



Gilead's Voluntary License on Lenacapavir

Key Limitations of the License and Recommendations to Improve Access

Introduction

In 2023, 1.3 million people globally became newly infected with HIV, with one new infection every 24 seconds.¹ This demonstrates an urgent need to scale up access to HIV medicines like lenacapavir, a long-acting antiretroviral (ARV) for HIV prevention and treatment with promising clinical trial data suggesting it is highly effective in stopping HIV acquisition.^{2,3,4}

However, when the pharmaceutical corporation Gilead Sciences (Gilead) announced it had signed non-exclusive bilateral voluntary licenses with six generic manufacturers for lenacapavir in October 2024, the restrictions of Gilead's licensing agreement quickly became clear.

Voluntary licenses are contractual agreements through which patent holders allow others to use, produce or sell a generic version of a patented medicine, but the terms often include restrictions, such as geographic limitations or supply controls that can undermine broad access. In this case, Gilead's voluntary license on lenacapavir excludes many middle-income countries – including some in which Médecins Sans Frontières (MSF) provides HIV care – and as such, could potentially block access to this promising tool for many people around the world.

Long-acting injectable pre-exposure prophylaxis (PrEP) has the potential to be a gamechanger for HIV prevention, particularly for marginalised and criminalised populations that are at higher risk of acquiring HIV. MSF is already supporting the rollout of long-acting cabotegravir (CAB-LA) for PrEP in Eswatini, Malawi, Mozambique, and Zimbabwe, and offers other forms of PrEP (oral and ring) and broader HIV prevention strategies in many regions, including in countries in Africa and Latin America. With individual choice and agency as central tenets of HIV prevention, expanding the range of available tools is a key priority. Lenacapavir's twice-yearly dosing offers distinct advantages in HIV prevention, such as improved adherence and less frequent visits to a health facility, making it critical for use in resource-limited settings, including those with MSF-supported programmes.

This briefing document outlines the key features of Gilead's voluntary license agreement for lenacapavir, highlights the limitations and challenges posed by the current terms of the license particularly in relation to broader access of lenacapavir, and recommends actions Gilead must take to expand access to lenacapavir.

Background

Lenacapavir belongs to a new class of drugs known as capsid inhibitors and represents a major breakthrough in HIV treatment and prevention. Lenacapavir is an especially promising option for treatment-experienced patients and those with multi-drug-resistant HIV.^{5,6} As a new drug with a novel mechanism, there is both limited pre-existing resistance and cross-resistance with existing ARV drugs. Twice-yearly lenacapavir was shown in clinical trials to be 100% effective in preventing HIV infection among cisgender women and girls, and reduced HIV risk by 96% in a gender-diverse group including cis- and transgender men and non-binary individuals, making it up to 89% more effective than daily oral medicine.^{7,8} The United States Food & Drug Administration (FDA) and the European Medicines Agency (EMA) have approved lenacapavir in both oral and injectable forms for the treatment of HIV infection in heavily treatment-experienced adults with multi-drug-resistant infection, with the injectable form requiring just two subcutaneous injections per year and thus mitigating cold chain storage

challenges. On June 18, 2025, the FDA approved twice-yearly injectable lenacapavir to be used for HIV prevention.⁹ New data from early studies now shows that lenacapavir may eventually have the potential for a once-yearly injection for HIV prevention.^{10,11} This once-yearly long-acting option, which is still under study, could offer even greater convenience and therefore enhance adherence even further for people who may need PrEP.

Despite lenacapavir's promise for the prevention and treatment of HIV, Gilead's licensing strategy continues a concerning trend of excluding many middle-income countries, particularly those in North Africa and Latin America where HIV infections have been increasing since 2010.¹² In addition, while the price of lenacapavir in excluded countries remains unknown, as Gilead has yet to publicly share this, there are signs the prices will be unacceptably high. For example, Gilead has priced lenacapavir treatment at US\$42,250 per year in the US for treatment and \$28,218 for PrEP despite research suggesting that the cost of production is under \$100, and could fall to around \$40 if economies of scale are reached through wide adoption of the drug.^{13,14,15,16}

Key Features of the License

Licensees

Gilead has signed non-exclusive and royalty-free voluntary license agreements with six generic pharmaceutical companies based in Egypt, India, and Pakistan: Dr. Reddy's Laboratories Limited, Emcure, Eva Pharma, Ferozsons Laboratories Limited, Hetero, and Mylan (a subsidiary of Viatris).¹⁷ These licenses permit these companies (the Licensees) to manufacture and supply lenacapavir within territories that include 120 countries and territories, subject to regulatory approval.

