Hepatitis B and C Treatment Expansion

Providing treatment for chronic viral hepatitis B (HBV) and hepatitis C (HCV) infection is a key focus of Gilead Sciences. We make it a priority to expand access to treatment for appropriate patients in need in developing countries.

Snapshot

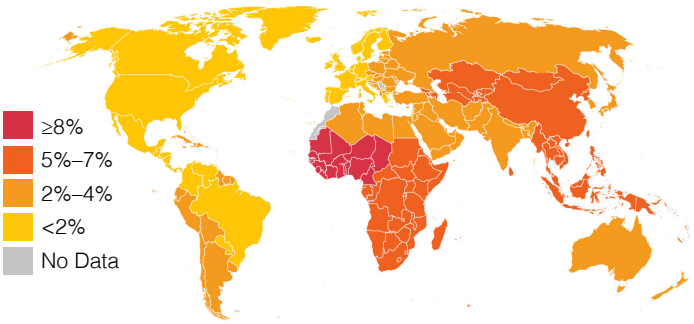
- Hepatitis B is **second only to tobacco** as a cause of cancer and leads to an estimated 600,000 deaths annually[1]
- HCV-related complications cause more than **350,000 deaths** each year[2]
- Gilead hepatitis treatment access strategies include **tiered pricing**, **generic licensing** and **partnerships**

Hepatitis B

Worldwide, approximately 400 million people are living with chronic hepatitis B infection. The disease is especially endemic in China and other parts of Asia, where more than eight percent of the adult population is chronically infected.[3]

Gilead's Viread® (tenofovir disoproxil fumarate)[4] is indicated for the treatment of chronic hepatitis B. Gilead is also developing new therapies for HBV, including tenofovir alafenamide (TAF), a novel investigational low-dose prodrug of tenofovir. Phase 3 clinical studies are currently underway to evaluate the efficacy and safety of TAF in patients with chronic hepatitis B, including patients who are co-infected with HIV.

Global Hepatitis B Prevalence[5]

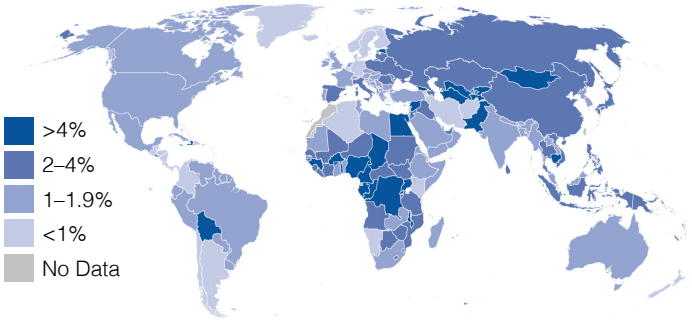


We work with regional business partners to provide branded Viread at reduced prices in 125 low- and middle-income countries. The company has also established licensing agreements with 19 generic drug manufacturers in India, South Africa and China, granting them rights to produce and sell high-quality, low-cost generic versions of Gilead HBV medicines in 112 developing countries.

Hepatitis C

More than 185 million people worldwide are infected with HCV, most of them in low- and middle-income countries.[6] Gilead's Sovaldi® (sofosbuvir),[7] approved in the United States in December 2013, is indicated for the treatment of HCV as a component of a combination antiviral treatment regimen.

Global Hepatitis C Prevalence[8]



Sovaldi's efficacy has been established in patients with HCV genotypes 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection, a condition that can complicate treatment for both diseases and adversely affect patient outcomes.

In October 2014, Harvoni®, a fixed-dose combination of ledipasvir and sofosbuvir, was approved by the FDA, making it the first and only once-daily single tablet regimen for HCV. Harvoni's efficacy has been established in patients with chronic HCV genotype 1 infection, with a treatment duration of eight, 12 or 24 weeks depending on treatment history, cirrhosis status and baseline viral load.

Gilead is working with regional partners to introduce branded Sovaldi and Harvoni in low- and middle-income countries, prioritizing those with the greatest disease burden. Countries are categorized in three pricing tiers according to per capita gross national income and hepatitis C prevalence; these tiers provide a starting point for negotiations with individual governments.

Final prices are determined on a country-by-country basis, taking into account each country's treatment needs, healthcare infrastructure and the government's commitment to expanding access to effective HCV therapy. Negotiations with high-burden countries are currently underway, and in July 2014, Gilead signed its first HCV treatment expansion agreement with the Egyptian government (see box).

In September 2014, Gilead signed licensing agreements with seven India-based generic pharmaceutical manufacturers to expand access to its HCV medicines for distribution in 91 developing countries. The countries within the agreement account for more than 100 million people living with hepatitis C around the world, representing 54 percent of the total global infected population. Generic partners will receive a complete technology transfer of Gilead's manufacturing process, enabling them to quickly scale up production, and partners will be able to establish their own prices and brands for the products they manufacture and sell.

Gilead continues to develop new treatments for HCV, including an investigational fixed-dose combination designed to be effective against the diverse range of viral genotypes found worldwide. This pan-genotypic option may be particularly important for resource-poor countries where genotypic testing is not feasible.[9,10]

Working Locally to Advance Access

Lowering prices is just one part of successfully scaling up HBV and HCV 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. Gilead works with a global network of regional business partners on these activities.

Expanding Access to Hepatitis C Treatment in Egypt

HCV prevalence is higher in Egypt than in any other country in the world – by some estimates, 14.7% of the population has chronic hepatitis C.[11] As part of Gilead's hepatitis C treatment access efforts, the company has agreed to provide Sovaldi to the Egyptian Ministry of Health at a significantly reduced price, for use when appropriate in a 24-week, interferon-free regimen with ribavirin. The Ministry of Health will provide Sovaldi through government programs, such as Egypt's National Liver Program and Health Insurance Organization. In addition, Gilead and the Ministry of Health will invest in local HCV medical education and prevention efforts, as well as screening and patient awareness initiatives.

To help inform Egyptian HCV treatment strategies, Gilead has conducted a Phase 3 clinical trial in Egypt evaluating the safety and efficacy of Sovaldi and ribavirin administered for either 12 or 24 weeks in treatment-naïve and treatment-experienced Egyptian adults with chronic genotype 4 HCV infection, which accounts for the large majority of HCV cases in Egypt.

TAF is an investigational agent, and its safety and efficacy have not been established.

References

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