

HIV Treatment Expansion



Gilead Sciences has contributed significantly to the improvement and simplification of antiretroviral HIV therapy and to expanding access to therapy for patients living in developing countries.

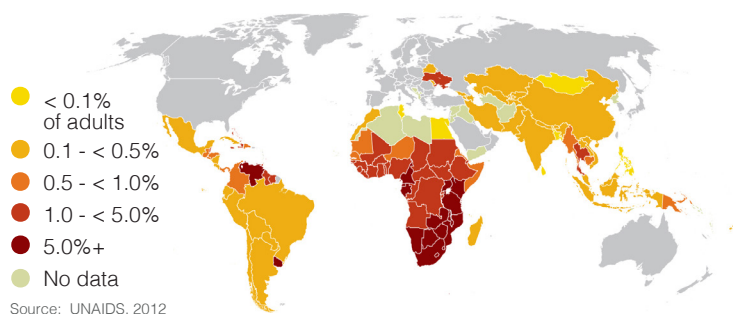
Snapshot

- **8 million people** with HIV in low- and middle-income countries are receiving a Gilead-based HIV regimen*
- The lowest price of generic tenofovir disoproxil fumarate (TDF)¹ is currently **US \$3.60** per patient per month
- Gilead was the **first company to license HIV drugs** to the Medicines Patent Pool

HIV in the Developing World

Nearly 37 million people are living with HIV-1, the vast majority of them in the developing world. Two million people are newly infected with HIV every year.² For more than a decade, the international community has made enormous progress in expanding access to antiretroviral treatment: between 2002 and 2014, the number of people in low- and middle-income countries receiving antiretroviral therapy increased from 300,000 to 13.5 million.^{3,4} Since 2000, HIV therapy has averted 7.8 million AIDS-related deaths worldwide.⁵ Additionally, there is growing evidence suggesting that people receiving HIV therapy are less likely to transmit HIV to other people, meaning that antiretroviral treatment may have an important role in HIV prevention.⁶

HIV Prevalence in the Developing World



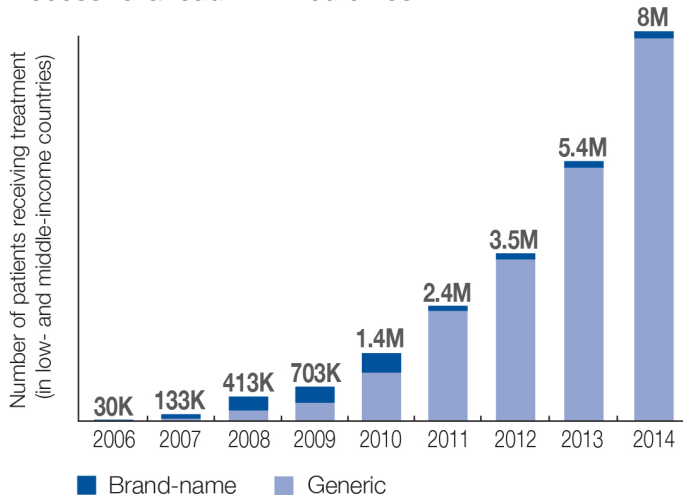
Yet substantial needs remain, with treatment scale-up a top priority. The World Health Organization (WHO) recently released new guidelines recommending immediate treatment for all, meaning that almost 22 million people worldwide are still in need of antiretroviral therapy.^{7,8}

Gilead's Approach

Recognizing that the greatest need for HIV treatment is in the least-developed parts of the world, the company has put in place innovative programs and partnerships to expand global access to its medicines.

Tiered Pricing. A key principle of Gilead's HIV treatment access efforts has been tiered pricing of its branded antiretroviral medicines. Developing countries are divided into two pricing tiers – low-income and lower middle-income – based on national income and HIV prevalence. Viread® (or TDF) has been available at reduced prices in developing countries since 2003. Truvada® (emtricitabine coformulated with TDF)⁹ and the single tablet regimens Stribild® (elvitegravir / cobicistat / emtricitabine / TDF)¹⁰ and Genvoya® (elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide)¹¹ were each added to the Access program following their U.S. approvals in 2004, 2012 and 2015, respectively. WHO recommends TDF-based regimens among the preferred options for initiating HIV treatment.¹²

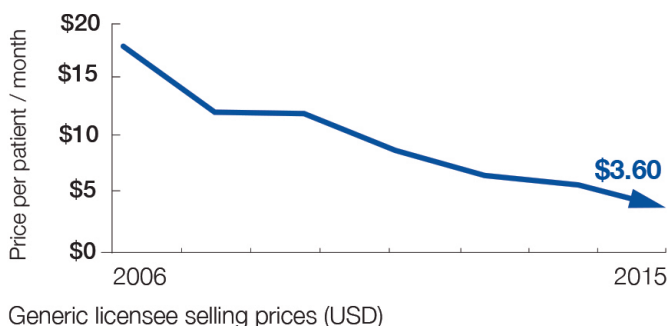
Access to Gilead HIV Medicines



*TDF-containing regimens from tech transfer recipients, branded sales, direct and Medicines Patent Pool licensees

Generic Licensing Partners. In 2006 Gilead began entering into voluntary licensing agreements with Indian manufacturers, granting them rights to produce and sell high-quality, low-cost generic versions of Gilead medicines.

