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For more information: See contacts below

KEI EUROPE ASKS ROMANIAN GOVERNMENT TO ISSUE COMPULSORY LICENCES ON HEPATITIS C MEDICINES

[Compulsory licence request and Proposed Order available here:
<http://keieurope.org/licences.html>]

Geneva, Switzerland 18 March 2015. On 10 March 2015, Knowledge Ecology International Europe (KEI Europe), in collaboration with affiliate Knowledge Ecology International (KEI), submitted a request to Romanian Minister of Health, Nicolae Băncicioiu, to petition the Court of Bucharest to issue compulsory licenses on patents necessary for the supply of low-cost hepatitis C virus (HCV) medicines. The request provides a legal basis, as well as an economic, medical and moral basis, for compulsory licences as the pathway to affordable treatment for the approximately 1 million Romanian citizens living with HCV.

Most studies put Romania at the highest rate of HCV-incidence in the EU, estimated at between 3.2 and 6 percent of the population. Hepatitis C can cause cirrhosis, liver cancer, and death, often drawn out over decades, driving up costs and causing unnecessary suffering and pain for affected populations. In Romania, the highest rates of HCV-incidence are found in patients over forty years old, most of whom were infected through blood transfusions prior to developments in medical safety in the 1990's.

Until recently, treatment for this disease has been very painful, difficult to use and largely ineffective. But the recent development of new Direct-Acting Antiviral (DAA) medicines for HCV, including sofosbuvir and the sofosbuvir/ledipasvir combination, make treatment shorter and easier with less toxic side effects, easy to use, and have cure rates of approximately 90 percent or higher.

Yet these new medicines are very expensive because "companies weigh the consequences of discounts in Romania on the prices they can obtain in other countries in the European Union." For a country with a gross national income (GNI) per capita of \$9,060, roughly one-quarter of the overall GNI per capita across the EU, the medicines are simply too costly to be within reach of patients in need, and put strains on the government's ability to provide reimbursements. This combination of factors has exacerbated the problem of access to medicines in the country.

Thiru Balasubramaniam, Managing Director of KEI Europe: “KEI Europe and KEI have received requests for assistance from stage-three and stage-four Romanian HCV patients -- patients either in the end-stages prior to cirrhosis or actually in the cirrhotic stage -- because they need the new DAA HCV medicines, but cannot afford them. They are afraid that they are going to die, in spite of the fact that a treatment is at their fingertips. The World Health Organization’s (WHO) HCV treatment guidelines clearly identify compulsory licensing as a pathway for securing access to affordable HCV medicines. The KEI and KEI Europe proposals focus on the practical steps for implementing compulsory licenses.”

By obtaining compulsory licenses to HCV patents, the Government of Romania can authorize third-parties to use the relevant patented inventions to “import, export, manufacture, offer for sale, sell, or use HCV medicines” without the authorization of the patent holders within Romania. KEI Europe predicts that cost of generic versions of the new HCV drugs, including some regimes with less than 50 grams of active pharmaceutical ingredients, will eventually fall well below \$200 per 12 week course of treatment, and indeed, as low as \$20, if the drugs can be obtained at the same \$.40 per gram the U.S. government is now paying for the combination of TDF+FTC to treat HIV. The lower prices will provide the possibility of much wider access to the drugs in Romania than are likely from voluntary negotiations with patent holders.

The legal basis for compulsory licences in Romania is Romanian patent law, and other international regulations and trade agreements. Andrew S. Goldman, KEI Counsel for Policy and Legal Affairs, said, “We drafted the request in such a way as to emphasize its compliance with Romanian law, relevant EU regulations, and with TRIPS Agreement. The Romanian Government is asked to petition the Court of Bucharest to issue compulsory licences that would expand access while reducing healthcare costs.”

KEI Europe is a not-for-profit Swiss association which includes in its mission efforts to improve access to medicines. KEI Europe is an affiliate of KEI, a 501(c)(3) based in Washington, D.C., founded in 2006 to searches for better outcomes, including new solutions, to the management of knowledge resources.

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