Publication of license

Gilead has made the license agreement available on its website, allowing for the terms of the license to be assessed in detail, including against previous licenses. The license discloses some current and pending patent applications filed in territories included in the license. Information on the patent status for wider range of countries is available through the Medicines Patents and Licenses Database (MedsPal).¹⁸

Waiver of exclusivity

Gilead agrees to waive its New Chemical Entity (NCE) exclusivity for the limited purpose of allowing a Licensee to get tentative approval for the Product in the licensed territory.^{19,20} Additionally, the Licensee is prohibited from pursuing or obtaining regulatory exclusivity for the licensed product in any country worldwide.

Concerns with the license

Geographical exclusions

Gilead's bilateral voluntary license grants six generic manufacturers the rights to produce both the active pharmaceutical ingredient (API) and the finished pharmaceutical product for distribution in 120 countries and territories. These are primarily low- and lower- middle-income countries, with many middle-income countries in Latin America, Asia, Europe, the Middle East and North Africa notably excluded, some of which are places where MSF provides HIV care. (See Annex I).

While global access to HIV treatment has improved significantly, with treatment coverage having risen from 47% in 2015 to 77% in 2023, progress has been uneven.²¹ In Latin America and the Middle East and North Africa, new HIV infections have risen sharply, especially among key populations such as men who have sex with men, sex workers, and transgender women.^{22,23} These groups, already facing systemic barriers to healthcare, are most in need of expanded access to newer treatment and prevention options like long-acting formulations.

MSF is supporting the introduction of injectable HIV PrEP (CAB-LA) in Eswatini, Malawi, Mozambique, and Zimbabwe and is planning to expand this work to additional countries, including

some in Latin America, where it is also exploring the introduction of lenacapavir. While some of these countries where MSF works are covered by Gilead's voluntary license, the restrictive conditions and limited geographic scope for manufacturing and supply means that access in many other countries, including many in Latin America, remains constrained.

Malaysia and Colombia, both of which have issued compulsory licenses (CLs), including for sofosbuvir for hepatitis C (Malaysia, 2017) and dolutegravir for HIV (Colombia, 2024), are excluded from Gilead's voluntary license.²⁴ The license also excludes China, a key global pharmaceutical manufacturing powerhouse that supplies most of the world's generic drugs, and regionally important manufacturers, including Argentina and Brazil. Until the six generic Licensees complete the generic development and enter the market, Gilead remains the sole global supplier of lenacapavir. This gives Gilead full control over the pricing and timing of market entry, leaving treatment providers with limited procurement options, and delaying the potential scale up of PrEP and treatment programmes in high-need and resource-limited settings that are unlikely to be able to afford broadly introducing lenacapavir at Gilead's anticipated price point.

Patents and restrictions on generic supplies in excluded countries

Access options for people living in the excluded countries are tied to the patent status of lenacapavir and the terms and conditions of the license in relation to whether generic Licensees are allowed to supply in these countries.

The patents on lenacapavir will start expiring in 2034. However, Gilead could extend its monopoly through secondary patents or other exclusivity mechanisms, potentially delaying generic competition until at least 2037 or beyond. This could further limit access in excluded middle-income countries and territories.

An analysis of the patent landscape (See Annex II) in excluded middle-income countries shows that at least 16 face barriers due to filed or granted patents, while 10 have no patents in force. However, despite the absence of patent barriers in 10 countries, the Licensee could still be prohibited from supplying generics.

