

Mr. Ira Magaziner
Vice-Chairman and Chief Executive Officer
Clinton Health Access Initiative (CHAI)
383 Dorchester Avenue
Boston, United States of America

Dated: 25 October 2016

Re: Clinton Health Access Initiative hepatitis C (HCV) Quick-Start Program

Dear Mr. Magaziner,

We, the undersigned advocates and organizations from nine Asian countries, are writing to you with regard to your Quick-Start program, which plans to treat 25,000 people living with HCV with second-generation direct-acting antivirals (DAAs). Three of the program's six focus countries are in our region.

We strongly agree that improving access to HCV diagnostics and DAA-based treatment is an urgent issue, one that will mean the difference between life and death for many of our friends and community members in Myanmar, Indonesia and Vietnam. To achieve the goal to "speed up access to HCV cures" we must make HCV diagnostics and treatment affordable throughout low- and middle-income countries.¹ With the rapid drop in the price of DAAs, some generic sources are providing diagnostics (including two HCV RNA PCR tests and genotyping) with a 12-week course of DAAs from India for as little as 325 USD. Only when prices are reduced to such affordable levels can we reach the goal of universal access to HCV treatment.

From what we understand of the Quick-Start program based on discussions your country staff have had with local national organizations in these three countries, we have identified some concerns we would like to bring to your attention.

- 1) Obtaining diagnostic and monitoring testing – including HCV RNA PCR, genotyping and liver fibrosis assessment – continues to be a challenge in our national settings. By making patients pay for their own laboratory testing, even if provided at preferential prices, the program will likely exclude a large proportion of those who need treatment.
- 2) While we appreciate that CHAI has secured daclatasvir (Daklinza®) as a donation from Bristol Myers Squibb, since it cannot be administered alone, we are concerned that patients are required to purchase a more expensive second DAA, (i.e. sofosbuvir), on their own. As most of the patients who would seek to participate in Quick-Start will be from economically disadvantaged groups, we believe that by requiring them to pay for part of their treatment regimen, the program will exclude a large proportion of people who need treatment.

Payments for viral load and sofosbuvir constitute a form of user fees. User fees can present a major financial barrier to accessing life-saving treatment to the most vulnerable people and end

¹ <http://www.clintonhealthaccess.org/press-release-quick-start/>, 15 April 2016

up excluding a substantial proportion of those most in need of medical care.² Your initiative, though well intentioned, may end up creating a significant obstacle to people living with HCV and would likely exclude many from marginalised communities, such as people who use drugs and people living with HIV/HCV co-infection. This model would set a negative precedent that may impact future models for scaling up HCV diagnosis and treatment in the region.

- 3) While we recognize the importance of this program, the unavailability of government treatment programs using DAAs, and the need for import through national regulatory mechanisms prior to formal registration and marketing approval, we would also like to note that the combination of sofosbuvir and daclatasvir is not approved by regulatory authorities for treatment of genotype 6, which is commonly found in patients in both Myanmar and Vietnam. Although it has been recommended by the European Association for the Study of the Liver (EASL), it has not been recommended by the WHO and most of the national programs targeted by Quick-Start, except Vietnam. We wanted to know how CHAI intends to begin implementation of Quick-Start and would like to better understand how this choice was made.

We would encourage CHAI not to base their initiative on the drug donation of a single company but to be willing to find ways to provide access to a complete DAA regimen (e.g., not just daclatasvir but also sofosbuvir) as well as to the diagnostics for monitoring for the patients enrolled in the Quick-Start program.

- 4) Questions have been raised among our partners about how many participants will be recruited for screening and treatment in each country, and the criteria for enrolment, specifically related to treatment and whether Quick-Start will have any option for re-treatment of people who fail initial DAA treatment. Additional clarification on these points would be appreciated.

In summary, while we recognize that this program may present an opportunity for access to HCV treatment for some, we remain concerned about the financial requirements for self-purchase of DAAs and laboratory testing, as well as the selection of the treatment regimen. We would be happy to discuss these issues with your team in order to work together towards improving access to affordable HCV diagnostics and treatment.

Sincerely,

- 1) AIDS Access Foundation, Thailand
- 2) AIDS Care China (ACC), China
- 3) Asia Pacific Network of People Living with HIV/AIDS (APN+), Thailand
- 4) Asian Network of People who Use Drugs (ANPUD), Thailand
- 5) Center for Supporting Community Development Initiatives (SCDI), Vietnam
- 6) Community Network for Empowerment (CoNE), India

² *Medicins Sans Frontieres, No cash, no care: how user fees endanger health--lessons learnt regarding financial barriers to healthcare services*, March 2008

- 7) Indonesian AIDS Coalition (IAC), Indonesia
- 8) Hepatitis Coalition of Nagaland (HepCoN), India
- 9) Jarigan Indonesia Positif (JIP), Indonesia
- 10) Khmer HIV/AIDS NGO Alliance (KHANA), Cambodia
- 11) Lawyers Collective, India
- 12) Myanmar Positive Group (MPG), Myanmar
- 13) Persaudaraan Korban Napza Indonesia (PKNI), Indonesia
- 14) Positive Malaysian Treatment Access & Advocacy Group (MTAAG+), Malaysia
- 15) Thai AIDS Treatment Action Group (TTAG), Thailand
- 16) TREAT Asia/amfAR – The Foundation for AIDS Research, Thailand
- 17) Union C, Nepal
- 18) Vietnam Network of People living with HIV (VNP+), Vietnam

For further information, please contact Giten Khwairakpam at giten.khwairakpam@treatasia.org or at +66 2 663 7561