Gilead Treatment Expansion Programs

Increasing Sustainable Access to Medicines and Healthcare



Gilead Sciences is a biopharmaceutical company that discovers and develops innovative medicines for life-threatening diseases, including HIV/AIDS, hepatitis B and visceral leishmaniasis. Gilead makes it a priority to increase access to these medicines for people who can benefit from them, regardless of where they live or their ability to pay.

Snapshot¹

- 5.4 million people with HIV in low- and middleincome countries are now receiving Gilead medicines
- More than **125 countries** are part of the company's programs to increase access to antiretroviral therapy
- Gilead HIV medicines are now registered in 109 countries



HIV/AIDS

Over the past decade, international efforts have greatly increased the number of people

in low- and middle-income countries receiving antiretroviral therapy for HIV/AIDS. Gilead medicines are recommended by the World Health Organization (WHO) as components of treatment.²

Gilead delivers its medicines in these countries by working with regional business partners to distribute brand-name products at prices that are based on a country's ability to pay and represent little or no profit to Gilead. Gilead also partners with manufacturers in India and South Africa that are licensed to produce generic versions of Gilead HIV therapies to sell to low- and middle-income countries.



Hepatitis B

Four hundred million people worldwide are estimated to be infected with the hepatitis B

virus (HBV). Chronic hepatitis B can cause serious liver disease and lead to liver cancer. HBV is second only to tobacco as a cancer-causing agent, and is common in China and other Asian countries where immunization against the virus is not routine. HBV is also common in Africa, the Amazon Basin, the Indian subcontinent, the Middle East and Eastern Europe.³

Through regional business and generic licensing partners, Gilead makes its HBV medicine available in more than 125 low- and middle-income countries at the same discounted prices as for HIV.



Two in five people in developing countries receiving HIV treatment are on Gilead medicines.



Visceral Leishmaniasis

Visceral leishmaniasis (VL) is the world's second-deadliest parasitic disease after malaria, affecting hundreds of thousands of people in developing countries annually. VL can also accelerate the onset of AIDS in people co-infected with HIV.⁴

Since 1992, Gilead has worked with WHO and other nongovernmental organizations to provide the company's treatment for VL at no-profit prices in countries affected by the disease. In 2011, Gilead announced a donation to WHO of 445,000 vials of its VL medicine to treat more than 50,000 people over five years.



Role of Generic Licensing

Critical to the company's efforts to expand access to HIV treatment has been the establishment of

generic licensing partnerships. Sixteen Indian manufacturers and one South African company hold licenses to produce generic versions of our HIV medicines for low- and middleincome countries.

- Generic Price Reductions: Licensing partners receive a full technology transfer of the manufacturing process and then set their own product prices. Over the past eight years, licensing partners have lowered prices by 80 percent.
- Access to New Medicines: In 2011, Gilead extended generic licenses to Indian partners to produce three of the company's new HIV medicines once they received U.S. regulatory approval.
- Medicines Patent Pool: Gilead was the first innovator pharmaceutical company to join the Medicines Patent Pool (MPP), which was established by UNITAID in 2009 to expand access to medicines through the sharing of drug patents. Gilead granted the MPP licenses for current and pipeline medicines.



Access to Gilead HIV Medicines

Sources

- ¹ Gilead internal data. Available at: http://www.gilead.com/access_hiv
- ² WHO. Antiretroviral Therapy for HIV infection in Adults and Adolescents: Recommendations for a public health approach, 2010 revision. Available at: http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf
- ³ WHO. Hepatitis B Factsheet No. 204, July 2012. Available at: http://www. who.int/mediacentre/factsheets/fs204/en/



Gilead undertakes a wide range of activities to support health workers in the appropriate use of the company's HIV medicines.



Critical Support Activities

Our company's efforts to increase access to medicines extend beyond lowering prices and enabling generic production. Other activities include:

- **Product Registration:** Working with regional business partners, Gilead files country-specific product registration applications to obtain local regulatory approvals in developing countries.
- Medical and Clinical Education: Regional business partners assist Gilead with activities to educate medical and clinical workers on the proper use of medicines. One of the newest initiatives is a mobile phone service that enables health workers in remote areas to ask questions about Gilead therapies via text messaging.
- **Collaborative Research:** Gilead supports collaborative research on the optimal use of medicines in developing-country settings. Gilead also donated drug for clinical trials evaluating the effectiveness of antiretroviral agents for preventing HIV when taken by uninfected individuals.
- ⁴ WHO. Control of the leishmaniases. Report of a meeting of the WHO expert committee on the control of the leishmaniases, Geneva, 22-26 March 2010. WHO Technical Report Series 949. Available at: http://apps.who.int/iris/bitstream/10665/44412/1/WHO_TRS_949_eng.pdf