GILEAD'S CHRONIC HEPATITIS C TREATMENT ~~EXPANSION~~ *RESTRICTIONS*

Committed to Limiting Access to Affordable Generic Medicines for Millions of People Who Can Benefit From Them in Developing Countries

Médecins Sans Frontières/ Doctors Without Borders (MSF) plans to start treating people infected with hepatitis C virus (HCV) in nine countries, requiring affordable access to direct acting antiviral (DAA) treatments, including those first registered by Gilead Sciences, and is looking for quality-assured generic versions that can help scale up treatment. However, Gilead's voluntary license restricts access to affordable generic versions for millions of people with HCV in middle-income countries (MICs).

Snapshot

Gilead has signed restrictive license agreements with eleven Indian companies on three HCV medicines – sofosbuvir, ledipasvir and velpatasvir. **Generic versions cannot be sold in 50 middle-income countries.**

There are approximately **49 million people living with HCV in excluded middle-income countries** – 30 million in China alone. Gilead is planning to charge thousands of dollars for its new HCV drugs in these countries.

The generic price of a three-month DAA regimen is expected to eventually be less than US $200 with fierce generic competition, but Gilead is working to make excluded middle-income countries dependent on tiered pricing, **resulting in much higher prices,** which could range from over $2,000 to $15,000.

Restrictive and Opaque Voluntary License Agreements

A voluntary license (VL) is an agreement between originator and a generics manufacturer on a medicine that is patented or has pending patent applications. Through a VL generics manufacturers can market more affordable versions of the medicine in certain territories without having to challenge the patent applications or patents in each jurisdiction. The generics manufacturer, in turn, pays royalties to the originator company. In cases when generics manufacturers withdraw or choose to not pursue patent challenges, such as pre-grant oppositions in key countries like India, the license works as a legal settlement for the originator and generics companies. Generics manufacturers view these licenses as an opportunity to enter the market without having to face the risk of long-drawn, very expensive patent disputes and the risk of their production being shut down if patents are granted later and asserted against them. However, some of the clauses in these agreements impose conditions on generics manufacturers that are anti-competitive and undermine access in middle-income developing countries.

Gilead's VL for Three Hepatitis C DAA Medicines (sofosbuvir, ledipasvir and velpatasvir) Raises Serious Concerns[1]:

