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Mr. Gregg Alton
Executive Vice President
Corporate and Medical Affairs
Gilead Sciences Inc.
333 Lakeside Dr
Foster City, CA 94404

Geneva, 5 September 2016

Re: Gilead Sciences attempts to remove generic sofosbuvir from Ukraine

Dear Mr. Alton,

On behalf of Médecins Sans Frontières (MSF), I am writing to express our serious concerns and strong opposition to Gilead's on-going efforts to remove the only existing source of generic sofosbuvir in Ukraine.

MSF is in the process of planning and beginning to deliver hepatitis C treatment to patients in Ukraine, a country suffering from the highest hepatitis C prevalence in the region - and which has one of the world's highest rates of hepatitis C infection. The availability of multiple sources of new DAAs - and, in particular, sofosbuvir - is critical for treatment providers, including MSF, to manage a sustainable and affordable supply for medical operations.

With the continued reduction of API prices for sofosbuvir and other DAAs, treatment providers and countries can anticipate much lower prices from generic producers in the next few years. Availability of generic versions of DAAs is critical for reducing prices (and ensuring that such prices remain affordable) and increasing availability of hepatitis C treatment to all patients.

Multiple suppliers for DAAs and other medicines are also critical to avoid shortages and stock outs. In our experience, having only one registered supplier of an essential medicine per country can lead to shortages and stock outs, including recent shortages and stock-outs of critical medicines to treat HIV and AIDS.

There are no patent barriers to the introduction of more affordable generic versions of sofosbuvir in Ukraine. In fact, Gilead did not file for the primary patents on sofosbuvir in Ukraine, and weak secondary patents have not been granted in the country.

We are now concerned to learn that Gilead is attempting to remove the only existing source of generic sofosbuvir in Ukraine, by legally challenging the market authorization of the generic company, the distributor and multiple government agencies, pressuring them to withdraw the generic sofosbuvir from the market. The current attempt to remove the existing generic source of sofosbuvir could limit our ability to scale-up hepatitis C treatment in Ukraine. We consider that this attempt was initiated without consideration of the serious public health consequences.

Over the past two years, MSF has requested that Gilead revise its commercial strategies on many occasions. These strategies threaten sustainable access to hepatitis C treatment in a number of countries where MSF is treating patients. Our requests have included asking Gilead to revise the current voluntary license agreements with generic manufacturers to include high-burden middle-income countries including Ukraine, and to eliminate its restrictive anti-diversion DAA distribution programme.

Once again, MSF urges Gilead to drop the case in Ukraine, and reconsider its business strategy in high-burden middle-income countries, especially Ukraine since it has been excluded from relevant voluntary license agreements.

We look forward to upcoming discussions with company representatives.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'RM' followed by a stylized flourish.

Rohit Malpani
Director of Policy & Analysis
Médecins Sans Frontières - Access Campaign