Acción Internacional para la Salud

PERU PARTICIPATES IN CLINICAL TRIALS YET IS EXCLUDED FROM THE BENEFITS ACHIEVED

Lessons from lenacapavir and alimatravir as an open opportunity

Peru participates in clinical trials yet is excluded from the benefits achieved

Pre-exposure prophylaxis (PrEP) is one of the most cost-effective tools for interrupting HIV transmission, offering protection to HIV-negative people with sexual exposure to the virus before infection occurs. Despite its availability for more than a decade, 2025 saw 1.2 to 1.3 million new HIV infections worldwide, nearly 3,300 people per day. Only 18% of those who could benefit from PrEP have effective access to it.

Daily oral PrEP, while effective, faces a structural adherence barrier: stigma, fear of involuntary disclosure of risk status, and the burden of daily dosing reduce sustained use among key populations. Long-acting formulations—semiannual injectables or monthly oral options—aim precisely to overcome that barrier, and represent the most promising innovation for reaching the global goal of 20 million PrEP users by 2030. However, recent evidence on two next-generation molecules, lenacapavir and alimatravir, shows that scientific innovation does not automatically translate into equitable access, and that Peru, despite its direct contribution to the global clinical evidence base, is excluded from its benefits.

Lenacapavir: advantages, development, and conditions for access

Lenacapavir (Yeztugo®/Sunlenca®), from the pharmaceutical company Gilead Sciences, is a first-in-class HIV-1 capsid inhibitor administered in just two subcutaneous injections per year. In the PURPOSE-1 and PURPOSE-2 phase 3 trials, it demonstrated 96–100% efficacy, superior to daily oral PrEP, mainly by eliminating dependence on daily adherence.

The PURPOSE clinical trial program included PURPOSE-1 (cisgender women, in South Africa and Uganda) and PURPOSE-2 (cisgender men, transgender women and men, and non-binary people); the latter was conducted in the United States, South Africa, Thailand, Argentina, Brazil, Mexico, and Peru. It was approved by the FDA as PrEP in June 2025 and recommended by the WHO in July of the same year.

Gilead holds patents on lenacapavir valid until 2037 in Peru and other countries in the region. The list price in the United States is $28,218 per person-year ($14,109 per semiannual dose). In September 2025, two complementary agreements to Gilead's license—one between Unitaid, the Clinton Health Access Initiative (CHAI), and the Wits Reproductive Health and HIV Institute (Wits RHI) with Dr. Reddy's Laboratories, and another between the Gates Foundation and Hetero Labs—set a projected price of $40 per person-year for 120 low- and lower-middle-income countries, with availability starting in 2027.

However, Peru has been excluded from access to the generic version of lenacapavir despite its participation in the clinical research that evaluated the drug's efficacy and safety. Peru was one of seven sites for the PURPOSE-2 trial that supported the drug's global approval, but it is not among the 120 countries covered by Gilead's voluntary licenses or the complementary agreements with Unitaid or the Gates Foundation.

In addition, Peru is subject to other restrictions:

Unprecedented contractual barrier against compulsory licenses. Gilead's license agreement prohibits the six generic manufacturers from selling outside the 120 designated countries, even to countries that issue a compulsory license. This means that if Peru declared lenacapavir to be in the public interest and issued a compulsory license—as Colombia did with dolutegravir in 2024, a decision upheld by the Andean Tribunal in 2026—it could not source from the manufacturers already licensed, and would have to turn to a manufacturer unaffiliated with Gilead or to local production, with all the regulatory, technological, and time-related complexity that entails.

Inequity by design. Middle-income countries like Peru fall into a "gray zone," not qualifying for voluntary licenses aimed at low-income countries, even though the regional epidemic shows a trend opposite to the global one: worldwide HIV incidence fell 39%, while in Latin America it rose about 9% over the same period.

Exclusionary pricing. In countries without a Gilead license to use the generic version, the reported cost of the brand-name product is around $42,250 per person-year, more than 1,000 times the estimated production cost of the generic version ($25–46/year).

Alimatravir: an open opportunity

Alimatravir (MK-8527, Merck/MSD) is an oral, once-monthly inhibitor with a dual mechanism to block viral replication that could offer protection starting within the first hour after dosing. It is in phase 3 trials, EXPrESSIVE-10 and EXPrESSIVE-11. The latter is being conducted, among other countries, in Peru, currently in the recruitment phase. If its efficacy is confirmed, it would represent a disruptive innovation: a monthly oral option, logistically simpler than an injection, to expand PrEP coverage in settings with limited access to clinical services.

Similar to lenacapavir, in July 2026 Merck signed bilateral, non-exclusive, royalty-free voluntary licenses with seven generic manufacturers to supply 129 low- and middle-income countries, including all of Africa and much of Asia. Although the final price has not yet been disclosed by the pharmaceutical company, a study published on PubMed projects that large-scale production of the generic version could cost between $4.46 and $24.91 per person-year. However, Peru, where the patent remains valid until 2035, is once again left off the list of licensed countries, despite being an active site for the EXPrESSIVE-11 trial. This repeated exclusion—covering two molecules from two different manufacturers—suggests a pattern of conduct that the industry uses in its access strategies for middle-income countries in Latin America.

The consequences of this exclusion are clear: while the 129 licensed countries will be able to access generic alimatravir at a cost of around $5–25 per person-year once efficacy is confirmed and regulatory approval granted, Peru, if the exclusion is not reversed, would be limited to whatever price Merck sets, replicating the inequity gap already documented with lenacapavir. This means postponing access to the most promising innovation in oral PrEP precisely when the country faces an adverse epidemiological trend, and it perpetuates an asymmetry in which Peru contributes scientific data to global trials without receiving, in exchange, the benefits that subsequent access to the product provides.

The State and civil society

Facing this scenario, it is incumbent upon the State and civil society to:

Demand participation as a beneficiary country. Organized civil society must actively demand that, when Peru serves as a clinical trial site, it be considered a beneficiary country of the access plans implemented, including voluntary licenses—a principle of post-trial justice that is currently absent from industry practice.

Press for Peru's inclusion, and that of other countries in the region, in the voluntary license. The process is not closed. Merck has explicitly stated that its licenses are not exclusive and that the inclusion of new countries or manufacturers remains open. This constitutes a concrete window for advocacy: the Peruvian State and civil society organizations must formally request their inclusion in the ongoing negotiations.

National regulatory framework. The Peruvian State should implement policies or guidelines that make authorization of industry-sponsored clinical trials conditional on verifiable access commitments, including the country's inclusion in voluntary licenses, priority regulatory registration, and prices equivalent to those offered to countries of comparable income.

Strengthen access governance. It is necessary to consolidate a technical unit within the Ministry of Health, in coordination with INDECOPI and DIGEMID, to systematically monitor the status of patents, voluntary licenses, and prices of emerging health technologies for HIV and other diseases, so that decisions such as opposing a patent or issuing a compulsory license can be activated in a timely manner, rather than reactively or belatedly in response to exclusions that have already taken effect.

Peru and other countries in the region must take a forward-looking view regarding other innovations under development for HIV prevention and other diseases, establishing clear, anticipatory rules that guarantee the country's participation in the benefits derived from clinical research. This should be a health policy priority, not a demand raised only after each case of exclusion from equitable access.

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