenacapavir inyectable para prevenir la infección por el VIH", 14 de julio de 2025. Available from <https://www.who.int/es/news/item/14-07-2025-who-recommends-injectable-lenacapavir-for-hiv-prevention>.

[3] Professor Jean-Michel Molina. See [https://www.sidaction.org/transversal/lenacapavir-pour-qui-est-destinee-cette-nouvelle-molecule/?gad\\_source=1&gad\\_campaignid=21495316067&gbraid=0AAAAAD6AP2XtRryhWFiFBNUWNfGyucOn1&gclid=Cj0KCQjw0NPGBhCDARisAGAzpp3EVWiQWrivkD83K8fWEQwCj0ZjR\\_CBDWjDuBbohxxhbyGoLi1vRFAaAvomEALw\\_wcB](https://www.sidaction.org/transversal/lenacapavir-pour-qui-est-destinee-cette-nouvelle-molecule/?gad_source=1&gad_campaignid=21495316067&gbraid=0AAAAAD6AP2XtRryhWFiFBNUWNfGyucOn1&gclid=Cj0KCQjw0NPGBhCDARisAGAzpp3EVWiQWrivkD83K8fWEQwCj0ZjR_CBDWjDuBbohxxhbyGoLi1vRFAaAvomEALw_wcB).

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