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Paris, May 6th 2015

Dear Mr Douste-Blazy, Mr Marmora, Mr Duneton,

On behalf of Médecins du Monde France (MDM), we want to **express** our concern over the UNITAID board's consideration of the Medicines Patent Pool's (MPP) proposal to expand its mandate to include direct-acting antivirals (DAAs) for the treatment of hepatitis C (HCV). We believe that this proposal will not solve the problem of lack of access to HCV treatment and will give a public health organisation's endorsement to a strategy that is merely based on commercial interests.

Current voluntary licence (VL) strategies exclude most middle-income countries (MICs), because they are seen by the pharmaceutical companies as profitable markets. For example Gilead's HCV DAA licensing agreement – which is already referred to as a model – leaves out 51 MICs, including Brazil, China, the Philippines, Thailand and Turkey – resulting in the exclusion of 43% of people living with HCV in MICs from access to quality, affordable generic medications.

Not only do VL strategies pursued by pharmaceutical companies exclude MICs from their scope, they also aggressively secure their commercial interests by controlling the market through entering into partnerships with major global quality assured Indian manufacturers. While becoming originators commercial partners generic manufacturers are unlikely to challenge pharmaceutical monopolies as they did for HIV drugs. Indeed, Indian based company Natco Pharma just withdrew its patent opposition against Gilead's sofosbuvir application immediately following its agreement to enter in to Gilead's VL. In addition, this partnership prevents purchase DAAs included in the Gilead licence for excluded countries – even where there is no patent or a CL is issued – from major global quality assured manufacturers because the agreement highly restricts the licensees ability to export outside the territory scope.



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Furthermore, the definition of a ‘product patent’ within Gilead’s VL goes way beyond the international standard of granted patent and includes patent application and litigation, secondary patents, patents on methods of use under this classification. This increases the scope of intellectual property rights (IPR) and therefore enforces damaging TRIPs-plus provisions. The company also requires distributors to enforce strict anti-diversion delivery measures that violate medical ethics and patients’ rights. Definition of legal scope of IPR and pharmaceutical delivery policies are prerogatives of countries, and should not be controlled by pharmaceutical companies’ agreements that secure commercial interests rather than serving public health.

Finally, the current VL is used by Gilead as a cover for charging extortionately high prices in high income countries. As you may know, DAAs are rationed in France; thousands of people living with HCV in the European Union cannot be treated, because high drug prices prevent public health systems from providing them – as in UK to date. While civil society organizations such as Médecins du Monde protest against those unfair prices, Gilead justifies them as counterpart of its VL policy.

We are very worried that the current voluntary licencing strategies do not enable better access to treatment; they instead allow pharmaceutical companies to control the global market and set up new policies to secure profits worldwide. A public health organisation such as the Medicine Patent Pool should not endorse these commercial strategies. We fear the MPP does not have the capacity to negotiate license terms that prevent this, and cannot transform VLs into public-health driven licences as it is its mandate. Indeed the MPP has already said that it will not be able to guarantee inclusion of many high-burden MICs.

We believe public health institutions should encourage and help countries to respond to public health needs through the use of TRIPs flexibilities. This is not compatible with strategies that are driven by pharmaceutical companies’ own interests.

We are aware this interpretation may not be universally shared at this point within civil society, although we know of many other civil society organizations who share our concerns and expressed them during the consultations held by the Dalberg firm on behalf of MPP. We expect to access the results of this consultation as part of your transparency policy. It will be very helpful to understand what the different positions on this matter are.

Kind Regards,

Thierry Brigaud
Chairman
Médecins du Monde

Olivier Lebel
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Médecins du Monde