



Statement of Civil Society Organizations in Thailand

Voluntary License on Sofosbuvir and Ledipasvir between Gilead Sciences Limited and Generic-medicine Manufacturers in India

September 16, 2014

Civil society organizations working on access to HIV and HCV treatment in Thailand, as listed at the end of the statement, are appalled by the announcement of the voluntary license agreed between Gilead Sciences Limited and a number of generic-medicine manufacturers in India. We were hoping that Gilead's new drug, sofosbuvir, would be both a life-line to the almost one and half million people infected with the hepatitis C virus (HCV) in Thailand and a potential means of eradicating this disease worldwide. Instead we are now faced with corporate greed building yet another barrier to access to a new medicine needed by millions of people with HCV infection in middle-income countries, instead of a mechanism promoting access to this life saving treatment for ALL who need it.

Gilead announced its great contribution to the promotion of access to HCV treatment by signing an agreement on licensing a new HCV medicine, known as sofosbuvir, to Indian generic-drug manufacturers yesterday. In fact, the agreement is a disastrous threat to the lives of people with HCV infection, particularly those in middle-income countries where 73% of people with HCV live. Due to restrictive conditions set down by Gilead, the Indian licensees are only allowed to supply affordable generic version of sofosbuvir to 91 low and middle income countries. In those middle-income countries not included in the deal, millions of people will be effectively handed a death sentence as Gilead's new lifesaving medicine will be unaffordable.

On the one hand, Gilead is filing patent applications on sofosbuvir in India. But the ground for these patents are questionable under Indian patent law and India civil society organizations have filed patent oppositions with the Intellectual Property Office of India and the patents have not yet been granted. In Egypt, the sofosbuvir patent was rejected.

On the other hand, Gilead is attempting to maintain their market monopoly by undermining generic competition and locking Indian low cost generic manufacturers into voluntary licenses that exclude many middle income countries such as Thailand, Brazil, Ukraine, Russia, Turkey, Romania, Mexico, Philippines, and China, where people with HCV infection is higher than 1 million. More than 49 million people in the excluded MICs with high HCV prevalence are not able to access affordable sofosbuvir. This tactic has been used in the past with voluntary licenses on HIV/AIDS medicines such as tenofovir.

Pegylated interferon (PEG-INF) and ribavirin (RBV) is the treatment for HCV infection that is currently widely used in developing countries. However, this treatment has a poor cure rate and many patients experience very unpleasant side effects.

Gilead's sofosbuvir is a new HCV treatment that gives better cure rates with less side effects but it is priced beyond the reach of most people. In the USA, the cost is US\$ 84,000 per treatment or US\$ 1,000 per pill. The generic version, to be made available under Gilead's licensing agreement, will cost in the region of US\$900 per treatment or US\$10 per pill for those 91 low and middle income countries included in the agreement. But what about those countries excluded from this licensing agreement? And, experts have shown that sofosbuvir can be produced generically for mass scale-up, including a profit margin, for \$101 for a 12-week course.

In Thailand, people with HCV infection are entitled to PEG-INF/RBV medication at no cost under the Universal Coverage Scheme. But, with such barriers (both patent protection and voluntary licenses), it is difficult for the Thai government to provide sofosbuvir for its own citizens with HCV infection. According to the global Hepatitis C prevalence data of 2010, it is estimated that approximate 1.45 million Thais having HCV infection (2.2% of the total population). Due to a lack of access to generic sofosbuvir to be sold by Indian manufacturers under the voluntary license, if the Thai government wants support a national HCV treatment programme with sofosbuvir, it will cost at least US\$ 121 billion, which is much higher than the Thailand's annual health budget of USD 8.4 billion in 2014, instead of US\$ 1.3 billion (generic version's price under the license).

Generic medicines' competition is the most effective mechanism to ensure significant reduction in drug prices. The Gilead voluntary licenses agreed with the Indian generic-medicine industry are restrictions that will jeopardize competition by selectively limiting countries who can purchase the medicines from India. Therefore, prices will remain high and large numbers of people with HCV infection globally will be denied access to this treatment.

Gilead must stop undermining the generic-medicine industry's competition and repeal the conditions in voluntary licenses that exclude millions of people in order to fulfill their stated commitment to addressing the unmet medical needs of patients living with life-threatening diseases around the world.

AIDS ACCESS Foundation
Drug Study Group
Foundation for AIDS Rights (FAR)
Foundation for Consumers (FFC)
FTA Watch
People's Health System Movement
Thai AIDS Treatment Action Group (TTAG)
Thai Network of People living with HIV/AIDS (TNP+)
Thai NGO Coalition on AIDS (TNCA)
Thai Holistic Health Foundation
The Rural Pharmacist Association
The Rural Pharmacist Foundation
12 D Thai Coalition on Harm Reduction