

5 Indian firms to sell Hepatitis C drug in 90 countries

15 September 2014 | News | By BioSpectrum Bureau

Gilead to allow 5 Indian firms to sell hepatitis C drugs in 90 countries



Approximately 180 million people live with Hepatitis C today, with 350,000 people dying annually of the disease.

New oral drugs like sofosbuvir and ledipasvir, known as direct-acting antivirals (DAAs), hold significant promise to improve treatment outcomes for Hepatitis C patients around the world, with studies showing high cure rates. US and EU regulators have approved two new DAAs within the last 10 months, and others are in development.

However, the high prices set by Gilead for sofosbuvir, for example, are an important barrier to scaling up access to diagnostics and treatment.

Increasing generic competition is an important strategy in reducing prices and increasing sustainable affordable access when companies file for patent protection for essential medicines.

Although the Gilead agreements will allow some generic companies to market generic versions of both drugs in approximately 90 countries regardless of the patent status in those countries, most of the countries expected to be included in the license agreements are low-income economies, many of which may not have had patent protection on these new drugs in the first place.

"Gilead's licensing terms fall far short of ensuring widespread affordable access to these new drugs in middle-income countries, where over 70 percent of people with Hepatitis C live today. Gilead's deal excludes many middle-income countries considered by industry to be profitable emerging markets, even though people living with chronic Hepatitis C in these countries often come from poor and marginalized communities with little ability to pay for expensive medicines," Mr Rohit Malpani, director, policy and analysis, MÃ©decins Sans FrontiÃ©res, Access Campaign.

Hepatitis C is especially prevalent in middle-income countries - with approximately 73 percent of the burden in these countries - but disappointingly many of these countries remain excluded from accessing both Gilead's lowest price and the generic versions licensed by these agreements.

It remains to be seen whether in reality the terms and conditions offered by Gilead will enable widespread access to an optimised and affordable regimen needed for millions of people in low and middle income countries, including patients seeking treatment from MSF.

MSF (Médecins Sans Frontières) is preparing to initiate treatment in a few medical projects using new direct acting antivirals for people living with chronic HCV.

"We welcome the interest of generic companies to scale up production of new direct-acting antivirals and Gilead's decision to make the final agreement public; however, a highly restrictive voluntary license that blocks millions of people with Hepatitis C from affordable prices is not acceptable. MSF hopes that excluded governments will take all relevant measures available under global trade rules and national patent laws to secure low-cost generic versions of these medicines," Mr Malpani added.