Lowest TDF Price



In 2011, Gilead became the first innovator pharmaceutical company to sign an agreement with the Medicines Patent Pool (MPP), an international organization that expands access to HIV medicines through the sharing of drug patents. As a result, MPP is authorized to sub-license generic drug manufacturers to produce Gilead medicines for developing countries.

Currently, 17 Indian manufacturers, one South African and three Chinese companies hold licenses to produce Gilead HIV medicines. Over the past nine years, licensing partners have lowered the developing world prices of Viread and Truvada by

80 percent. The lowest price of generic Viread is currently US \$3.60 per patient per month.

Working Locally to Advance Access

Lowering prices is just one part of successfully scaling up HIV treatment. Also critical are in-country activities that support drug availability and use, including product registration, medical and clinical education, demand forecasting and collaborative research.



October 2013 medical education event in Myanmar supported by Gilead

Gilead conducts many of these activities in partnership with regional business partners that distribute its medicines throughout Africa, Asia, the Caribbean, Eastern Europe, Latin America, the Middle East and the Pacific region. In addition to delivering treatment, these partners help register medicines with regulatory authorities, ensuring that dossiers conform to national requirements and are processed efficiently, and assist with education for healthcare workers.

Country Program Examples

Myanmar: Gilead donates generic Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate)¹³ to the Myanmar government's National AIDS Program to treat patients at public hospitals.

- The donation supports the HIV treatment of 2,000 people in Myanmar who are living with HIV.
- Gilead also provides educational materials and financial support to strengthen local and regional health systems.

Tanzania: Gilead partners with the Good Samaritan Foundation of the Roman Catholic Church to support an HIV “test-and-treat” demonstration project in Shinyanga, a province in northern Tanzania. It is designed to save lives and boost HIV prevention efforts in the region.

- The program will screen 120,000 patients at four health centers in Shinyanga for HIV and provide antiretroviral treatment to 20,000 diagnosed individuals.

Ethiopia and Uganda: Gilead supported the Mayo Clinic and Chelsea Westminster Hospital's pilot HiV-Link program, which leverages mobile phone technology to connect healthcare providers in rural Ethiopia and Uganda with HIV treatment experts in the United States and United Kingdom. Through HiV-Link, African healthcare workers can text specific clinical questions to U.S./U.K.-based physicians and receive rapid responses that help to guide their treatment decisions for patients.

References

¹ Prescribing Information, Oct 2013. Available at: http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/viread/viread_pi.pdf.

² WHO. HIV/AIDS Fact sheet N°360. July 2015. Available at: <http://www.who.int/mediacentre/factsheets/fs360/en/>.

³ WHO. A Commitment to Action for Expanded Access to HIV/AIDS Treatment (2002).

⁴ WHO. HIV/AIDS Fact sheet N°360. July 2015. Available at: <http://www.who.int/mediacentre/factsheets/fs360/en/>.

⁵ UNAIDS. How AIDS Changed Everything (2015).

⁶ Cohen, M., et al. Prevention of HIV-1 infection with early antiretroviral therapy. *New England Journal of Medicine*, 2011;365:493-505.

⁷ WHO. Guideline On When To Start Antiretroviral Therapy And On Pre-Exposure Prophylaxis For HIV (2015).

⁸ UNAIDS. How AIDS Changed Everything (2015).

⁹ Prescribing Information, Oct 2013. Available at: http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdf.

¹⁰ Prescribing Information, Dec 2014. Available at: http://www.gilead.com/~media/Files/pdfs/medicines/hiv/stribild/stribild_pi.pdf.

¹¹ Prescribing Information, Nov 2015. Available at: http://www.gilead.com/~media/Files/pdfs/medicines/hiv/genvoya/genvoya_pi.pdf?la=en.

¹² WHO. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (2013).

¹³ Prescribing Information, Jan 2015. Available at: http://www.gilead.com/~media/Files/pdfs/medicines/hiv/atrilpa/atrilpa_pi.pdf.