

THE PROBLEM

Since its discovery, HIV has taken 30 million lives and infected more than 34 million people worldwide. Over 95 percent of these people live in low- to middle-income developing countries already struggling with public health challenges, and the disease further reduces life expectancy, destabilizes families, and deepens poverty. There is no cure or vaccine for HIV, but effective antiretroviral (ARV) therapy significantly slows the progression of HIV to AIDS. Today, nearly 10 million people in low- and middle-income countries receive ARV therapies, an increase of 3,100 percent from 2002.

The United Nations has set a goal of reaching an additional 7 million people by 2015, which requires continued innovation in treatment, manufacturing, distribution, and financing. Discovering, producing and delivering a pill from the R&D lab to the patient is a complex supply chain, and poor supply chains and weak public health systems present significant obstacles, as different rules and regulations exist across more than 100 developing country markets. Overcoming these challenges requires global cooperation and partnerships, capital commitments, and aligned incentives for companies, governments, humanitarian organizations, and health providers.

FINDING A SOLUTION

Gilead Sciences is a biopharmaceutical company that develops innovative medicines for life-threatening diseases, including a range of groundbreaking ARV therapies, particularly the first complete HIV treatment regimen dosed in a single, once-daily tablet. Gilead has created innovative programs and partnerships to expand access to its medicines, regardless of where patients live or their ability to pay.

By 2005, it became clear that Gilead's approach to commercializing medicines in the developed-world could not sufficiently account for the myriad and unique challenges of delivering in low- and middle-income countries. In response, Gilead made adjustments, including the development of a tiered pricing system that takes into account countries' GDP and rate of HIV prevalence. For low-income countries, Gilead medicines were priced to cover only production cost and generate no profit for the company.

To accomplish this, Gilead established partnerships with regional business partners in the regions where it was working to increase access, providing the critical link between Gilead and governments, medical organizations, and other stakeholders. This provides Gilead with the knowledge to conform to local and national regulations, and helps regional partners develop their own expertise with Gilead's technical, medical and marketing support. These partnerships helped to overcome some distribution hurdles, but did not do enough to meet challenges facing manufacturing and financing.

In 2006, Gilead entered into voluntary licensing agreements with manufacturers to produce generic versions of its medicines which today are for sale in 112 low- and middle-income countries. Partners receive a full technology transfer of the Gilead manufacturing process, enabling them to quickly scale up production. Gilead collects royalties to support product registration, medical education, and other activities undertaken on behalf of the licensees, as trained healthcare workers and health infrastructure are essential for the safe, effective delivery of medicines to patients.

THE RESULTS

Gilead led the pharmaceutical industry in working with generic drug manufacturers and was the first company to join the Medicines Patent Pool, which is focused on further reducing the time required for the best HIV medicines to become globally available. Gilead's unique partnership program with generic manufacturers has supported the advancement of manufacturing innovation, standards, and efficiency in India through a groundbreaking technology transfer program that has ultimately driven down the price of generic therapy by 80 percent (4.00 per patient per month). As a result, 4.2 million patients in the developing world receive Gilead-based HIV therapy. The company's scalable and sustainable access model is designed to continue reaching additional patients in the coming years and the model proves that effective intellectual property protection and access to medicines can coexist.