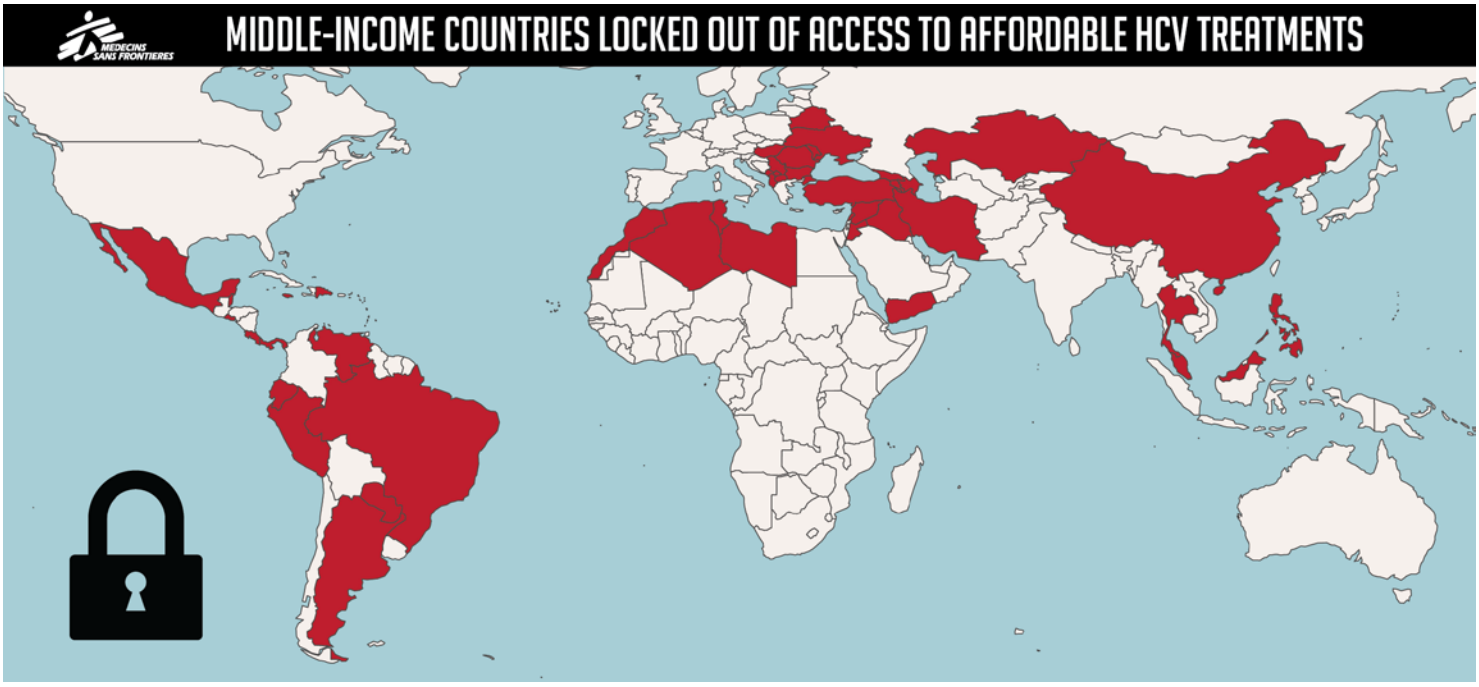
1. Many MICs have been excluded from the license. These include China, Thailand, Ukraine, Iran, the Philippines, Argentina and Brazil. The license restricts signatory generics manufacturers (licensees) from marketing and supplying the three DAAs in these excluded countries, even when no patent barriers exist.
2. Only Indian companies have been offered the license. Generics manufacturers in countries such as Brazil, China, Thailand and the Philippines have not been offered the license.
3. The license mandates egregious restrictions on sales to patients and providers that create barriers for marginalized communities for accessing DAA-based treatment and undermine patient confidentiality. Licensees are prohibited from making the generic versions available in local pharmacies. They are also required to track patients and dispense the drug in limited quantities at a time.[2]

Photo credit: Siddharth Singh

4. Gilead is filing applications for multiple patents for each DAA, including for fixed-dose combinations (FDCs), which simply combine several medicines into one pill. This industry strategy called 'evergreening' could allow Gilead to extend monopoly protection beyond a 20-year patent term in many developing countries. Even if the patent on the base compound is rejected due to lack of an 'inventive step,' numerous applications or granted patents on derivatives, process, composition and FDCs will be used to try and block generic competition.
5. The license furthers Gilead's evergreening strategy by applying excessively broad definitions of 'patents' that include pending applications and pending appeals to rejected claims – even for patents on methods of use or manufacture, which are not categorized as product patents in legal terms. These definitions will effectively increase long-term control over generics manufacturers.
6. The license is fully binding for five years with no way for generics manufacturers to exit the agreement.
7. The license seeks to control the market for the active pharmaceutical ingredients (APIs) needed to produce the drugs, by requiring companies that have signed the license to buy APIs from other licensees or from Gilead's suppliers. It also prevents new generics producers in other developing countries from accessing low-cost APIs from Indian suppliers who have signed the license.
8. The license sets complex rules for excluded countries that want to access generic versions of the drug produced under the Gilead license by issuing 'compulsory licenses' to allow for the procurement of affordable generic versions of these three drugs.

