

Dr. Philippe Douste-Blazy, Chair of the Board, UNITAID
Mr. Lelio Marmora, Executive Director, UNITAID
Dr. Philippe Duneton, Deputy Executive Director, UNITAID

22 April 2015

Dear Dr. Douste-Blazy, Mr. Marmora and Dr. Duneton,

We are writing to express our concern about UNITAID's upcoming decision to expand the Medicines Patent Pool's (MPP) mandate for direct-acting antivirals (DAAs) to treat the hepatitis C virus (HCV).

As set out below, we believe that it is too early for the MPP to be entering into the HCV licensing space. We hope that any decision to extend the MPP's role to HCV will be delayed for at least three years. This is the minimum period of time necessary to allow for other interventions, such as pressuring companies to reduce their prices, advocacy, and legal strategies by civil society/governments¹, to take their course and create the leverage that is necessary for effective negotiations. We welcome, as always, the important work that the MPP conducts to make patent information public and user-friendly.

The key reasons for our objections to expand the MPP's mandate to HCV licensing at this point in time are as follows:

1. The MPP will not be able to expand licenses to middle-income countries (MICs)

The vast majority of the 150 million people chronically infected with HCV live in middle-income countries (MICs). Gilead's current DAA license excludes 51 MICs, where there are approximately 49 million people living with HCV. It is understood that Bristol Myers-Squibb (BMS), who are already in discussions with the MPP for licensing daclatasvir, will likely exclude the same territories.

Voluntary licenses for HIV negotiated thus far by the MPP systematically leave out most MICs. Given that access to DAAs is and will be a MIC issue, we do not envisage how the MPP can add value to DAA licenses. This includes the MPP adding a handful of additional countries to existing licenses that do not have sufficient impact as compared to the greater trade-offs discussed throughout this letter. As such, we do not believe it is a wise strategy or investment at this point to be trading away any leverage or negotiating ground through licenses that will not deliver where the need is greatest.

2. Undermining rather than complementing TRIPS flexibilities

The MPP will not be able to deliver on one of its key value-adds: improving the terms of bilateral licenses. Aside from expanding geographic coverage, this essentially means

¹ E.g. the use of TRIPS flexibilities (patent examination/oppositions and compulsory licensing/government use).

negotiating clauses that complement the use of TRIPS flexibilities, which can then be used to expand any licenses to territories that are excluded. However, to date, many of the key agreements the MPP has negotiated include clauses that undermine rather than complement on-going work on TRIPS flexibilities. These include clauses that:

- a) *de facto* provide rights equivalent to that of a granted patent where one does not actually exist. This is irrespective of whether:
 - (i) a patent application is still pending (including if the application has been successfully opposed/refused by the patent office) in an excluded country e.g. Argentina, and in India as the exporting country, or
 - (ii) if a patent application does not even exist in an excluded country but there is a 'pending' application(s) in India, the exporting country; and
- b) create additional barriers and delay to obtaining a compulsory license because the language in the license has to be tested to see how the clause works in practice.

As a result, these clauses do not serve to create certainty and expand the use of TRIPS flexibilities. Instead they are designed to delay and restrict any potential effect that the successful use of TRIPS flexibilities may have in an excluded country, or India as the exporting country where the licensee is usually based. Merely inserting language that gives the illusion that a license complements the possibility of the use of TRIPS flexibilities should not amount to being a value-add and improvement over an existing bilateral licence. The value-add of such clauses - if they are to complement the use of TRIPS flexibilities - has to be whether they actually work in practice. Based on the scenarios that I-MAK has evaluated, including a review of patent status in excluded countries, these clauses will not be effective in practice.

Indeed, a review of Gilead's licenses for its DAAs shows that Gilead has essentially lifted such terms from its agreement with the MPP for the HIV drug tenofovir alafenamide fumarate (TAF). These clauses have been problematic since the MPP signed its first HIV licenses with Gilead, and have yet to yield any benefit in practice. The misinformation that has been spread about the potential benefits of such clauses is not only masking the greater problem with such licenses, but also provides false hope for excluded MIC countries. Furthermore, given that Gilead's existing licenses already include these clauses, we do not believe the MPP can make a better deal to change these terms.

Ultimately, if such clauses continue to be endorsed in any new licenses the MPP approves, they will only further undermine the impact of UNITAID's own investment in projects that protect and promote TRIPS flexibilities in India and excluded MICs.

3. Tying up generic suppliers and leaving no alternatives for supply to excluded countries

With Gilead already tying up many of India's leading generic producers and the active pharmaceutical ingredient supply for its products, finding alternative suppliers for excluded MICs is now a significant barrier to treatment scale-up. This situation will be further compounded if the MPP enters the HCV space. Once the MPP enters this space, there will be a natural push to get as many generic suppliers into the pool. This then leaves few (if any) options for excluded countries who may successfully utilise TRIPS flexibilities, but then cannot find a suitable supplier as they are all locked in by the licenses. Rather, what UNITAID

should be ensuring at this pivotal moment is that there are enough generic suppliers staying *outside* licenses to supply excluded MICs.

4. Endorsing anti-diversion programmes that violate patient rights

Gilead's current licenses require its licensees to implement an anti-diversion plan that places undue burden on patients, thereby violating medical ethics and patient confidentiality. The MPP endorsing such terms in any licenses would be considered public support to a violation of patient rights. This is unacceptable.

5. The need for political solutions and supporting civil society

Access to DAAs is, and will be, a MIC issue. We believe what is required at the outset of this public health battle are political solutions and support for civil society. Lessons from treatment scale-up for HIV show that there is no substitute for grassroots civil society advocacy. The MPP's entry into HCV licensing at this stage of the fight for access to DAAs will not only be premature, but it will further cement an industry-driven solution. This will make future access more difficult, from which it will be virtually impossible to recover. Unlike the HIV issue, UNITAID should consider focusing its investment on impacting MICs, and not adopting the "take what we can" approach that has been used to date. This will simply not work for HCV if UNITAID intends to have meaningful impact on the market and on health outcomes.

In light of the above, we ask that before any decision is made with respect to the MPP entering into licensing deals for DAAs, an open consultation take place with all relevant actors from communities involved. Such a consultation could lay out a strategic three year plan for when the MPP may enter the HCV licensing space and how it would need to re-frame its approach to licensing negotiations to deal with the HCV marketplace.

This would also mean redesigning the indicators for how the MPP's impact is measured. Success would not be measured by the number of deals signed, but by licenses that actually significantly (rather than 'sufficiently' as appears to have become the standard for some licenses) improve access and simultaneously complement TRIPS flexibilities. **Simply put, the MPP must be prepared to walk away from bad licenses.**

We also ask that well before any decision is made on this matter, Dalberg's feasibility study for the MPP entering the HCV space be made public for comment.

We trust that you will take these views into consideration and that UNITAID will continue to be transparent in its decision making process. We are open for discussion and advising on how we believe UNITAID can make the most impact in the HCV patent space at this critical juncture and going forward.

Kind regards,



Tahir Amin (Director of Intellectual Property)
Priti Radhakrishnan (Director of Treatment Access)