Some of the existing lenacapavir patent applications have been challenged by civil society organisations across the world, including in Argentina, India, Vietnam, Thailand, and at the Eurasian Patent Office.^{25,26} In Argentina, one such pre-grant patent opposition on the grounds of insufficient novelty resulted in the Instituto Nacional de la Propiedad Industrial (INPI) rejecting two lenacapavir patents.²⁷

Despite the absence of patent barriers in some countries, the license terms and conditions may still restrict access options in countries excluded from the license territories:

First, Gilead's license gives a broad definition of "patents" to include both the granted patents and applications, including secondary patents, as well as any other patents or applications that are owned or controlled by Gilead and are necessary for the Licensee to manufacture, use, or sell lenacapavir. This definition also extends to any modifications, extensions, or restorations of these patents. While this broad coverage ensures that the Licensee has the necessary rights to produce and distribute within the territory, it also means that selling or distributing generic lenacapavir in excluded countries could be prohibited even if there are only pending patent applications in said excluded countries.

Second, the license does not contain language that explicitly permits generic Licensees to supply non-territory markets in which patent-related barriers are removed. This stands in stark contrast to some voluntary licenses negotiated by the Medicines Patent Pool (MPP) as well as some earlier Gilead licenses where Licensees are permitted to supply outside the defined territory where patent-related barriers have been addressed. Such a provision would give the Licensees greater flexibility to meet demand in countries outside the defined territory where patent-related barriers have been addressed.

Third, the license term states that Licensees are prohibited to supply outside of the territories overall with "such outside territories and/or fields being exclusively reserved to Gilead".²⁸ This restrictive condition could prohibit generic Licensees from supplying non-territory markets under any

circumstances, regardless of whether Gilead's patents are in force there, thus contributing to anti-competitive effects by limiting generic supplies in excluded countries.

Exclusion of countries that have populations who contributed to clinical trials

Gilead's voluntary license for lenacapavir excludes 11 countries in Latin America and 6 in the Middle East and North Africa, limiting access to a critical long-acting HIV treatment in regions facing a growing epidemic.^{29,30} This exclusion is particularly egregious given the contribution and involvement of communities in Argentina, Brazil, Mexico, and Peru to the clinical development of lenacapavir through the PURPOSE-2 trial.³¹ Denying access to populations that directly participated in the research and development of a medical tool is unethical.

Restrictions on sourcing

The licensing agreement imposes stringent restrictions that significantly limit the autonomy of generic manufacturers over sourcing and supply chain management. Licensees are prohibited from procuring lenacapavir, its raw materials, intermediates, or even packaging components, including vial kits, from contract manufacturing organisations (CMOs) or suppliers that also serve Gilead, unless the supplier first provides written confirmation that they can first fulfil Gilead's 12 month forecasted demand.³² Given the volatility and unpredictability of global supply chains in the 2020s, exacerbated by geopolitical disruptions, tariffs, and logistical bottlenecks, this level of supply certainty is not only difficult to guarantee, but is also unrealistic.

The clause is also operationally impractical: manufacturers frequently consolidate orders for items like packaging materials or vial kits across multiple products that use shared inputs to achieve economies of scale. Under these license terms, they would be compelled to artificially separate such orders by product line, adding inefficiencies and cost. Gilead is leveraging its licensing terms to create a de facto two-tier system in the global market for raw materials that privileges its own supply needs over broader access and affordability.

Strict anti-diversion measures and penalties

The license has strict anti-diversion measures to ensure that lenacapavir and related products are sold only within the designated territory and for approved uses. The Licensees are prevented from selling, offering to sell, or permitting third parties, such as resellers or customers, to distribute the product outside the territory or for any purpose beyond the licensed use.³³ Furthermore, the Licensee's direct trading partners, including Third Party Resellers and Customers, are prohibited from reselling the product and any unsold or unused product is required to be returned to the Licensee.³⁴

The Licensee is required to include a unique product identifier, such as a serial number, on both the primary and secondary packaging of every individual unit intended for sale within a territory.³⁵ In addition, the Licensee must establish a system to trace each of their units to their immediate downstream trading partner.³⁶ While these measures may be included to prevent counterfeiting and enhance supply chain security, they can create serious challenges for treatment providers and people receiving care.

