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Mr. Lelio Marmora
Executive Director, UNITAID

Dr. Phillippe Duneton
Deputy Executive Director, UNITAID

Dear Mr. Marmora and Dr. Duneton,

We, the civil society organizations working on access to essential medicines and public health in Thailand, have a serious concern over the intention of the Medicine Patent Pool (MPP) to negotiate licenses on new medicines for the treatment of hepatitis C (HCV) infection, known as direct-acting antivirals (DAAs), with originator pharmaceutical companies.

The same concern is repeating itself after the MPP signed a license with Gilead Sciences, Inc. in July 2011 on a HIV antiretroviral, tenofovir, by accepting a strict geographical condition that limited the supply of the ARV to a few countries and excluded millions of people living with HIV in middle-income countries from accessing this life-saving medicine. That agreement made by the MPP was a very disappointing and dreadful decision for the PLHIV community in the excluded middle-income countries.

At present the HCV pandemic is a critical threat to the global public health; 150 million people are living with chronic HCV infection worldwide and they are unable to access effective treatment at affordable prices. Pegylated interferon, the standard of care until recently, is available in many countries, but is associated with many unpleasant, even unbearable side effects and guarantees only low cure rates. The hope of the people with HCV infection worldwide is inevitably placed with new DDAs, including sofosbuvir, of which cure rate has reached 100% in clinical trials and with minimal side effects. But, the US market price for sofosbuvir (Sovaldi), now considered the backbone of DAA treatment, is prohibitively expensive, at USD $84,000.

In addition to its price, sofosbuvir has been patented or has patents pending in various countries even though its patentability is questionable. This is an extra barrier that undermines competition from the generic medicine industry that plays a crucial role in bringing down the medicines' prices globally.

However, the situation got worse when Gilead signed voluntary licenses on sofosbuvir and ledipasvir with 11 major generic manufacturers in India and the licenses contain the same geographical condition as the MPP had with Gilead on tenofovir. As a result of the licenses, lives of over 50 million people who live with chronic HCV infection in Thailand and the other 50 low- and middle-income countries, which are excluded from the voluntary licenses between Gilead and the Indian generic manufacturers, are under fatal threat. Even in countries that can benefit from the voluntary licenses, Gilead requires a very strict control of the distribution, known as an "anti-diversion" program, that is unethical and violates patients' privacy and autonomy.

Despite that fact that the HCV treatment with pegylated interferon and ribavirin has been included in Thailand's universal coverage scheme, its patients still need new HCV DAAs due to the currently available medicines' adverse side effects and low successful cure rate. It is estimated that 1.6 million people in Thailand are living with HCV infection. It is impossible that the Thai government will be able to address its HCV pandemic effectively if the HCV DAAs' prices are vastly expensive. An option of the importation of affordable generic versions from India has been shut down as a result of the voluntary licenses. Local production is unfeasible as well due to intellectual property barriers and the control over active pharmaceutical ingredients by the licenses. Patent oppositions are an extensive process while a great number of patients require timely medication. Such voluntary licenses leave no option for a country with high HCV infection rate like Thailand to address the fatal-but-curable disease.

In our opinion, such actions initiated both by the MPP and by the multinational pharmaceutical industry in the forms of voluntary licensing and anti-diversion program are tantamount to a new form of monopolization, rather than creating an improved mechanism to promote universal access to essential medicines.

The MPP should listen to the people with HIV and HCV, community-based and civil society organizations' reflections carefully on the mistakes they did in the past and are unable to find a resolution, until now, to address discrimination due to its previously-signed licenses on ARVs.

We are by no means confident that the MPP will be able to negotiate licenses on sofosbuvir and other HCV DAAs that can ensure access to HCV DAAs for all people who need them without any conditions. The existing voluntary licenses between the pharmaceutical giant and the Indian generic-drug manufacturers are making the situation desperate enough, we do not want to see the MPP replicate its faults by endorsing the problematic voluntary licenses on HCV DAAs. Instead, UNTAID and the MPP should encourage and provide direct support to governments to fully implement public health safeguards and TRIPS flexibilities and promote the use of quality generic HCV DAAs at affordable prices to fight against the HCV pandemic.

Sincerely yours,

Chalermsak Kittitrakul
Coordinator for Access to Medicine Campaign, AIDS ACCESS Foundation

Drug Study Group
Foundation for AIDS Rights (FAR)
Foundation for Consumers (FFC)
FTA Watch
Ozone Foundation
People's Health System Movement
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
Thai Coalition on Harm Reduction (12D)

CC: Mr. Nimit Tienudom, Director, AIDS ACCESS Foundation