

Gilead Sciences

Achieving Sustainable Access to HIV/AIDS Medicines in the Developing World

An estimated 34 million people worldwide are living with HIV. More than 15 million need antiretroviral treatment now, and nearly all may need to begin treatment within the next five years. Collaborative research and development efforts have helped create better therapies for patients, but treatment too often remains out of reach, particularly for the nearly 95 percent of people with HIV who live in developing countries.

Gilead Sciences, a research-based biopharmaceutical company that works to expand treatment options and improve the care of people with HIV/AIDS and other life-threatening diseases, has established an innovative access model that has significantly increased the number of developing world patients receiving the company's HIV treatments – from just 100 people in 2003, when the Access Program was established, to approximately 2.1 million today. **The majority of people worldwide who currently receive one of Gilead's HIV therapies live in developing countries.**

The Need for Treatment Access Programs

The advent of combination therapy has helped many people living with HIV in industrialized countries, and over the past 15 years treatments have continued to improve. Striving to address global treatment needs, international agencies, governments and nongovernmental organizations around the world have launched large-scale efforts to expand access. They have made impressive progress: between 2002 and 2010, the number of people in developing countries receiving treatment increased by 2,100 percent, from fewer than 300,000 to 6.65 million. Yet millions more still lack access to the treatment they need.

The Gilead Access Model

As the market leader in the development of therapeutics for the treatment of HIV, Gilead makes it a company priority to ensure that its innovative medicines are accessible to all who can benefit from them, regardless of their location or ability to pay. The Gilead Access Program provides the company's HIV medications at steep discounts in 132 countries, representing the regions hardest hit by the HIV/AIDS epidemic. Gilead uses a tiered pricing system for countries in its Access Program. Product prices in the wealthiest nations of the world are based on the product's full value, and substantial discounts are given in low- and lower middle-income pricing tiers. The tiers are determined by a country's economic status (using gross national income per capita) and HIV prevalence.

Viread® (tenofovir disoproxil fumarate) is currently registered in 96 countries and Truvada® (emtricitabine and tenofovir disoproxil fumarate) is now registered in 91 countries, up from 21 and 19, respectively, in 2006.

Role of Gilead's Distributors

The Access Program delivers medications through two parallel tracks: branded distribution and licensing partnerships. The first track focuses on the manufacture and delivery of branded products. To guarantee adequate drug supplies, Gilead has established manufacturing partnerships with organizations in the Bahamas (PharmaChem Technologies and the Grand Bahama Port Authority) and South Africa (Aspen Pharmacare). A network of 11 distribution partners and 48 sub-distributors around the world ensures that Gilead's medicines reach patients securely and efficiently.

In addition to delivering treatment, Gilead's distribution partners help register the products (leveraging their knowledge of local systems), manage on-the-ground, supply-chain logistics and assist Gilead in the delivery of medical education initiatives. Gilead provides these partners with comprehensive training so they can offer clinical and community-based education, address medical information requests and set up standard reporting systems within their respective regions.

Innovative Licensing Partnerships

In 2006, Gilead further expanded its Access Program by providing non-exclusive licenses to multiple Indian drug manufacturers. Gilead's 12 Indian partners have the right to manufacture and sell generic versions of Gilead products in developing countries and sell active pharmaceutical ingredient to each other. In 2007, Gilead provided Aspen Pharmacare with a similar license, enabling the production of both branded and generic Gilead products in Africa. Gilead provides its partners with a full technology transfer, and licensees are free to establish pricing for their products and to develop fixed-dose combinations. Under these agreements, Gilead receives a three percent royalty on finished product sales based on the generic price, which supports product registration, medical education, safety monitoring and other critical activities.

Highlights

- Approximately 2.1 million patients receiving Gilead HIV medicines in developing countries
- 132 countries in the Access Program
- Majority of patients on Gilead therapies live in developing countries
- Licensing partnerships with 12 Indian companies and one South African company
- Price of generic Viread® is as low as \$5.50/month per patient (18 cents per day), and price of generic Truvada® is as low as \$9.00/month per patient (30 cents per day)

Gilead's licensing partners are able to manufacture high volumes of product at relatively low costs of production. Additionally, extending the licenses to multiple companies effectively creates market competition that drives prices down. To date, the per-patient price of generic Viread has fallen to as low as \$5.50 per month (18 cents per day) and the price of generic Truvada to as low as \$9.00 per month (30 cents per day) in low-income countries. Most importantly, 2 million patients are now receiving high-quality, low-cost HIV products manufactured by Gilead's licensing partners. Of these, 1.75 million patients are receiving therapies produced by licensees in India, and the remaining receive generic products manufactured in South Africa. Overall, 95 percent of HIV patients on Gilead medications in developing countries are receiving generic versions.

Expediting Access to Future Medicines

Gilead has an active research and development program to identify and bring to market effective new antiretroviral therapies and is committed to facilitating rapid global access to these medicines. In July 2011, Gilead granted its Indian partners future rights to manufacture and sell generic versions of three Gilead HIV therapies currently completing late-stage clinical development (subject to the regulatory approval of these products): elvitegravir, a member of the class of antiretrovirals known as integrase inhibitors; cobicistat, an antiretroviral boosting agent that could allow for once-daily dosing of elvitegravir and protease inhibitors; and the Quad, which combines four Gilead HIV medicines (elvitegravir, cobicistat and the two components of Truvada) into a once-daily, single-tablet regimen. By issuing licenses in advance of initial product approval, Gilead hopes to ensure that high-quality, low-cost versions of new therapies can be made available in developing countries as quickly as possible.

Medicines Patent Pool

Gilead is the first pharmaceutical company to sign an agreement with the Medicines Patent Pool Foundation, which is working with a number of companies and other organizations to increase global access to high-quality, low-cost antiretroviral therapy through the sharing of patents. The Patent Pool has been granted similar licensing terms for Gilead's HIV medicines as our Indian partners, including a license for Viread and Truvada and future rights to medicines completing late-stage clinical development.

Meeting the Global Need

Gilead's innovative approach to treatment access has directly translated into patient benefit across the developing world, and provides a comprehensive, self-sustaining model for scaling up antiretroviral coverage. In collaboration with its partners, Gilead's long-term goal is to reach millions more patients in developing countries with medicines for HIV and other diseases that represent areas of unmet medical need.

Achieving the goal of universal access to treatment will require ongoing commitment from governments, industry and multilateral and nongovernmental organizations. Gilead is committed to playing our part, alongside our key collaborators and partners, in this critical effort.

For More Information

To learn more about Gilead Sciences and the company's efforts to increase HIV drug access in the developing world, please contact us via email at public_affairs@gilead.com.

Elvitegravir, cobicistat and the Quad are investigational agents and have not yet been determined safe or efficacious in humans.

Sources

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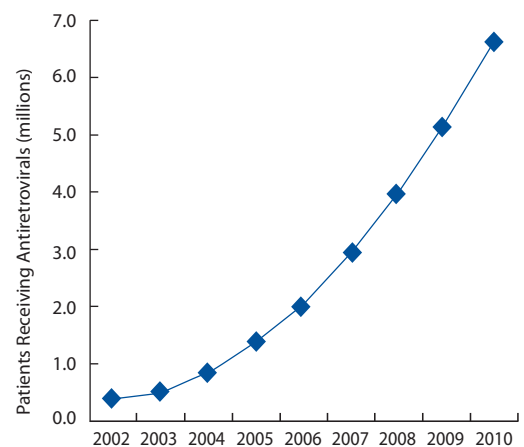
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Progress in Global Treatment Access



Growth of the Gilead Access Program