The Licensees must also require third-party resellers to adhere to onerous reporting requirements, such as collecting and transmitting sales data, including the names and addresses of health facilities, as well as the quantity, associated lot, and serial numbers.

Additionally, the license also specifies terms related to implementing programmes, including Commercially Reasonable Efforts to minimise diversion and ensure lenacapavir is sold directly to patients and individuals who would benefit medically from PrEP within a country and as may be determined by Gilead and the Licensee.³⁷ Such anti-diversion clauses have been included in the past by Gilead in its voluntary licenses, and MSF has highlighted its drawbacks, including how treatment providers implementing programmes under this clause may be burdened with dispensing restrictions that may interfere with patient confidentiality.^{38,39}

For example, these stringent requirements would complicate how MSF and other treatment providers deliver care, especially in humanitarian or mobile settings where flexibility and discretion are essential.

They would risk undermining treatment adherence for individuals who are on the move, displaced, or need to cross borders for care, and who often rely on flexible and discreet access to care without exposing their identity. Packaging linked to traceability systems may not be easily transferable across borders, and could link medicines to specific individuals or locations of individuals, either of which could complicate continuity of care. Such measures may also discourage individuals from seeking treatment due to concerns about confidentiality and the possible resulting stigma, discrimination, or other negative consequences if their health status is inadvertently disclosed.

Non-compliance with these anti-diversion measures carries significant consequences, including the immediate cessation of sales and imports of lenacapavir in a specific country.⁴⁰ Furthermore, Gilead is entitled to extensive damages, calculated at estimated lost net revenue plus associated costs, or, if those revenues cannot be estimated, as much as two times Gilead's incurred cost related to such diversion.⁴¹ Importantly, Gilead retains the right to terminate the license agreement with Licensees if it determines a material breach of anti-diversion has occurred.

Pricing and availability

Gilead retains the control to supply lenacapavir to territories excluded from its voluntary licensing agreement, including the 26 middle-income countries listed in Annex I. Furthermore, until generic versions become available, Gilead has announced that it will prioritise registration to supply its own product in 18 “target countries” – high-burden countries listed in the license. These countries are Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Philippines, Rwanda, South Africa, Tanzania, Thailand, Uganda, Vietnam, Zambia and Zimbabwe.⁴²

However, the corporation has not disclosed the pricing of lenacapavir for either the “target countries” or those countries excluded from the license. It is likely that access to lenacapavir in these countries and territories will be determined by Gilead's own interests, using a confidential, country-by-country tiered pricing model. In MSF's experience, this lack of transparency in pricing delays procurement, increases unpredictability around costs, and limits our ability to scale up treatment. It also forces governments and treatment providers to negotiate without clear benchmarks, which is not in good faith and often results in prices going unscrutinised.

In the US, lenacapavir costs approximately \$42,250 per person annually for treatment and \$28,218 per person annually for PrEP.^{43,44} Meanwhile, recent research suggests that generic manufacturers could dramatically reduce the cost of long-acting lenacapavir. With large-scale production, lenacapavir could be produced and sold for around \$40 per person per year, while still allowing a 30% profit margin.^{45,46}

Lenacapavir is approved by the FDA and the EMA for “treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations”.⁴⁷ In June 2025, following the results of the PURPOSE 1 and PURPOSE 2 trials, the FDA approved Gilead's New Drug Application (NDA) for lenacapavir as twice-yearly PrEP.

As per the terms of the license, the Licensee's field of use is specifically limited to lenacapavir for use as PrEP and for the treatment of HIV infection in heavily treatment-experienced patients. The current license does not cover potential future indications, such as use in antiretroviral therapy simplification strategies for individuals on full suppressive therapy and, in the future, potentially as a first-line treatment.

Research restrictions

The agreement restricts the Licensee from manufacturing or selling lenacapavir “for any other purpose other than use in the Field”, which is defined by use for PrEP or treatment in heavily treatment-experienced patients.⁴⁸ This could potentially restrict companies from supplying lenacapavir for use in clinical trials.

