# Latin American Civil Society Statement on Equitable Access to Lenacapavir

**May 8, 2025**

Medicines for the People, AIDS Healthcare Foundation (AHF), Public Citizen, regional networks, and the undersigned civil society organizations committed to the HIV response, issue an urgent call to governments across Latin America to ensure equitable access to Lenacapavir—an innovative, long-acting injectable medication with the potential to transform HIV prevention.

In 2023, 1.3 million people acquired HIV globally—well above the international targets for reducing new infections. This alarming reality underscores the need for a bold and immediate response.

Lenacapavir provides six-month protection through a single injection and holds significant promise for reducing new infections. However, its current price—exceeding USD 40,000 per person per year—renders it inaccessible, even for upper-middle-income countries in the region. This stands in stark contrast to an estimated production cost of less than USD 100. Gilead's voluntary licensing arrangement has unjustly excluded key countries such as Brazil, Colombia, Mexico, and Peru—even though some participated in clinical trials—violating fundamental ethical principles of research.

In 2024, Latin American civil society mobilized to demand equitable access to Lenacapavir. On December 1, World AIDS Day, 113 organizations denounced the region's exclusion under the slogan "Gilead in debt to Latin America." On December 18, a new initiative—"Latin America Demands Equitable Access to Lenacapavir"—brought together 94 organizations and 13 social leaders to submit a regional appeal to 22 national governments.

These actions aim to encourage the use of legal flexibilities under the World Trade Organization's TRIPS Agreement, including compulsory licensing, strengthened regulatory frameworks, and the promotion of local medicine production.

This collective response signals Latin American civil society's strong opposition to Gilead's prioritization of profits over public health and affirms the urgent need for governments to utilize all available legal mechanisms to ensure access, with the right to health and public interest as guiding principles.

In Argentina, the GEP Foundation successfully challenged Gilead's patent application for Lenacapavir, arguing that the compounds lacked novelty and inventiveness. The National Institute for Industrial Property (INPI) subsequently rejected the application, citing failure to meet national patentability standards.

Secondary patent applications should also be rejected when they merely serve to extend monopolies without offering therapeutic benefits or meaningful innovation.

Access to Lenacapavir is further hindered by high costs, a lack of transparency, export restrictions within Gilead's licensing agreements, and delays in the availability of generic alternatives—currently not expected before 2028—factors that threaten to widen the gap in the global HIV response.

Ensuring access to Lenacapavir must be part of a broader structural shift recognizing publicly funded medicines as global public goods. We call on the international community to adopt policies that place public health above private profits.

We urge Latin American governments to act swiftly to improve access and promote regional production of essential medicines. Civil society organizations remain ready to collaborate with national authorities despite the lack of institutional response to date.

If concrete progress is not achieved in the near term, we strongly encourage governments to consider issuing compulsory licenses—an approach that has yielded success in countries such as Colombia, Brazil, and Ecuador in response to other patented medicines.

We, the undersigned, call on the governments of Latin America to:

- Ensure equitable access to Lenacapavir, a long-acting injectable medication used for HIV prevention and as an alternative for individuals with resistance to other antiretroviral treatments.

- Strengthen regulatory frameworks to facilitate the registration and availability of generic versions and support regional pharmaceutical production.

- Utilize the flexibilities under the WTO TRIPS Agreement, including compulsory licensing, and invite interest from generic manufacturers to produce the medication.

- Reject unjustified secondary patents that extend monopolies and hinder access to essential medicines.

- Involve civil society in dialogue and decision-making processes related to access to innovative treatments.