

Times of India, Delhi  
Saturday 30th August 2014, Page: 21  
Width: 20.57 cms, Height: 15.16 cms, a4r, Ref: pmin.2014-08-30.37.177

# Hepatitis C drugs face multiple hurdles

## Medicines Not Available Due To Pharma Cos' High Prices, Govt Apathy, IPR Regimes

English Media Service  
@timesgroup.com

**Mumbai:** Life-saving medicines, especially for complex chronic diseases like hepatitis C (Hep C), are facing multiple hurdles here in the form of Big Pharma's pricing strategy, government apathy to accelerate approvals and intellectual property challenges. This is particularly true for newer "miracle cures" for life-threatening diseases that have been launched globally but, sadly, are not available in India.

Breakthrough drugs like sofosbuvir (Gilead's Sovaldi) could be revolutionizing treatments overseas, but their unavailability here is potentially threatening millions suffering from the disease.

Hep C is a silent killer spread through a blood-borne virus that can cause liver disease and, if untreated, can be fatal. About 12 million people are chronically infected with the virus in India, with a majority not knowing their status.

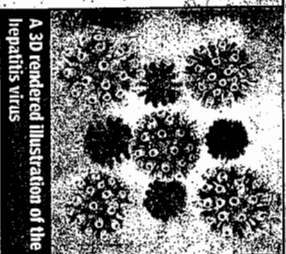
Industry experts say the drugs are not available in the domestic market as companies are yet to submit "registration dossiers" to the drug regulatory authority seeking approval

### WHAT IS HEPATITIS C

> Hepatitis C (Hep C or HCV) is a virus that can cause liver disease and, if untreated, can be fatal

> It is a blood-borne virus that gets transmitted through unsafe injection practices, inadequate sterilization of medical equipment and blood transfusions

> Chronic HCV is a 'silent killer' as usually people do not have any symptoms until they have serious liver damage, which takes many years to develop



A 3D rendered illustration of the hepatitis virus

> Many deaths from serious liver disease or liver cancer can be prevented with early diagnosis and treatment

to launch the drug. Most countries are accelerating approval of these life-saving medicines — the new oral drugs for Hep C sofosbuvir, simeprevir (Aristo) and daclatasvir (Bristol-Myers Squibb) — which offer a solution to chronic HCV patients who have failed or been unable to tolerate existing treatments based on interferon injections. The Indian government is yet to take any action on accelerating approvals.

For example, Egypt — which has the world's largest incidence of Hep C — has already announced that it is re-

see if a waiver can be granted in this case. In the meantime, we are moving forward to conduct the local clinical trials as required," a Gilead Science executive said, adding the drug will be available in 2015 and.

Amid criticism globally over the eye-popping price of its hepatitis C pill Sovaldi, Gilead has offered to supply the medicine at a 99% discount to the US price at \$300 per bottle to NGOs and Indian government. This is a fraction of the \$84,000 (over Rs 50 lakh) price tag for the same treatment in US.

"We know from our experience treating HIV over the last decade and a half that treatment needs to be simple and affordable — full hepatitis C treatment and diagnosis needs to be available for no more than \$300 per person. We are treating a small number of patients with the disease in India, but want to expand treatment to more people in more countries, and having affordable access to this drug (Sovaldi) will be crucial," Rohit Malpani, director of policy and analysis, MSF, said earlier.

Many feel that the discounted price is "restrictive" as NGOs say they do not have the capacity to scale up treatment

to thousands who will need the pills in the coming years. "The number of people who are going to get sick or die due to liver disease is expected to keep rising in India as HCV infections acquired years ago are increasingly taking their toll. Though treatment is improving dramatically with the new oral medications which have high cure rates, the Indian health ministry lacks strategy. They are facing multiple hurdles here in India to access these new oral drugs — from apathy to fast-track registration to intellectual property barriers," Leena Menhargarey of MSF, an international medical humanitarian organization, said.

Generic companies could also look at producing these medicines, but till now no company has stepped forward. Many of these new oral drugs can be produced generically in India and marketed at very affordable prices, just like antiretrovirals used in the treatment of HIV, experts added.

Also, Gilead Sciences has applied for multiple patents on sofosbuvir in India, which has been opposed by Initiative for Medicines Access and Knowledge, and patient group DNR+ in the Delhi Patent Office.

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