Conclusion and Recommendations

Lenacapavir is a critical therapeutic breakthrough in HIV prevention and treatment. However, Gilead's voluntary licensing terms impose serious limitations that undermine the potential public health impact of this key medicine. The license's exclusion of key territories, along with restrictive provisions on sourcing, research use, and anti-diversion, collectively create significant barriers to equitable access.

As a medical treatment provider delivering HIV care in some of the most affected and underserved regions of the world, MSF is concerned about the implications of these restrictions. The extremely restrictive anti-diversion clauses can substantively undermine patients' confidentiality and treatment outcomes, especially in fragile, displaced and mobile populations. Moreover, by excluding countries where no patent barriers exist or where they have been addressed, Gilead's agreement sets a problematic precedent for broader access.

At the time of publishing this briefer, Gilead has not disclosed lenacapavir pricing outside of the US market, leaving countries excluded from the license without clarity on affordability.

To facilitate meaningful, timely, and equitable access to lenacapavir, the below actions are recommended:

1. Gilead should expand the license territories to include all middle-income countries, including those that have a high incidence of HIV infections and those that hosted lenacapavir clinical trials.
2. Gilead should stop mandating an onerous implementation of the anti-diversion programme by its Licensees.
3. Gilead should announce the price at which it will make lenacapavir available in both its "target countries" and the excluded middle-income countries.
4. Gilead should explicitly allow Licensees to supply to countries where no patent barriers exist or to supply to countries where patent barriers have been addressed by domestic mechanisms, including patent oppositions, revocation, or compulsory licenses.
5. Governments of countries excluded from the license territory should use other measures including compulsory licenses to overcome restrictions and limitations of Gilead's voluntary license, and to facilitate the introduction of generic lenacapavir.

Annex I:**Table 1: Middle-income countries and territories excluded from the lenacapavir voluntary license**

<i>Asia</i>	<i>Europe and Central Asia</i>	<i>Latin America & Caribbean</i>	<i>Middle East and North Africa</i>
China Malaysia	Albania Bosnia and Herzegovina Kosovo Montenegro North Macedonia Serbia Türkiye	Argentina Brazil Colombia Costa Rica Ecuador El Salvador Guatemala Mexico Paraguay Peru Venezuela	Algeria Iran Iraq Jordan Lebanon Palestine

Annex II:**Table 2: Patent status of lenacapavir in excluded middle-income countries/territories**

<i>Patent Description</i>	<i>Granted</i>	<i>Filed</i>	<i>Not Filed or Rejected or Withdrawn</i>
Lenacapavir compound and its use in HIV (oral and parenteral) [WO/2018/035359]	Brazil China Colombia Malaysia Mexico North Macedonia Peru Türkiye	Albania Costa Rica Guatemala Jordan Serbia	Algeria Argentina Bosnia and Herzegovina Ecuador El Salvador Iran Iraq Kosovo Lebanon Montenegro Paraguay Palestine Venezuela
Lenacapavir and analogues (Markush formula) and their use in HIV [WO/2014/134566]	Albania Bosnia and Herzegovina Brazil China Colombia Costa Rica Malaysia Mexico Montenegro North Macedonia Peru Serbia Türkiye	Argentina (opposed)	Algeria Ecuador El Salvador Guatemala Iran Iraq Jordan Kosovo Lebanon Paraguay Palestine Venezuela
Crystalline forms of Lenacapavir sodium salt	Albania North Macedonia Türkiye	China Serbia	Argentina Bosnia and Herzegovina Montenegro

[WO/2019/035904]			
Lenacapavir manufacturing processes and intermediates [WO/2019/161280]	Albania China North Macedonia Türkiye	Serbia Türkiye	Argentina Bosnia and Herzegovina Montenegro
Lenacapavir use in HIV pre-exposure prophylaxis (PrEP) [WO2021108544]		Albania China North Macedonia Serbia Türkiye	Bosnia and Herzegovina Montenegro
Lenacapavir use to treat multidrug resistant HIV infection in heavily treatment-experienced [WO2020018459]		Albania China North Macedonia Serbia Türkiye	Bosnia and Herzegovina Montenegro

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