



April 23, 2015

Mr. Lelio Marmora  
Executive Director  
UNITAID

Dr. Philippe Duneton  
Deputy Executive Director  
UNITAID

Dear Lelio, dear Philippe,

As a global network of treatment advocates we are writing to express our grave concerns over the possible decision to expand the Medicines Patent Pool (MPP) mandate to negotiate voluntary licenses of anti-hepatitis C virus (HCV) direct-acting antivirals (DAA) with originator companies.

According to the World Health Organization (WHO), at least 700,000 people die each year of HCV-related complications and more than 150 million people are infected with chronic HCV across the world, with the majority living in middle-income countries (MICs). Over the next few years, the treatment of HCV infection has the potential to change significantly as new all-oral treatment options become available with a shorter duration of treatment and more manageable side effects. HCV infection will be curable in nearly all patients and eradication of the disease would be feasible.

However, the cost of such medicines, directly linked to intellectual property rights (IPRs), is one of the most challenging barriers. We believe that UNITAID can play an important role to help removing such IPRs barriers. However, we do not believe that voluntary licenses are the appropriate solution to address the problem, especially now. Given the high burden of the HCV epidemic in MICs and the extremely high prices claimed by multinational pharmaceutical companies, any solution that ignores such countries will not lead to any significant improvement of coverage of treatment at the levels needed globally.

The five years of experience of the MPP have revealed its inability to include several MICs in the geographical scope of the signed licenses *including* countries with high burden of HCV; yet MICs have the greatest income inequality. According to the World Bank, nearly 75 percent of the world's poorest people (earning less than US\$1.25 a day) live in MICs. So far, apart from potential public relations benefits for companies, the MPP has not yet any leverage power to negotiate a better inclusion of key MICs most affected by the epidemic. In the pediatric license on raltegravir, the MPP failed to include countries with less than twenty children on HIV treatment, all regimens included (e.g. Jordan, Tunisia) because companies considered them "*emerging markets*".

Another concern relates to the new anti-diversion measures imposed by companies like Gilead in their recent VL, which will set standards of other companies and other medicines. Such measures undermine confidentiality of patients including extremely marginalized populations, create additional barriers - costs, and undermine efforts to facilitate access for those in need. While the debate on the use of the legal mechanisms such as TRIPS flexibilities has become rampant, even in high-income countries, the recourse to voluntary licenses has become a public relations and competition control strategy by multinational pharmaceutical companies.

As treatment advocates, and at this critical time, we cannot imagine UNITAID, as a public health institution, supporting industry-driven strategies to restrict access and make scandalous profits at the detriment of millions of lives. We also cannot conceive of a world where UNITAID would support unethical behaviors through anti-diversion measures that essentially aim to prevent desperate people in need of lifesaving treatment from accessing it. On the contrary, we expect UNITAID to be leading organizations to support countries and civil society to fully use and implement all the legal mechanisms available such as TRIPS flexibilities to ensure access to treatment and public health are protected; especially at this moment where patents are filed and being examined, negotiations are taking place and prices are being set.

At this historical moment, we believe UNITAID should not support an extension of the MPP mandate to HCV but rather invest in strengthening the capacity of countries to address IPRs barriers. We urge UNITAID to support the creation of a strong movement for HCV treatment access, to encourage advocacy – community mobilization and demand creation – and to mobilize resources for legal and technical interventions such as patent oppositions to ensure unmerited patents are not granted and robust generic competition can drive prices to levels that will enable access for all.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Christine Stegling', written in a cursive style.

Christine Stegling  
Executive Director