The Licensing Agreement Excludes the Following 50 MICs:

Albania	Columbia	Jordan	Montenegro	Tunisia
Algeria	Costa Rica	Kazakhstan	Morocco	Turkey
Argentina	Dominican Republic	Kosovo	Panama	Ukraine
Armenia	Ecuador	Lebanon	Paraguay	Venezuela
Azerbaijan	El Salvador	Libya	Peru	West Bank & Gaza
Belarus	Georgia	Macedonia	Philippines	Yemen
Belize	Grenada	Malaysia	Romania	
Bosnia Herzegovina	Hungary	Marshall Islands	Serbia	
Brazil	Iran	Mexico	St. Lucia	
Bulgaria	Iraq	Micronesia	Syria	
China	Jamaica	Moldova	Thailand	



Chronic Hepatitis C Treatment Expansion Challenges for MSF

The DAAs coming to market provide an opportunity to cure chronic HCV more effectively across all genotypes and simplify treatment, particularly for HIV/HCV co-infected patients and marginalized communities. The World Health Organization has recently issued the first ever HCV treatment guidelines, with strong recommendations on use of sofosbuvir. However, access to DAA-based regimens for MSF and other treatment providers is heavily dependent on affordability and availability of these drugs in the private and public sectors of developing countries. Prices and access differ dramatically depending on the country. Sofosbuvir, marketed as Sovaldi by Gilead Sciences, is available at $900 or less for a three-month supply in MICs like India, Egypt, and Pakistan, but not in other MICs like Thailand, Ukraine and Brazil. Availability of generic versions will be heavily dependent on the licenses, local patent status and use of legal safeguards in countries like Brazil, Ukraine and Thailand.

"Gilead's drug access program for developing countries is already showing its limitations, with the company planning to impose conditions for the supply and distribution of the drug to patients and treatment providers in developing countries, in order to protect the company's ability to charge unaffordable prices in wealthy countries."

– Dr. Manica Balasegaram, Executive Director of MSF Access Campaign

Working Locally to Restrict Access

By pricing its new HCV medicine sofosbuvir at $1,000 a pill or $95,000 for a three-month regimen of two DAAs – sofosbuvir/ledipasvir – Gilead has created a high-profile problem in developed countries that are forced to pay these prices, such as the U.S., Spain, the UK and France, but also in developing countries. Developed countries' healthcare systems are now rationing treatment to the sickest people, delaying and potentially denying treatment for many with chronic HCV. However, in response to government pressure, the threat of using TRIPS flexibilities to overcome patent barriers, and as part of Gilead's own tiered pricing scheme, prices are significantly lower in some developing countries. For example in Egypt's public sector and India's private sector, a three-month regimen of sofosbuvir costs $900.

To ensure Gilead can cut off all pathways for patients in developed countries to access low-cost versions not available in their own countries, Gilead's license dictates how the generics company licensees can sell generic DAAs in India and other developing countries. In particular, Gilead is using the license to pressure and negotiate stringent conditions with licensees that prevent retail sales on prescriptions and restrict the sale of the drug to patients who can prove citizenship, provide their medical records and who agree to be tracked. Thus, the impact of exorbitant pricing in developed countries is not just being felt by those countries' governments, insurance mechanisms and patients, but also by patients in developing countries whose access will be restricted and rights violated by conditions that are antithetical to basic human rights.[2]

"What choice do I have? If pharma companies coerce me to share my medical records and treat me like a criminal by tracking me and asking me to account for every bottle, I will be forced to do it. Right now they can ask me to sign blank papers and I will do it. Without the medicine I will die."

– Person living with chronic HCV in India

Conclusion

Gilead's license includes a number of restrictions, ambiguities and exclusions that undermine access to low-cost generic HCV medicines in developing countries. Patient groups, governments, human rights bodies, Competition Commissions, the World Health Organisation and other UN bodies must take action to monitor and amend the terms of the license. Read MSF's recommendation to improve Gilead's license in our full analysis, available online.[1]

[1] Learn more about these concerns and additional barriers to affordable treatment created by Gilead's license in our full analysis, available here: http://www.msfaccess.org/content/barriers-access-and-scale-hepatitis-c-hcv-treatment-gileads-voluntary-license-agreement.

[2] Learn more about the impact of Gilead's anti-diversion programme in MSF's brief, available here: http://www.msfaccess.org/content/barriers-access-and-scale-hepatitis-c-hcv-treatment-gileads-anti-diversion-program.