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On behalf of the Community Advisory Board in Eastern Europe and Central Asia (EECA CAB), established in 2009 by International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru) and East Europe and Central Asia Union of people living with HIV (ECUO), we want to express our concerns regarding the recently announced license agreement for Sofosbuvir between Gilead and several Indian generic companies.

The main goal of EECA CAB is to improve access to the treatment of HIV, hepatitis C and TB in the countries of the region using the joint forces of the patient community. EECA CAB unites treatment access activists from the following countries: Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Russia, Tajikistan, Ukraine, Uzbekistan and Estonia. Taking into account that the region has one of the highest rates of HIV epidemic, as well as drastic mortality rates in HIV/HCV coinfected patients, EECA is in urgent need of universal access to modern HCV treatment for saving hundreds of thousands of lives and ensuring effective response to both HCV and HIV epidemics.

The experience of expanding access to life-saving HIV treatment shows that access to generic competition is critical for obtaining sustainable prices affordable for governments and international donors that run treatment programs.

In different media publications we have read that with this license Gilead is seeking to provide access to Sofosbuvir for all people who need it in middle- and low-income countries. We were all the more disappointed to find out that, according to the announced terms of the license, almost all the middle-income countries in EECA region hardly hit by HCV epidemic are to be excluded from its geographic scope (Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Moldova, and Ukraine). Thus, the license will prohibit major Indian generic companies from manufacturing the life-saving medicine for most countries in the EECA region.

At the same time, the differential price for MICs announced by Gilead is still very high even though it is just above 1 % of the original price. According to the study done by Andrew Hill from Liverpool University (UK), since Sofosbuvir is a typical small chemical molecule with a structure similar to those of the HIV drugs, the actual cost of manufacturing this drug is in the range of USD68 - USD136. According to some observers, generic companies can easily market the product at around USD 150-300 for a 12-week treatment.

Such news raises our concern about sustainability of Gilead's policy and is breaking our trust in the company's statements about access to all people in need and social commitment. We are ready to provide comprehensive justification based on epidemiological, economic and political data from our region in order to build effective dialogue on including EECA countries into the list of countries in the voluntary license where generic versions of Sofosbuvir can be sold.

It has to be noted that in EECA Sofosbuvir is still not registered in any country of the region. Also, EECA CAB expresses its regret over the fact that Gilead has not yet provided a plan for registering Sofosbuvir in the EECA countries.

Last year, Ukraine and other countries developed comprehensive laws and regulatory norms to apply certain TRIPS flexibilities in situations where access to life-saving medications is threatened, and we find it important to stress that if Gliead's policy will continue blocking access to Sofosbuvir in the region we consider it our duty to take measures in cooperation with other stakeholders to ensure that everyone in need of HCV treatment gets it through implementing safeguards in the national regulatory frameworks.

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