



16 March 2014

Dear Dr Douste-Biazy, Mr Marmora, and Mr Duneton

We are writing to you to express our deep concern about the apparent intent of the Medicines Patent Pool (MPP) to expand its mandate from HIV drugs to move into the market for the newly introduced Direct Acting Antiretrovirals for the treatment of hepatitis C.

According to recent World Health Organisation data some 150 million people are living with hepatitis C infection globally. Approximately 350 000 people die annually as a result of untreated HCV related illnesses, making the hepatitis C pandemic a global public health disaster of immense proportions, one that has been described by WHO as a "viral time bomb". In spite of the scale of the pandemic, the response from global institutions and national governments has been weak and under resourced, whilst the strategy of those pharmaceutical companies that hold the patents on the DAAs, drugs that have shown an extraordinarily high level of efficacy and an almost 100% cure rate across genotypes, has been rapacious, uncontrolled and obstructive.

The new DAAs have been covered by a series of extensive patents, patents that are not due to expire for another fourteen years, should this situation remain unchecked some 10 million people are estimated to die before the expiration. The vast bulk, some 73%, of those living with HCV are living in middle income countries (MIC), whilst only 12% are living in low income countries (LIC). In spite of World Bank country classifications, the vast majority of the world's poor also live in MIC.

We would also like to note that people who inject drugs have been massively disproportionately affected by HCV, carrying some 90% of the global disease burden.

Given this picture we are deeply concerned by the apparent intent of the MPP to proceed with negotiating new voluntary licences (VLs) on the DAAs. What concerns us is the apparent lack of weight that the MPP has to expand the geographical scope of the licences to those countries with the highest HCV burden (several of which are the countries with the largest populations of people who inject drugs globally) including China, Indonesia¹, Brazil, Ukraine, Russia, and Thailand.

We are alarmed that by negotiating VLs that exclude most MIC, that the MPP, as an institution wholly funded by UNITAID, and supported by WHO, will add a veneer of respectability and acceptability to these licenses, thus setting a model for the future. A model that will dramatically hamper access to treatment and undermine the application of TRIPS flexibilities. We would urge

¹ Whilst Indonesia was not included in the original VL offered by Gilead to the Indian generic companies, during the negotiations one of the latter argued for its inclusion; the country has however, never been included in a VL negotiated by the MPP.



UNITAID instead to focus on securing access to DAAs for the excluded MIC, something that will not be possible if the MPP supports the current VLs.

In addition to the severe geographical limitation of the extant VLs, they also contain a provision that poses a serious violation of human rights and undermines the doctor-patient relationship, namely Gilead's misleadingly named "anti-diversion" clause. This clause poses substantial barriers to access for all living with HCV, and only adds to the already extant barriers to access that people who inject drugs face.

Since bringing sofosbuvir to market Gilead has taken a particularly aggressive stance to attempts to widen access. These include:

- 1) Negotiating a VL that excludes 73 million people living with HCV in MIC, including China, the country with the single largest number of people infected.
- 2) Building an "anti-diversion" clause into the VL that is in breach of human rights and severely limits access.
- 3) Setting extortionate prices for sofosbuvir in high income countries, most notably, USD\$ 84 000 for a twelve week course in the USA, when it has been estimated that the actual production cost is between USD\$ 68 and USD\$ 136.

Given all of this we emphasise our concern that the entry of the MPP into the hepatitis C space will not further the cause of universal access to medicines which is at the core of its mission as a wholly UN funded agency, but will instead give cover to wholly inadequate VLs that only serve the interests of the pharmaceutical industry.

Yours sincerely

A handwritten signature in purple ink, appearing to read 'Eliot Ross Albers', written over a light blue horizontal line.

Dr Eliot Ross Albers
Executive Director
International Network of People who Use Drugs