

Statement from Latin American Civil Society to Gilead Sciences for Equitable Access to Lenacapavir

The undersigned civil society organizations and networks from Latin America, committed to a comprehensive response to HIV/AIDS, express our deep concern about the high price of Lenacapavir, which renders it inaccessible. We reject the exclusion of our region from equitable access to the generic versions licensed by Gilead, condemning thousands of people in the region to not having access to a proven effective prophylactic medication.

In Latin America, new HIV infections increased by 9% between 2010 and 2023, reaching approximately 120,000 new infections in the last year alone. Sixty-six percent of these cases are concentrated among key populations such as men who have sex with men, sex workers, transgender women, and their partners.

Efforts to prevent HIV infection through PrEP programs have not achieved the expected results. Epidemiological models show that unless coverage exceeds 30% in key populations, Latin America will not meet the goal of ending HIV by 2030.

We, the civil society organizations of Latin America, denounce the following barriers by Gilead:

- **Unjust geographic exclusion.** Countries such as Argentina, Brazil, Mexico, and Peru, which participated in clinical trials of Lenacapavir, have been omitted from the scope of the license for generic producers, without explanation.
- **Restrictive clauses.** Gilead imposed export restrictions and limiting clauses that prevent access to generic versions of Lenacapavir, even in the event of a compulsory license.
- **Unaffordable price.** At over USD 40,000 per person/year compared to an estimated production cost of under USD 100, Lenacapavir is unaffordable for public health systems in the region.
- **Exclusivity.** Multiple patent applications for the compound and formulations of Lenacapavir are pending in various Latin American countries, delaying the entry of generics and increasing costs. This patent thicket extends exclusivity until at least 2034 and hinders regional production efforts.

The patent system must be used legitimately. As is publicly known, the National Institute of Industrial Property (INPI) of Argentina rejected Gilead's patent applications for Lenacapavir following a challenge from civil society, citing a lack of novelty and inventive step. This ruling demonstrates that many of the claimed patents lack technical and legal justification and calls into question the validity of similar applications in other countries in the region.

In a recent article published by Gilead, the company states its goal to “end the HIV epidemic for everyone, everywhere” and announces partnerships with governments and generic manufacturers. While we acknowledge the inclusion of a global access plan, these proposals are limited to low-income countries and fail to recognize the urgency of access in

most Latin American countries. No details are provided regarding supply timelines, distribution mechanisms, or clear and affordable pricing strategies for our region.

As organizations and leaders of civil society in Latin America, we urgently call for the following:

- The immediate withdrawal of unjustified patent applications for Lenacapavir in Latin America.
- To allow affordable generics to enter the market.
- The elimination of abusive clauses imposed on generic producers.
- Transparency in price-setting based on real production costs.
- In the medium term, the development of technology transfer strategies to strengthen regional manufacturing capacity.
- The establishment of an ongoing dialogue with Latin American civil society to build sustainable solutions.

We, the undersigned, urge Gilead Sciences to act following the principles and values it claims to uphold, by expanding the scope of access to generics and translating its commitments into concrete, inclusive, and transparent actions that lead to ending the epidemic and ensure the right to health for thousands of people in Latin America.

We reiterate our willingness to meet with Gilead Sciences to agree on measures that will provide equitable access to Lenacapavir and future PrEP innovations.

Latin America, May 2025

Signed

1. Acción Internacional por la Salud AIS Perú
2. AIDS Healthcare Foundation AHF
3. Global Humanitarian Progress Corp.
4. Medicinas para la Gente, Capítulo Latinoamérica
5. Public Citizen USA
6. REDNAJCER República Dominicana
7. Misión Salud Colombia
8. ITPC LATCA Perú
9. Asociación INPACVIH Perú
10. Voluntades Lima Norte Perú
11. Eugenio Villar Profesor Universidad Peruana Cayetano Heredia Perú
12. CEPESJU Perú
13. Organización de personas con VIH, familiares y amistades Juntos por la Vida Chile
14. Red Latinoamericana y del Caribe de personas con VIH
15. Red Uruguay de PVVs REDLAC+
16. Fundación Amigos por la Vida Colombia

17. Richard Stern Lider independiente Costa Rica
18. REDBOL Bolivia
19. Red de Medicamentos de Guatemala RedMedGua
20. Corresponsales Clave Latinoamerica
21. Giovanni Melendez Lider independiente Guatemala
22. Tierra de niños y niñas libres Perú
23. Fundacion FUNDINVE Venezuela
24. ITPC Bolivia
25. Si, da vida Perú
26. GIVAR Perú
27. Colectivo Los pacientes importan Perú
28. Colectivo TLGB de Bolivia
29. Asociación Vivo en Positivo Bolivia
30. KARUNA, Salud y Desarrollo A.C. México
31. RED SOMOS Colombia
32. Orlando Mauricio Bolívar Historiador Colombia
33. Sandra Ballenas Docente/ Inv. Pontificia Universidad Católica del Perú
34. Health GAP Global
35. SANGRAM India
36. Veshya anyay Mukti Parishad India
37. Sankalp Rehabilitation Trust India
38. DURBAR MAHILA SAMANWAYA COMMITTEE India
39. National Coalition of People with HIV in India
40. Mona Mishra India
41. South India AIDS Action Programme
42. Global Alliance for Human Rights India
43. PMA Global Campaign Lisboa
44. Salud y Fármacos USA
45. Fundación para estudio e investigacion de la mujer FEIM Argentina